

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH  
CERTIFICATE OF NEED (CON) COMMISSION MEETING**

**Thursday September 22, 2011**

**Capitol View Building  
201 Townsend Street  
MDCH Conference Center  
Lansing, Michigan 48913**

**APPROVED MINUTES**

**I. Call to Order & Introductions**

Chairperson Falahee called the meeting to order @ 9:38 a.m.

**A. Members Present:**

James B. Falahee, Jr., JD, Chairperson  
Edward B. Goldman, Vice-Chairperson  
Bradley Cory  
Kathleen Cowling, DO  
Charles Gayney  
Robert Hughes  
Marc Keshishian, MD  
Brian Klott  
Gay L. Landstrom, RN  
Suresh Mukherji, MD  
Michael A. Sandler, MD

**B. Department of Attorney General Staff:**

Joe Potchen arrived @ 10:05 a.m.

**C. Michigan Department of Community Health Staff Present:**

Melanie Brim  
Jessica Austin  
Scott Blakeney  
Natalie Kellogg  
Sallie Flanders  
Tania Rodriguez

## **II. Review of Agenda**

Motion by Commissioner Gayney and seconded by Commissioner Cowling to accept the agenda as presented. Motion Carried.

## **III. Declaration of Conflicts of Interest**

Chairperson Falahee provided a brief overview of conflicts of interest. No conflicts declared.

## **IV. Review of Minutes**

Motion by Commissioner Gayney and seconded by Commissioner Landstrom to accept the minutes as presented from the June 9, 2011 meeting. Motion Carried.

## **V. Computed Tomography (CT) - Public Hearing Comments**

Ms. Brim gave a brief summary of the proposed language submitted to the Commission for final action (see attachments A & B).

### **A. Public Comment:**

Robert Meeker, Spectrum Health (see Attachment C)  
Steve Szelag, University of Michigan  
Amy Barkholz, Michigan Hospital Assoc. (MHA)  
Dennis McCafferty, Economic Alliance of Michigan (EAM)  
Melissa Cupp, Weiner Assoc.  
Michael Ketslars, National Diagnostics Services

### **B. Commission Discussion**

Discussion followed.

### **C. Commission Final Action**

Motion by Vice-Chairperson Goldman and seconded by Commissioner Landstrom to approve the draft language and Mr. Meeker's amendment (see Attachment C) with acknowledgement that it is a substantive change and will need to go back to Public Hearing. In addition, the Commission suggested the Department analyze this topic further and bring back a recommendation regarding its position on the amendment to the December 15, 2011 meeting.

Motion Carried in a vote of 8- Yes, 3- No, 0- Abstained.

**VI. Magnetic Resonance Imaging (MRI) Services- Intra-Operative MRI (iMRI)- Public Hearing Comments**

Ms. Brim gave a brief summary of the proposed language submitted to the Commission for final action (see attachments A & D).

**A. Public Comment**

None.

**B. Commission Discussion**

Commissioner Keshishian gave a brief overview of the NEWTAC meeting and the impact it will have on the MRI and PET standards.

Discussion followed.

**C. Commission Final Action**

Motion by Commissioner Keshishian and seconded by Commissioner Sandler to accept the proposed language and move it forward to the JLC and Governor for the 45-day review period. In addition, the Commission asked the department to draft language in collaboration with a group of experts for the PET/MR scanner(s) and CC/MR device(s), for review at the December 15, 2011 Commission meeting.

Motion Carried in a vote of 11- Yes, 0- No, and 0- Abstained.

**VII. Megavoltage Radiation Therapy (MRT) - Public Hearing Comments**

Ms. Brim gave a brief summary of the proposed language submitted to the Commission for final action (see attachments A & E).

**A. Public Comment**

Peter Skiles, Sparrow  
Richard Ward, MSU  
Robert Meeker, Spectrum Health  
Dennis McCafferty, EAM

**C. Commission Discussion**

Discussion followed.

#### **D. Commission Final Action**

Motion by Commissioner Keshishian and seconded by Commissioner Gayney to accept the proposed language and amendment to Section 12(3) and move it forward to the JLC and Governor for the 45-day review period.

Motion Carried in a vote of 7- Yes, 3- No, 0-Abstained.

### **VIII. Positron Emission Tomography (PET) - Public Hearing Comments**

Ms. Brim gave a brief summary of the proposed language submitted to the Commission for final action (see attachments A & F).

#### **A. Public Comment**

None.

#### **B. Commission Discussion**

None.

#### **C. Commission Final Action**

Motion by Vice-Chairperson Goldman and seconded by Commissioner Cowling to accept the proposed language and amendments (see Attachment G), as they are deemed technical and non-substantive and move it forward to the JLC. In addition, the Commission asked the department to bring back recommendations for the PET/MR scanner(s) at a future meeting. Motion Carried in a vote of 11-Yes, 0- No, and 0- Abstained.

### **IX. Surgical Services**

Ms. Brim gave a brief summary of the proposed language submitted to the Commission for proposed action (see attachments A & H).

#### **A. Public Comment**

Joe Garcia, RMS Lifeline  
Robert Meeker, Spectrum Health  
Dennis McCafferty, EAM

#### **B. Commission Discussion**

Discussion followed.

### **C. Commission Proposed Action**

Motion by Vice-Chairperson Goldman and seconded by Commissioner Gayney to send the proposed language on for Public Hearing and to the JLC seeking more information on the following topics: Trauma Room deduction, Hybrid OR, and Vascular Access.

Motion Carried in a vote of 11-Yes, 0- No, and 0- Abstained.

Break at 11:58 a.m. - 12:13 p.m.

## **XI. Cardiac Catheterization**

### **A. Review of Proposed Language**

Ms. Brim gave a brief summary of the proposed language submitted to the Commission for proposed action (see attachments A & I).

### **B. Public Comment**

Doug Weaver MD, Henry Ford  
Arthur Riba MD, Oakwood Hospital & Medical Center  
Robert Meeker, Spectrum Health  
Patrick O'Donovan, Beaumont

### **C. Commission Discussion**

Discussion followed.

### **D. Commission Proposed Action**

Motion by Commissioner Landstrom and seconded by Commissioner Sandler to amend the draft language presented to include the "de-coupling" language. In addition, to take final action on the CC standards in December after the language has been drafted to final form.

Motion Failed in a vote of 2- yes, 9- No, and 0- Abstained.

Motion by Commissioner Mukherji and seconded by Vice-Chairperson Goldman to accept the language as presented and amend lines 290 & 652 to 48 primary PCI cases.

Motion Failed in a vote of 5- Yes, 5- No, and 1- Abstained.

Motion by Commissioner Sandler and seconded by Commissioner Cory to accept the proposed language as presented and move it forward to Public Hearing and to the JLC.

Motion Carried in a vote of 11- Yes, 0- No, and 0- Abstained.

**XI. Open Heart Surgery Services Discussion**

The Commission discussed the rationalization behind the purpose of seating an Open Heart Standard Advisory Committee (OHSAC). The Commission consensus was moving forward to seat a SAC, and Chairperson Falahee and Vice-Chairperson Goldman will work with the Department to set that up and get it moving.

**XII. Hospital Beds Standard Advisory Committee (HBSAC) Written Report**

Chairperson Falahee gave a brief summary of the written update provided by Rob Casalou (see Attachment J).

**XIII. Standing New Medical Technology Advisory Committee (NEWTAC)**

Commissioner Keshishian gave a brief verbal update of the informational NEWTAC discussion that took place on August 17, 2011.

**XIV. Legislative Report**

None.

**XV. Administrative Update**

Ms. Brim gave a brief update, and she offered for the Department to provide a brief overview on compliance at the next meeting.

**A. Health Policy Section Update**

None.

**B. CON Evaluation Section Update**

1. Compliance Report (Written Report – Attachment K)
2. Quarterly Performance Measures (Written Report – Attachment L)

**XVI. Legal Activity Report**

Mr. Potchen gave a brief update of legal activity (see Attachment M).

**XVII. Future Meeting Dates**

- A. December 15, 2011
- B. January 26, 2012 (Special Commission Meeting)
- C. March 22, 2012
- D. June 14, 2012
- E. September 27, 2012
- F. December 13, 2012

**XVIII. Public Comment**

Lody Zwarenstejn, Alliance for Health  
Ken Nysson, Metro Health

**XIX. Review of Commission Work Plan**

Ms. Brim gave a brief summary of the work plan (see Attachment N).

- A. Commission Discussion
- B. Commission Action

Motion by Vice-Chairperson Goldman and seconded by Commissioner Klott to approve the work plan as amended at the meeting.  
Motion Carried in a vote of 11- Yes, 0- No, and 0- Abstained.

**XX. Adjournment**

Motion by Chairperson Falahee and seconded by Commissioner Sandler to adjourn the meeting @ 1:42 p.m. Motion Carried.

Michigan Department of Community Health (MDCH or Department)  
**MEMORANDUM**  
Lansing, MI

Date: August 1, 2011  
TO: Brenda Rogers  
FROM: Natalie Kellogg  
RE: Summary of Public Hearing Comments on Computed Tomography (CT) Services, Magnetic Resonance Imaging (MRI) Services, Megavoltage Radiation Therapy (MRT) Services/Units, and Positron Emission Tomography (PET) Scanner Services Standards

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**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 CT, MRI, MRT, and PET Standards at its June 9, 2011 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed CT, MRI, MRT, and PET Standards on July 14, 2011. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from one organization and all testimony is summarized as follows:

**CT Services**

*Amy Barkholz, Michigan Health & Hospital Association (MHA)*

MHA expressed their concern on recent changes made within the Medicare & Medicaid Services (CMS). Effective January 1, 2011 providers are no longer allowed to charge separately for abdomen & pelvis CTs performed in one session. Under the new CMS policy these procedures are now bundled and have a single CPT code. MHA requests that the weights be adjusted within the CT standards to offset and reflect the intended volume levels due to the bundling of these procedures. MHA believes this technical amendment will address the unforeseen policy change.

*Joy Szilagi, Sparrow Hospital*

Sparrow Hospital strongly supports the modifications to the CT standards and encourages the CON Commission to give final approval at the September 2011 meeting.

*Steven Szelag, University of Michigan Health System (UMHS)*

UMHS strongly supports the work conducted by the CT Standard Advisory Committee (SAC). However, CMS began bundling groups of multiple CT CPT codes for procedures performed together. The result has been a reduction in billable procedures and a reduction in the number of CT Equivalentents (CTE). UMHS suggests to avoid unintended results and to assure predictability in the application of the revised Standards, UMHS recommends that the CON Commission add the following language to the definition of “billable procedures” in Section (2)(1)(b):

“Billable procedure” means a CT Procedure or set of procedures commonly billed as a single unit AS OF DECEMBER 31, 2010, and performed in Michigan.”

*Robert Meeker, Spectrum Health*

Spectrum Health has no objections to the most recent proposed changes to the CT Standards. However, CMS revised their CPT codes defining billable procedures for certain categories of body CT scans. Specifically, separate billing codes for abdominal and pelvic CT scans were eliminated and replaced with combined codes. The effect of this change on volume reporting for CON is a 30% reduction in CTEs for body scans at 6 different CT sites operated by Spectrum Health. Spectrum Health suggests making a simple change to the definition of “billable procedures,” specifically referencing billing codes in effect prior to January 1, 2011. Spectrum Health is willing to draft a proposed definition, as described above, for consideration by the Commission at the next CON meeting on September 22, 2011.

### **MRI Services**

No public hearing testimony received.

### **MRT Services/Units**

*Melissa Cupp, Wiener Associates*

Sparrow Health System and the Michigan State University Health Team support the overall revisions to the MRT Standards but do have one suggested modification; to add language to Section 12. The proposed language would clearly state that new cancer cases that are presently treated or reported by an existing MRT service cannot be used by an applicant to support a new MRT service. Under Section 12(3):

“ An entity currently operating or approved to operate an MRT service shall not contribute new cancer cases to initiate any MRT service NOR SHALL NEW CANCER CASES TREATED OR REPORTED BY AN EXISTING MRT SERVICE BE USED BY ANY APPLICANT TO SUPPORT A NEW MRT SERVICE.”

*Robert Meeker, Spectrum Health*

Spectrum Health supports the proposed revisions to the CON Review Standards for MRT Services. MDCH did an excellent job of leading discussions resulting in consensus regarding revisions to the standards. Spectrum endorses the addition to the requirements for research specific MRT units, and continues to support any move to simplify reporting requirements for CON covered services. Spectrum continues to oppose efforts to eliminate minimum volume requirements for replacement of existing machines for all CON covered services. Spectrum is willing to consider minimum volume requirements for replacement that are substantially below that of initiation.

*Tricia L. Sommer, MidMichigan Health*

MidMichigan Health would recommend that Section 14(2) (C) be modified to reflect current CMS guidelines. MidMichigan Health recommends that this section be revised to reflect, “All MRT treatments shall be performed in accordance to current CMS guidelines for direct supervision” OR “All MRT treatments shall be performed pursuant to a radiation oncologist and the supervisory physician or non-physician practitioner must be present on the same campus and immediately available throughout the performance of the procedure.”

### **PET Scanner Services**

*Mary Zuckerman, Detroit Medical Center (DMC) and Children’s Hospital of Michigan (CHM)*

DMC & CHM are supportive of all of the recommended changes, and commends the Department on the way they reviewed these standards and brought forth change. However, they express one concern with the language related to Positron Emission Mammography (PEM). CHM currently provides PET services for all of Karmanos Cancer Center’s patients. Because they are physically connected to Karmanos, this set up is not only cost effective but convenient for their patients. The issue at hand is CHM and Karmanos combined cannot be the legal applicant for a CON. They are suggesting CHM to be the applicant entity and hold the CON for PEM service as an addition to DMC’s existing PET services. DMC has drafted proposed changes to the PEM language and are hoping to present at the September 22, 2011 CON Commission meeting.

*Alice Pichan, St. Joseph Mercy Health System Ann Arbor (SJHMS-AA)*

SJMHS-AA continues to have concerns regarding the proposed changes to the PET CON Standard. SJMHA-AA is on track to achieve the 4500 PET Equivalent data (Eq) required for conversion to a fixed site by the end of CY2011. But the proposed change in both methodology and total PET Eq required for conversion will delay the project by an estimated 3 years. SJMHS-AA supports the change in methodology to determine PET Eqs through the assignment of value to the CPT code. The proposed conversion factor is 2.4 PET Eqs/patient and is the basis for the new requirement of 1700 patients for an urban location converting from host to fixed. SJMHS-AA feels a more realistic conversion factor would be 2.93 PET Eqs/patient as submitted by the six fixed PET sites in 2009, resulting in 1535 patients per year rather than the 1700 patients per year requirement under the proposed standard. SJMHS-AA would be more than happy to discuss their analysis and recommendations at the next CON Commission meeting on September 22, 2011.

*Gregory S. Dobis, McClaren Regional Medical Center (MRMC)*

McClaren is currently building a Proton beam Therapy (PBT) Center for the treatment of cancer patients. An integral part of this PBT center is a fixed PET/CT scanner unit, which they are working to establish. Under current and proposed CON review standards, it is not possible to use the volume of the site-specific mobile PET/CT scanners to initiate a fixed PET/CT scanner service at the PBT Center because of City and Township requirements of separate addresses. McClaren is suggesting that an effective and technical alternative would be to allow for additional language [similar to that in the MRI Standards under Section 3(2) (d)] to be added under Section 3(4) and would read as follows:

“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 metropolitan area county.”

Once the fixed site was established at the PBT Center, both mobile host sites currently on the campus of MRMC would discontinue operation.

*Carol Christner, Karmanos Cancer Center*

Karmanos commends and appreciates the Departments open process on proposed changes to the PET Review Standards. However, they express one concern with the language related to Positron Emission Mammography (PEM). CHM currently provides PET services for all of Karmanos Cancer center's patients. Because they are physically connected to Karmanos, this set up is not only cost effective but convenient for their patients. They suggested language

that would allow CHM to be the applicant and CON holder for PEM service. In addition, they have concerns about references in section 9:

“AN APPLICANT PROPOSING TO ADD A PEM SCANNER SERVICE TO AN EXISTING PET SCANNER SERVICE.”

Karmanos has drafted proposed changes to the PEM language and are hoping to present at the September 22, 2011 CON Commission meeting.

*Robert Meeker, Spectrum Health*

Spectrum Health supports the proposed revisions to the CON Review Standards for PET Scanners. MDCH did an excellent job of leading discussions resulting in consensus regarding revisions to the standards. Spectrum endorses the addition of the PEM language and continues to support any move to simplify reporting requirements for CON covered services. Spectrum continues to oppose efforts to eliminate minimum volume requirements for replacement of existing machines for all CON covered services. Spectrum is willing to consider minimum volume requirements for replacement that are substantially below that of initiation.

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**  
**COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES**

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

**Section 1. Applicability**

~~Sec. 1. (1) These standards are requirements for the approval and OF THE INITIATION, EXPANSION, REPLACEMENT, RELOCATION, OR ACQUISITION OF CT SERVICES AND THE delivery of services for all projects approved and certificates of need issued under Part 222 of the Code which involve CT scanners.~~

~~(2) CT scanner is a covered clinical service for purposes of PURSUANT TO Part 222 of the Code. CT IS A COVERED CLINICAL SERVICE.~~

~~(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 21, and 22, as applicable, THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

~~The Department shall use sections 19 and 20, as applicable, in applying AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

~~(4)~~

**Section 2. Definitions**

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

(a) "Acquisition of an existing CT scanner service" means obtaining possession or control of an existing fixed or mobile CT scanner service or existing CT scanner(s) by contract, ownership, or other comparable arrangement. For proposed projects involving mobile CT scanners, this applies to the central service coordinator and/or host facility.

(b) "Billable procedure" means a CT procedure or set of procedures commonly billed as a single unit, and performed in Michigan.

(c) "Body scans" include all spinal CT scans and any CT scan of an anatomical site below and including the neck.

(d) "Central service coordinator" means the organizational unit which has operational responsibility for a mobile CT scanner and which is a legal entity authorized to do business in the state of Michigan.

(e) "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.

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

(g) "Computed tomography" or "CT" means the use of radiographic and computer techniques to produce cross-sectional images of the head or body.

(h) "CT equivalents" means the resulting number of units produced when the number of billable procedures for each category is multiplied by its respective conversion factor tabled in Section 21.

(i) "CT scanner" means x-ray CT scanning systems capable of performing CT scans of the head, other body parts, or full body patient procedures including Positron Emission Tomography (PET)/CT scanner hybrids if used for CT only procedures. The term does not include emission-computed tomographic systems utilizing internally administered single-photon gamma ray emitters, positron annihilation CT systems, magnetic resonance, ultrasound computed tomographic systems, CT simulators

54 used solely for treatment planning purposes in conjunction with an MRT unit, and non-diagnostic, intra-  
55 operative guidance tomographic units.

56 (j) "CT scanner services" means the con-approved utilization of a CT scanner(s) at one site in the  
57 case of a fixed CT scanner service or at each host site in the case of a mobile CT scanner service.

58 (k) "Dedicated pediatric CT" means a fixed CT scanner on which at least 70% of the CT procedures  
59 are performed on patients under 18 years of age.

60 (l) "Dental CT examinations" means use of a CT scanner specially designed to generate CT images  
61 to facilitate dental procedures.

62 (m) "Dental procedures" means dental implants, wisdom teeth surgical procedures, mandibular or  
63 maxillary surgical procedures, or temporal mandibular joint evaluations.

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

65 (o) "Emergency room" means a designated area physically part of a licensed hospital and  
66 recognized by the Department as having met the staffing and equipment requirements for the treatment  
67 of emergency patients.

68 (p) "EXCESS CT EQUIVALENTS" MEANS THE NUMBER OF CT EQUIVALENTS PERFORMED  
69 BY AN EXISTING CT SCANNER SERVICE IN EXCESS OF 10,000 PER FIXED CT SCANNER AND  
70 4,500 PER MOBILE CT SCANNER OR EITHER AN EXISTING FIXED OR MOBILE CT SCANNER  
71 SERVICE, THE NUMBER OF CT SCANNERS USED TO COMPUTE EXCESS CT EQUIVALENTS  
72 SHALL INCLUDE BOTH EXISTING AND APPROVED BUT NOT YET OPERATIONAL CT SCANNERS.  
73 IN THE CASE OF A CT SCANNER SERVICE THAT OPERATES OR HAS A VALID CON TO OPERATE  
74 THAT HAS MORE THAN ONE FIXED CT SCANNER AT THE SAME SITE, THE TERM MEANS  
75 NUMBER OF CT EQUIVALENTS IN EXCESS OF 10,000 MULTIPLIED BY THE NUMBER OF FIXED CT  
76 SCANNERS AT THE SAME SITE. FOR EXAMPLE, IF A CT SCANNER SERVICE OPERATES, OR HAS  
77 A VALID CON TO OPERATE, TWO FIXED CT SCANNERS AT THE SAME SITE, THE EXCESS CT  
78 EQUIVALENTS IS THE NUMBER THAT IS IN EXCESS OF 20,000 (10,000 X 2) CT EQUIVALENTS. IN  
79 THE CASE OF AN EXISTING MOBILE CT SCANNER SERVICE, THE TERM MEANS THE SUM OF  
80 ALL CT EQUIVALENTS PERFORMED BY THE SAME MOBILE CT SCANNER SERVICE AT ALL OF  
81 THE HOST SITES COMBINED THAT IS IN EXCESS OF 4,500. FOR EXAMPLE, IF A MOBILE CT  
82 SCANNER SERVICE SERVES FIVE HOST SITES WITH 1 MOBILE CT SCANNER, THE TERM MEANS  
83 THE SUM OF CT EQUIVALENTS FOR ALL FIVE HOST SITES COMBINED THAT IS IN EXCESS OF  
84 4,500 CT EQUIVALENTS.

85 (Q) "Existing CT scanner service" means the utilization of a CON-approved and operational CT  
86 scanner(s) at one site in the case of a fixed CT scanner service or at each host site in the case of a  
87 mobile CT scanner service.

88 (qR) "Existing CT scanner" means a CON-approved and operational CT scanner used to provide CT  
89 scanner services.

90 (rS) "Existing mobile CT scanner service" means a CON-approved and operational CT scanner and  
91 transporting equipment operated by a central service coordinator serving two or more host sites.

92 (sT) "Expand an existing CT scanner service" means the addition of one or more CT scanners at an  
93 existing CT scanner service.

94 (tU) "Head scans" include head or brain CT scans; including the maxillofacial area; the orbit, sella, or  
95 posterior fossa; or the outer, middle, or inner ear; or any other CT scan occurring above the neck.

96 (V) "HEALTH SERVICE AREA" OR "HSA" MEANS THE GROUPS OF COUNTIES LISTED IN  
97 SECTION 24.

98 (uW) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

99 (vX) "Hospital-based portable CT scanner OR PORTABLE CT SCANNER" means a CT scanner  
100 capable of being transported into patient care areas (i.e., ICU rooms, operating rooms, etc.) to provide  
101 high-quality imaging of critically ill patients.

102 (wY) "Host site" means the site at which a mobile CT scanner is authorized to provide CT scanner  
103 services.

104 (xZ) "Initiate a CT scanner service" means to begin operation of a CT scanner, whether fixed or  
105 mobile, at a site that does not perform CT scans as of the date an application is submitted to the

106 Department. The term does not include the acquisition or relocation of an existing CT scanner service or  
 107 the renewal of a lease.

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

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

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

118 (bbDD) "Mobile CT scanner service" means a CT scanner and transporting equipment operated by a  
 119 central service coordinator and which must serve two or more host facilities.

120 (eeEE) "Mobile CT scanner network" means the route (all host facilities) the mobile CT scanner is  
 121 authorized to serve.

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

123 (eeGG) "Relocate a fixed CT scanner" means a change in the location of a fixed CT scanner from the  
 124 existing site to a different site within the relocation zone.

125 (#HH) "Relocate an existing CT scanner service" means a change in the geographic location of an  
 126 existing fixed CT scanner service from an existing site to a different site.

127 (ggII) "Relocation zone," means a site that is within a 10-mile radius of a site at which an existing fixed  
 128 CT scanner service is located if an existing fixed CT scanner service is located in a metropolitan  
 129 statistical area county, or a 20-mile radius if an existing fixed CT scanner service is located in a rural or  
 130 micropolitan statistical area county.

131 (hhJJ) "Replace an existing CT scanner" means an equipment change of an existing CT scanner, that  
 132 requires a change in the radiation safety certificate, proposed by an applicant which results in that  
 133 applicant operating the same number of CT scanners before and after project completion, at the same  
 134 geographic location.

135 (iiKK) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
 136 statistical areas as those terms are defined under the "standards for defining metropolitan and  
 137 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of  
 138 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as  
 139 shown in Appendix A.

140 (jjLL) "Sedated patient" means a patient that meets all of the following:

141 (i) Patient undergoes procedural sedation and whose level of consciousness is either moderate  
 142 sedation or a higher level of sedation, as defined by the American Association of Anesthesiologists, the  
 143 American Academy of Pediatrics, the Joint Commission on the Accreditation of Health Care  
 144 Organizations, or an equivalent definition.

145 (ii) Who requires observation by personnel, other than technical employees routinely assigned to the  
 146 CT unit, who are trained in cardiopulmonary resuscitation (CPR) and pediatric advanced life support  
 147 (PALS).

148 (kkMM) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of  
 149 the following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),  
 150 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric  
 151 disorders, and other conditions that make the patient unable to comply with the positional requirements of  
 152 the exam.

153  
 154 (2) The definitions in Part 222 shall apply to these standards.  
 155

156 **Section 3. Requirements for approval for applicants proposing to initiate a CT scanner service**  
 157 **other than a dental CT scanner service or hospital-based portable CT scanner service**  
 158

159 Sec. 3. An applicant proposing to initiate a CT scanner service shall demonstrate each of the  
 160 following, as applicable:

161 (1) A hospital proposing to initiate its first fixed CT scanner service shall demonstrate each of the  
 162 following:

163 (a) The proposed site is a hospital licensed under Part 215 of the Code.

164 (b) The hospital operates an emergency room that provides 24-hour emergency care services as  
 165 authorized by the local medical control authority to receive ambulance runs.

166  
 167 (2) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1),  
 168 proposing to initiate a fixed CT scanner service shall project an operating level of at least 7,500 CT  
 169 equivalents per year for the second 12-month period after beginning operation of the CT scanner.

170  
 171 (3) An applicant proposing to initiate a mobile CT scanner service shall project an operating level of  
 172 at least 3,500 CT equivalents per year for the second 12-month period after beginning operation of the  
 173 CT scanner.

174  
 175 **Section 4. Requirements for approval for applicants proposing to initiate a dental CT scanner**  
 176 **service**

177  
 178 Sec. 4. An applicant proposing to initiate a dental CT scanner service shall demonstrate each of the  
 179 following, as applicable:

180  
 181 (1) An applicant is proposing a fixed CT scanner service for the sole purpose of performing dental  
 182 CT examinations.

183  
 184 (2) The CT scanner generates a peak power of 5 kilowatts or less as certified by the manufacturer.

185  
 186 (3) An applicant proposing to initiate a dental CT scanner service, **OTHER THAN AN APPLICANT**  
 187 **THAT IS PROPOSING A DENTAL CT SCANNER SERVICE IN HSA 8**, shall project an operating level of  
 188 at least 200 dental CT examinations per year for the second 12-month period after beginning operation of  
 189 the dental CT scanner.

190  
 191 (4) The applicant has demonstrated to the satisfaction of the Department that the person(s) (e.g.,  
 192 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by  
 193 one of the following groups, as recognized by the Department: a dental radiology program in a certified  
 194 dental school, an appropriate professional society, or a dental continuing education program accredited  
 195 by the American Dental Association.

196  
 197 (5) The applicant has demonstrated to the satisfaction of the Department that the dental CT  
 198 examinations generated by the proposed dental CT scanner will be interpreted by a licensed dentist(s)  
 199 trained and/or certified by one of the following groups, as recognized by the Department: a dental  
 200 radiology program in a certified dental school, an appropriate professional society, or a dental continuing  
 201 education program accredited by the American Dental Association.

202  
 203 **Section 5. Requirements for approval for applicants proposing to expand an existing CT scanner**  
 204 **service other than a dental CT scanner service or hospital-based portable CT scanner service**

205  
 206 Sec. 5. (1) An applicant proposing to expand an existing fixed CT scanner service shall demonstrate  
 207 that all of the applicant's fixed CT scanners, excluding CT scanners approved pursuant to sections 13  
 208 and 17, have performed an average of at least 10,000 CT equivalents per fixed CT scanner for the most  
 209 recent continuous 12-month period preceding the applicant's request. In computing this average, the  
 210 Department will divide the total number of CT equivalents performed by the applicant's total number of  
 211 fixed CT scanners, including both operational and approved but not operational fixed CT scanners.

212

213 (2) An applicant proposing to expand an existing fixed CT scanner service approved pursuant to  
 214 Section 17 shall demonstrate that all of the applicant's dedicated pediatric CT scanners have performed  
 215 an average of at least 3,000 CT equivalents per dedicated pediatric CT scanner for the most recent  
 216 continuous 12-month period preceding the applicant's request. In computing this average, the  
 217 Department will divide the total number of CT equivalents performed by the applicant's total number of  
 218 dedicated pediatric CT scanners, including both operational and approved but not operational dedicated  
 219 pediatric CT scanners.

220

221 (3) If an applicant proposes to expand an existing mobile CT scanner service, the applicant shall  
 222 demonstrate that all of the applicant's mobile CT scanners have performed an average of at least 5,500  
 223 CT equivalents per mobile CT scanner for the most recent continuous 12-month period preceding the  
 224 applicant's request. In computing this average, the Department will divide the total number of CT  
 225 equivalents performed by the applicant's total number of mobile CT scanners, including both operational  
 226 and approved but not operational mobile CT scanners.

227

### 228 **Section 6. Requirements for approval for applicants proposing to expand an existing dental CT** 229 **scanner service**

230

231 Sec. 6. An applicant proposing to expand an existing fixed dental CT scanner service shall  
 232 demonstrate that all of the applicant's dental CT scanners have performed an average of at least 300  
 233 dental CT examinations per fixed dental CT scanner for the most recent continuous 12-month period  
 234 preceding the applicant's request. In computing this average, the Department will divide the total number  
 235 of dental CT examinations performed by the applicant's total number of fixed dental CT scanners,  
 236 including both operational and approved but not operational fixed dental CT scanners.

237

### 238 **Section 7. Requirements for approval for applicants proposing to replace an existing CT scanner** 239 **other than a dental CT scanner or hospital-based portable CT scanner**

240

241 Sec. 7. An applicant proposing to replace an existing CT scanner shall demonstrate each of the  
 242 following, as applicable:

243

244 (1) An applicant, other than an applicant meeting all of the applicable requirements of subsection (a),  
 245 (b) or (c) below, proposing to replace an existing fixed CT scanner shall demonstrate that the fixed CT  
 246 scanner(s) performed at least an average of 7,500 CT equivalents per fixed CT scanner in the most  
 247 recent 12-month period for which the Department has verifiable data.

248 (a) A hospital proposing to replace an existing CT scanner which is the only fixed CT scanner  
 249 operated at that site by the hospital shall demonstrate each of the following:

250 (i) The proposed site is a hospital licensed under Part 215 of the Code.

251 (ii) The hospital operates an emergency room that provides 24-hour emergency care services as  
 252 authorized by the local medical control authority to receive ambulance runs.

253 (iii) The replacement CT scanner will be located at the same site as the CT scanner to be replaced.

254 (b) An applicant proposing to replace an existing fixed CT scanner shall be exempt once from the  
 255 volume requirements if the existing CT scanner demonstrates that it meets all of the following:

256 (i) The existing CT scanner has performed at least 5,000 CT equivalents in the most recent 12-  
 257 month period for which the Department has verifiable data.

258 (ii) The existing CT scanner is fully depreciated according to generally accepted accounting  
 259 principles.

260 (iii) The existing CT scanner has at one time met its minimum volume requirements.

261 (c) An applicant proposing to replace an existing fixed CT scanner on an academic medical center  
 262 campus, at the same site, shall be exempt once, as of the effective date of the standards MAY 5, 2008,  
 263 from the minimum volume requirements for replacement if the existing CT scanner is fully depreciated  
 264 according to generally accepted accounting principles.

(D) AN APPLICANT PROPOSING TO REPLACE AN EXISTING FIXED CT SCANNER HAVING A CONFIGURATION OF LESS THAN 16 MULTIDETECTOR ROWS SHALL BE EXEMPT ONCE, AS OF THE EFFECTIVE DATE OF THE STANDARDS, FROM THE MINIMUM VOLUME REQUIREMENTS FOR REPLACEMENT IF IT MEETS BOTH OF THE FOLLOWING:

(i) THE PROPOSED CT SCANNER TO BE OBTAINED WILL HAVE A CONFIGURATION OF SIXTEEN (16) OR MORE MULTIDETECTOR ROWS, AND

(ii) THE EXISTING CT SCANNER IS FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED ACCOUNTING PRINCIPLES.

(2) An applicant proposing to replace an existing mobile CT scanner(s) shall demonstrate that the mobile CT scanner(s) performed at least 3,500 CT equivalents if the applicant operates only one mobile CT scanner or an average of 5,500 CT equivalents for each CT scanner if the applicant operates more than one mobile CT scanner for the same mobile CT scanner network, in the most recent 12-month period for which the department has verifiable data.

(3) An applicant proposing to replace an existing dedicated pediatric CT scanner(s) shall demonstrate that the dedicated pediatric CT scanner(s) performed at least an average of 2,500 CT equivalents per dedicated pediatric CT scanner in the most recent 12-month period for which the Department has verifiable data.

(4) An applicant under this section shall demonstrate that the existing CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or, that the proposed replacement CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

#### **Section 8. Requirements for approval for applicants proposing to replace an existing dental CT scanner**

Sec. 8. An applicant proposing to replace an existing dental CT scanner shall demonstrate each of the following:

(1) An applicant proposing to replace an existing fixed dental CT scanner shall demonstrate that the fixed dental CT scanner(s) performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most recent 12-month period for which the Department has verifiable data.

(2) An applicant under this section shall demonstrate that the existing dental CT scanner(s) proposed to be replaced is fully depreciated according to generally accepted accounting principles, or, that the existing equipment clearly poses a threat to the safety of the public, or that the proposed replacement dental CT scanner offers technological improvements which enhance quality of care, increase efficiency, and/or reduce operating costs and patient charges.

#### **Section 9. Requirements for approval for applicants proposing to relocate an existing CT scanner service and/or CT scanner(s) other than an existing dental CT scanner service and/or dental CT scanner(s) or hospital-based portable CT scanner(s)**

Sec. 9. (1) An applicant proposing to relocate an existing fixed CT scanner service shall demonstrate that the proposed project meets all of the following:

(a) The existing fixed CT scanner service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.

(b) The proposed new site is in the relocation zone.

(c) The requirements of sections 5 or 7, as applicable, have been met.

(d) The CT scanner service to be relocated performed at least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which the Department has verifiable data.

318 (e) The applicant agrees to operate the CT scanner service in accordance with all applicable project  
319 delivery requirements set forth in Section 19 of these standards.

320  
321 (2) An applicant proposing to relocate a fixed CT scanner(s) of an existing CT scanner service shall  
322 demonstrate that the proposed project meets all of the following:

323 (a) The existing CT scanner service from which the CT scanner(s) is to be relocated has been in  
324 operation for at least 36 months as of the date an application is submitted to the Department.

325 (b) The proposed new site is in the relocation zone.

326 (c) The requirements of sections 5 or 7, as applicable, have been met.

327 (d) Each existing CT scanner at the service from which a scanner is to be relocated performed at  
328 least an average of 7,500 CT equivalents per fixed scanner in the most recent 12-month period for which  
329 the Department has verifiable data.

330 (e) The applicant agrees to operate the CT scanner(s) at the proposed site in accordance with all  
331 applicable project delivery requirements set forth in Section 19 of these standards.

332  
333 **Section 10. Requirements for approval for applicants proposing to relocate an existing dental CT**  
334 **scanner service and/or dental CT scanner(s)**

335  
336 Sec. 10. (1) An applicant proposing to relocate an existing fixed dental CT scanner service shall  
337 demonstrate that the proposed project meets all of the following:

338 (a) The existing fixed dental CT scanner service to be relocated has been in operation for at least 36  
339 month as of the date an application is submitted to the Department.

340 (b) The proposed new site is in the relocation zone.

341 (c) The requirements of sections 6 or 8, as applicable, have been met.

342 (d) The dental CT scanner service to be relocated performed at least an average of 200 dental CT  
343 examinations per fixed dental CT scanner in the most recent 12-month period for which the Department  
344 has verifiable data.

345 (e) The applicant agrees to operate the dental CT scanner service in accordance with all applicable  
346 project delivery requirements set forth in Section 19 of these standards.

347  
348 (2) An applicant proposing to relocate a fixed dental CT scanner(s) of an existing dental CT scanner  
349 service shall demonstrate that the proposed project meets all of the following:

350 (a) The existing dental CT scanner service from which the dental CT scanner(s) is to be relocated  
351 has been in operation for at least 36 months as of the date an application is submitted to the Department.

352 (b) The proposed new site is in the relocation zone.

353 (c) The requirements of sections 6 or 8, as applicable have been met.

354 (d) Each existing dental CT scanner at the service from which a scanner is to be relocated  
355 performed at least an average of 200 dental CT examinations per fixed dental CT scanner in the most  
356 recent 12-month period for which the Department has verifiable data.

357 (e) The applicant agrees to operate the dental CT scanner(s) at the proposed site in accordance with  
358 all applicable project delivery requirements set forth in Section 19 of these standards.

359  
360 **Section 11. Requirements for approval for applicants proposing to acquire an existing CT**  
361 **scanner service or an existing CT scanner(s) other than an existing dental CT scanner service**  
362 **and/or an existing dental CT scanner(s) or hospital-based portable CT scanner(s)**

363  
364 Sec. 11. (1) An applicant proposing to acquire an existing fixed or mobile CT scanner service shall  
365 demonstrate that a proposed project meets all of the following:

366 (a) The requirements of sections 5, 7, or 9, as applicable, have been met.

367 (b) For an application for the proposed first acquisition of an existing fixed or mobile CT scanner  
368 service, for which a final decision has not been issued after June 4, 2004, an existing CT scanner service  
369 to be acquired shall not be required to be in compliance with the volume requirement applicable to the  
370 seller/lessor on the date the acquisition occurs. The CT scanner service shall be operating at the

371 applicable volume requirements set forth in Section 19 of these standards in the second 12 months after  
 372 the date the service is acquired, and annually thereafter.

373 (c) For any application for proposed acquisition of an existing fixed or mobile CT scanner service, an  
 374 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least  
 375 7,500 CT equivalents in the most recent 12-month period for which the Department has verifiable data.  
 376

377 (2) An applicant proposing to acquire an existing fixed or mobile CT scanner(s) of an existing fixed or  
 378 mobile CT scanner service shall demonstrate that the proposed project meets all of the following:

379 (a) The requirements of sections 5, 7 or 9, as applicable, have been met.

380 (b) For any application for proposed acquisition of an existing fixed or mobile CT scanner(s) of an  
 381 existing fixed or mobile CT scanner service, an applicant shall be required to demonstrate that the fixed  
 382 or mobile CT scanner(s) to be acquired performed at least 7,500 CT equivalents in the most recent 12-  
 383 month period for which the Department has verifiable data.  
 384

### 385 **Section 12. Requirements for approval for applicants proposing to acquire an existing dental CT** 386 **scanner service or an existing dental CT scanner(s)** 387

388 Sec. 12. (1) An applicant proposing to acquire an existing fixed dental CT scanner service shall  
 389 demonstrate that a proposed project meets all of the following:

390 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.

391 (b) For an application for the proposed first acquisition of an existing fixed dental CT scanner  
 392 service, for which a final decision has not been issued after the effective date of these standards, an  
 393 existing dental CT scanner service to be acquired shall not be required to be in compliance with the  
 394 volume requirement applicable to the seller/lessor on the date the acquisition occurs. The dental CT  
 395 scanner service shall be operating at the applicable volume requirements set forth in Section 19 of these  
 396 standards in the second 12 months after the date the service is acquired, and annually thereafter.

397 (c) For any application for proposed acquisition of an existing fixed dental CT scanner service, an  
 398 applicant shall be required to demonstrate that the CT scanner service to be acquired performed at least  
 399 200 dental CT examinations in the most recent 12-month period, for which the Department has verifiable  
 400 data.

401 (2) An applicant proposing to acquire an existing fixed dental CT scanner(s) of an existing fixed  
 402 dental CT scanner service shall demonstrate that the proposed project meets all of the following:

403 (a) The requirements of sections 6, 8, or 10, as applicable, have been met.

404 (b) For any application for proposed acquisition of an existing fixed dental CT scanner(s) of an  
 405 existing fixed dental CT scanner service, an applicant shall be required to demonstrate that the fixed  
 406 dental CT scanner(s) to be acquired performed at least 200 dental CT examinations in the most recent  
 407 12-month period for which the Department has verifiable data.  
 408

### 409 **Section 13. Pilot program requirements for approval of a hospital-based portable CT scanner for** 410 **initiation, expansion, replacement, and acquisition** 411

412 Sec. 13. As a pilot program, an applicant proposing to initiate, expand, replace, or acquire a hospital-  
 413 based portable CT scanner shall demonstrate that it meets all of the following:

414 (1) An applicant is limited to the initiation, expansion, replacement, or acquisition of no more than two  
 415 hospital-based portable CT scanners.  
 416

417 (2) The proposed site is a hospital licensed under Part 215 of the Code.  
 418

419 (3) The hospital has been certified as a level I or level II trauma facility by the American College of  
 420 Surgeons, **OR HAS PERFORMED >100 CRANIOTOMIES IN THE MOST RECENT 12- MONTH**  
 421 **PERIOD VERIFIABLE BY THE DEPARTMENT.**  
 422  
 423

424 (4) The applicant agrees to operate the hospital-based portable CT scanner in accordance with all  
 425 applicable project delivery requirements set forth in Section 19 of these standards.

426  
 427 (5) The approved hospital-based portable CT scanner will not be subject to CT volume requirements.  
 428

429 (6) The applicant may not utilize CT procedures performed on a hospital-based portable CT scanner  
 430 to demonstrate need or to satisfy CT CON review standards requirements.  
 431

432 (7) **THE COMMISSION MAY DECIDE TO HAVE THE REQUIREMENTS OF THE PILOT**  
 433 **PROGRAM DESCRIBED IN THIS SECTION BECOME A PERMANENT PART OF THE CT SCANNER**  
 434 **SERVICES STANDARDS. IF THE COMMISSION DOES NOT TAKE ACTION TO MAKE THE PILOT**  
 435 **PROGRAM A PERMANENT PART OF THE STANDARDS, The-~~THE~~ provisions of Section 13, are aS**  
 436 **part of a pilot program, approved by the CON Commission and shall ~~WILL~~ expire ON DECEMBER 31,**  
 437 **2016 and be of no further force and effect AFTER DECEMBER 31, 2016. ANY APPLICANT SEEKING**  
 438 **TO BE PART OF THE PILOT PROGRAM DESCRIBED IN THIS SECTION MUST SUBMIT ITS**  
 439 **APPLICATION ON OR BEFORE DECEMBER 1, 2013, and THESE PROVISIONS shall not be**  
 440 **applicable to any application which has not been submitted by ~~October~~ DECEMBER 1, 20082013.**  
 441

#### 442 **Section 14. Requirements for approval of a PET/CT hybrid for initiation, expansion, replacement,** 443 **and acquisition** 444

445 Sec. 14. An applicant proposing to initiate, expand, replace, or acquire a PET/CT hybrid shall  
 446 demonstrate that it meets all of the following:  
 447

448 (1) There is an approved PET CON for the PET/CT hybrid, and the PET/CT hybrid is in compliance  
 449 with all applicable project delivery requirements as set forth in the CON review standards for PET.  
 450

451 (2) The applicant agrees to operate the PET/CT hybrid in accordance with all applicable project  
 452 delivery requirements set forth in Section 19 of these standards.  
 453

454 (3) The approved PET/CT hybrid will not be subject to CT volume requirements.  
 455

456 (4) A PET/CT scanner hybrid approved under the CON Review Standards for PET Scanner Services  
 457 and the Review Standards for CT Scanner Services may not utilize CT procedures performed on a hybrid  
 458 scanner to demonstrate need or to satisfy CT CON review standards requirements.  
 459

#### 460 **Section 15. Additional requirements for approval of a mobile CT scanner service** 461

462 Sec. 15. (1) An applicant proposing to initiate a mobile CT scanner service in Michigan shall  
 463 demonstrate that it meets all of the following:  
 464

465 (a) A separate CON application shall be submitted by the central service coordinator and each  
 466 Michigan host facility.

467 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all  
 468 potential contracts related to the mobile CT scanner service shall be included in the CON application  
 469 submitted by the central service coordinator.

470 (c) The requirements of sections 3, 5, or 7, as applicable, have been met.  
 471

472 (2) An applicant proposing to become a host facility on an existing mobile CT scanner network shall  
 473 demonstrate that it meets all of the following:  
 474

475 (a) Approval of the application will not result in an increase in the number of operating mobile CT  
 476 scanners for the mobile CT scanner network unless the requirements of Section 5 have been met.

(b) A separate CON application has been filed for each host facility.

477 (3) An applicant proposing to replace a central service coordinator on an existing mobile CT scanner  
 478 network shall demonstrate that approval of the application will not replace the CT scanner and  
 479 transporting equipment unless the applicable requirements of Section 7 have been met.  
 480

481 **Section 16. Requirements for approval of an applicant proposing a CT scanner used for the sole**  
 482 **purpose of performing dental CT examinations exclusively for research**  
 483

484 Sec. 16. (1) An applicant proposing a CT scanner used for the sole purpose of performing dental CT  
 485 examinations exclusively for research shall demonstrate each of the following:

486 (a) The applicant operates a dental radiology program in a certified dental school.  
 487 (b) The research dental CT scanner shall operate under a protocol approved by the applicant's  
 488 institutional review board.

489 (c) The applicant agrees to operate the research dental CT scanner in accordance with the terms of  
 490 approval in Section 19(4).  
 491

492 (2) An applicant meeting the requirements of subsection (1) shall also demonstrate compliance with  
 493 the requirements of sections 4(2), 4(4) and 4(5).  
 494

495 **Section 17. Requirements for approval of an applicant proposing to establish dedicated pediatric**  
 496 **CT**  
 497

498 Sec. 17. (1) An applicant proposing to establish dedicated pediatric CT shall demonstrate all of the  
 499 following:

500 (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges  
 501 (excluding normal newborns) in the most recent year of operation.

502 (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most  
 503 recent year of operation.

504 (c) The applicant shall have an active medical staff, at the time the application is submitted to the  
 505 Department that includes, but is not limited to, physicians who are fellowship-trained in the following  
 506 pediatric specialties:

- 507 (i) pediatric radiology (at least two)
- 508 (ii) pediatric anesthesiology
- 509 (iii) pediatric cardiology
- 510 (iv) pediatric critical care
- 511 (v) pediatric gastroenterology
- 512 (vi) pediatric hematology/oncology
- 513 (vii) pediatric neurology
- 514 (viii) pediatric neurosurgery
- 515 (ix) pediatric orthopedic surgery
- 516 (x) pediatric pathology
- 517 (xi) pediatric pulmonology
- 518 (xii) pediatric surgery
- 519 (xiii) neonatology

520 (d) The applicant shall have in operation the following pediatric specialty programs at the time the  
 521 application is submitted to the Department:

- 522 (i) pediatric bone marrow transplant program
- 523 (ii) established pediatric sedation program
- 524 (iii) pediatric open heart program

525

526 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
 527 requirements of Section 3 of these standards.

528 **Section 18. Requirements for approval -- all applicants**  
 529

530 Sec. 18. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
 531 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
 532 to the Department within six (6) months from the offering of services, if a CON is approved.  
 533

534 **Section 19. Project delivery requirements -- terms of approval for all applicants**  
 535

536 Sec. 19. (1) An applicant shall agree that, if approved, the services provided by the CT scanner(s)  
 537 shall be delivered in compliance with the following terms of CON approval:

538 (a) Compliance with these standards

539 (b) Compliance with applicable safety and operating standards

540 (c) Compliance with the following quality assurance standards:

541 (i) The approved CT scanners shall be operating at the applicable required volumes within the time  
 542 periods specified in these standards, and annually thereafter.

543 (ii) The applicant shall establish a mechanism to assure that the CT scanner facility is staffed so  
 544 that:

545 (A) The screening of requests for CT procedures and interpretation of CT procedures will be  
 546 performed by physicians with training and experience in the appropriate diagnostic use and interpretation  
 547 of cross-sectional images of the anatomical region(s) to be examined, and

548 (B) The CT scanner is operated by physicians and/or is operated by radiological technologists  
 549 qualified by training and experience to operate the CT scanner safely and effectively.

550 For purposes of evaluating (ii)(A), the Department shall consider it prima facie evidence of a  
 551 satisfactory assurance mechanism as to screening and interpretation if the applicant requires the  
 552 screening of requests for and interpretations of CT procedures to be performed by physicians who are  
 553 board certified or eligible in radiology or are neurologists or other specialists trained in cross-sectional  
 554 imaging of a specific organ system. For purposes of evaluating (ii)(B) the Department shall consider it  
 555 prima facie evidence of a satisfactory assurance mechanism as to the operation of a CT scanner if the  
 556 applicant requires the CT scanner to be operated by a physician or by a technologist registered by the  
 557 American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical  
 558 Radiography Technologists (ARCRT). However, the applicant may submit and the Department may  
 559 accept other evidence that the applicant has established a mechanism to assure that the CT scanner  
 560 facility is appropriately and adequately staffed as to screening, interpretation, and/or operation of a CT  
 561 scanner.

562 (iii) The applicant shall employ or contract with a radiation physicist to review the quality and safety of  
 563 the operation of the CT scanner.

564 (iv) The applicant shall assure that at least one of the physicians responsible for the screening and  
 565 interpretation as defined in subsection (ii)(A) will be in the CT facility or available on a 24-hour basis  
 566 (either on-site or through telecommunication capabilities) to make the final interpretation.

567 (v) In the case of an urgent or emergency CT scan, the applicant shall assure that a physician so  
 568 authorized by the applicant to interpret initial scans will be on-site or available through telecommunication  
 569 capabilities within 1 hour following completion of the scanning procedure to render an initial interpretation  
 570 of the scan. A final interpretation shall be rendered by a physician so authorized under subsection (ii)(A)  
 571 within 24 hours.

572 (vi) The applicant shall have, within the CT scanner facility, equipment and supplies to handle clinical  
 573 emergencies that might occur within the CT unit, with CT facility staff trained in CPR and other  
 574 appropriate emergency interventions, and a physician on site in or immediately available to the CT  
 575 scanner at all times when patients are undergoing scans.

576 (vii) Fixed CT scanner services at each facility shall be made available 24 hours a day for emergency  
 577 patients.

578 (viii) The applicant shall accept referrals for CT scanner services from all appropriately licensed  
 579 practitioners.

580 (ix) The applicant shall establish and maintain: (a) a standing medical staff and governing body (or its  
581 equivalent) requirement that provides for the medical and administrative control of the ordering and  
582 utilization of CT patient procedures, and (b) a formal program of utilization review and quality assurance.  
583 These responsibilities may be assigned to an existing body of the applicant, as appropriate.

584 (x) An applicant approved under Section 17 must be able to prove that all radiologists, technologists  
585 and nursing staff working with CT patients have continuing education or in-service training on pediatric  
586 low-dose CT. The site must also be able to provide evidence of defined low-dose pediatric CT protocols.

587 (xi) The applicant, to assure that the CT scanner will be utilized by all segments of the Michigan  
588 population, shall:

589 (A) not deny CT scanner services to any individual based on ability to pay or source of payment;

590 (B) provide CT scanning services to any individual based on the clinical indications of need for the  
591 service; and

592 (C) maintain information by payor and non-paying sources to indicate the volume of care from each  
593 source provided annually.

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

595 (xii) The applicant shall participate in a data collection network established and administered by the  
596 Department or its designee. The data may include, but is not limited to, annual budget and cost  
597 information, operating schedules, through-put schedules, demographic and diagnostic information, the  
598 volume of care provided to patients from all payor sources, and other data requested by the Department,  
599 and approved by the Commission. The applicant shall provide the required data on a separate basis for  
600 each separate and distinct site as required by the Department; in a format established by the Department;  
601 and in a mutually agreed upon media. The Department may elect to verify the data through on-site  
602 review of appropriate records.

603 (xiii) Equipment to be replaced shall be removed from service.

604 (xiv) The applicant shall provide the Department with a notice stating the date the approved CT  
605 scanner service is placed in operation and such notice shall be submitted to the Department consistent  
606 with applicable statute and promulgated rules.

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

609 (d) An applicant approved under Section 4 shall not be required to be in compliance with subsection  
610 (c) but shall be in compliance with the following quality assurance standards:

611 (i) The CT scanner shall be operating at least 200 CT equivalents per year for the second 12-month  
612 period after beginning operation of the dental CT scanner and annually thereafter.

613 (ii) The CT scanner will be used for the sole purpose of dental CT examinations.

614 (iii) The applicant shall demonstrate to the satisfaction of the Department that the person(s) (e.g.,  
615 technician, dentist) operating the dental CT scanner has been appropriately trained and/or certified by  
616 one of the following groups, as recognized by the Department: a dental radiology program in a certified  
617 dental school, an appropriate professional society, or a dental continuing education program accredited  
618 by the American Dental Association.

619 (iv) The applicant shall demonstrate to the satisfaction of the Department that the dental CT  
620 examinations generated by the dental CT scanner will be interpreted by a licensed dentist(s) trained  
621 and/or certified by one of the following groups, as recognized by the Department: a dental radiology  
622 program in a certified dental school, an appropriate professional society, or a dental continuing education  
623 program accredited by the American Dental Association.

624 (v) The applicant shall demonstrate to the satisfaction of the Department that the dentists using the  
625 dental CT examinations for performing dental procedures has had the appropriate training and/or  
626 experience certified by one of the following groups, as recognized by the Department: a dental radiology  
627 program in a certified dental school, an appropriate professional society, or a dental continuing education  
628 program accredited by the American Dental Association.

629 (vi) The applicant, to assure that the dental CT scanner will be utilized by all segments of the  
630 Michigan population, shall:

631 (A) not deny dental CT scanner services to any individual based on ability to pay or source of  
632 payment;

633 (B) provide dental CT scanning services to any individual based on the clinical indications of need for  
634 the service; and

635 (C) maintain information by payor and non-paying sources to indicate the volume of care from each  
636 source provided annually. Compliance with selective contracting requirements shall not be construed as  
637 a violation of this term.

638 (vii) The applicant shall participate in a data collection network established and administered by the  
639 Department or its designee. The data may include, but is not limited to, annual budget and cost  
640 information, operating schedules, through-put schedules, demographic and diagnostic information, the  
641 volume of care provided to patients from all payor sources, and other data requested by the Department,  
642 and approved by the Commission. The applicant shall provide the required data on a separate basis for  
643 each separate and distinct site as required by the Department; in a format established by the Department;  
644 and in a mutually agreed upon media. The Department may elect to verify the data through on-site  
645 review of appropriate records.

646 (viii) Equipment to be replaced shall be removed from service.

647 (ix) The applicant shall provide the Department with a notice stating the date the approved dental CT  
648 scanner service is placed in operation and such notice shall be submitted to the Department consistent  
649 with applicable statute and promulgated rules.

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

652

653 (2) The agreements and assurances required by this section shall be in the form of a certification  
654 agreed to by the applicant or its authorized agent.

655

656 (3) The operation of and referral of patients to the CT scanner shall be in conformance with 1978 PA  
657 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

658

659 (4) An applicant for a CT scanner used for dental research under Section 16(1) shall agree that the  
660 services provided by the CT scanner approved pursuant to Section 16(1) shall be delivered in compliance  
661 with the following terms of CON approval:

662 (a) The capital and operating costs relating to the CT scanner used for dental research pursuant to  
663 Section 16(1) shall be charged only to a specific research account(s) and not to any patient or third-party  
664 payor.

665 (b) The CT scanner used for dental research approved pursuant to Section 16(1) shall not be used  
666 for any purposes other than as approved by the institutional review board unless the applicant has  
667 obtained CON approval for the CT scanner pursuant to part 222 and these standards, other than Section  
668 16.

669

670 (5) An applicant approved under Section 13 shall be in compliance with the following:

671 (A) PORTABLE CT SCANNER CAN ONLY BE USED BY A QUALIFYING PILOT PROGRAM FOR  
672 THE FOLLOWING PURPOSES:

673 (I) BRAIN SCANNING OF PATIENTS BEING TREATED IN AN ADULT OR PEDIATRIC  
674 INTENSIVE CARE UNIT (ICU).

675 (II) NON-DIAGNOSTIC, INTRAOPERATIVE GUIDANCE IN AN OPERATING ROOM.

676 (a) The APPROVED applicant agrees to MUST provide quarterly ANNUAL reports to the Department  
677 within one month following the end of each calendar quarter, starting with the quarter the applicant  
678 initiates use of the hospital-based portable CT scanner BY JANUARY 31<sup>ST</sup> OF EACH YEAR FOR THE  
679 PRECEDING CALENDAR YEAR;-. THIS REQUIREMENT APPLIES TO ALL APPLICANTS APPROVED  
680 UNDER SECTION 13 AND BEGINS WITH 2010 DATA WHICH IS TO BE REPORTED IN 2011.

681 (C) THE FOLLOWING DATA MUST BE REPORTED TO THE DEPARTMENT:

682 (b) The Department will develop a questionnaire to be used by the applicant for the quarterly report.  
683 This questionnaire, at a minimum, will include information regarding the utilization, cost, and benefit for  
684 patient care as compared to the use of full-body CT scanners. NUMBER OF ADULT STUDIES  
685 (AGE >= 18)

686 (II) NUMBER OF PEDIATRIC STUDIES (AGE<18)

687 (III) NUMBER OF STUDIES PERFORMED USING A PORTABLE CT ON THE SAME PATIENT  
688 WHILE THAT PATIENT IS IN AN ICU

689 (IV) NUMBER OF PATIENTS SCANNED ON A PORTABLE CT THAT UNDERWENT SUBSEQUENT  
690 SCANNING ON A FIXED CT WITHIN 12 HOURS OF THE PORTABLE CT SCAN

691 ~~— (c) The Department will summarize the information from the quarterly reports and provide an  
692 assessment to the Commission prior to the March 2010 Commission meeting. The Commission may  
693 request updates on the status of the pilot program at its discretion.~~

694 **Section 20. Project delivery requirements -- additional terms of approval for applicants involving  
695 mobile CT scanners**

696  
697  
698 Sec. 20. (1) In addition to the provisions of Section 19, an applicant for a mobile CT scanner shall  
699 agree that the services provided by the mobile CT scanner(s) shall be delivered in compliance with the  
700 following terms of CON approval:

701 (a) A host facility shall submit only one CON application for a CT scanner for review at any given  
702 time.

703 (b) A mobile CT scanner with an approved CON shall notify the Michigan Department of Community  
704 Health prior to ending service with an existing host facility.

705 (c) A CON shall be required to add a host facility.

706 (d) A CON shall be required to change the central service coordinator.

707 (e) Each host facility must have at least one board certified or board eligible radiologist on its medical  
708 staff. The radiologist(s) shall be responsible for: (i) establishing patient examination and infusion  
709 protocol, and (ii) providing for the interpretation of scans performed by the mobile CT scanner.

710 (f) Each mobile CT scanner service must have an Operations Committee with members  
711 representing each host facility, the central service coordinator, and the central service medical director.  
712 This committee shall oversee the effective and efficient use of the CT scanner, establish the normal route  
713 schedule, identify the process by which changes are to be made to the schedule, develop procedures for  
714 handling emergency situations, and review the ongoing operations of the mobile CT scanner on at least a  
715 quarterly basis.

716 (g) The central service coordinator shall arrange for emergency repair services to be available 24  
717 hours each day for the mobile CT scanner as well as the vehicle transporting the equipment. In addition,  
718 to preserve image quality and minimize CT scanner downtime, calibration checks shall be performed on  
719 the CT scanner at least once each work day and routine maintenance services shall be provided on a  
720 regularly scheduled basis, at least once a week during hours not normally used for patient procedures.

721 (h) Each host facility must provide a properly prepared parking pad for the mobile CT scanner of  
722 sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for  
723 patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host  
724 facility must also provide the capability for processing the film and maintaining the confidentiality of  
725 patient records. A communication system must be provided between the mobile vehicle and each host  
726 facility to provide for immediate notification of emergency medical situations.

727 (i) A mobile CT scanner service shall operate under a contractual agreement that includes the  
728 provision of CT scanner services at each host facility on a regularly scheduled basis.

729 (j) The volume of utilization at each host facility shall be reported to the Department by the central  
730 service coordinator under the terms of Section 19(1)(c)(xi).

731  
732 (2) The agreements and assurances required by this section shall be in the form of a certification  
733 agreed to by the applicant or its authorized agent.

734  
735 **Section 21. Determination of CT Equivalents**

736  
737 Sec. 21. CT equivalents shall be calculated as follows:

738 (a) Each billable procedure for the time period specified in the applicable section(s) of these  
739 standards shall be assigned to a category set forth in Table 1.

740 (b) The number of billable procedures for each category in the time period specified in the applicable  
741 section(s) of these standards shall be multiplied by the corresponding conversion factor in Table 1 to  
742 determine the number of CT equivalents for that category for that time period.

743 (c) The number of CT equivalents for each category shall be summed to determine the total CT  
744 equivalents for the time period specified in the applicable section(s) of these standards.

745 (d) The conversion factor for pediatric/special needs patients does not apply to procedures  
746 performed on a dedicated pediatric CT scanner.

747

748 Table 1	Number of		Conversion		CT
749 Category	Billable CT		Factor		Equivalents
750	Procedures				
751					
752 Head Scans w/o Contrast	_____	X	1.00	=	_____
753 (includes dental CT examinations)					
754 Head Scans with Contrast	_____	X	1.25	=	_____
755 Head Scans w/o & w Contrast	_____	X	1.75	=	_____
756 Body Scans w/o Contrast	_____	X	1.50	=	_____
757 Body Scans with Contrast	_____	X	1.75	=	_____
758 Body Scans w/o & w Contrast	_____	X	2.75	=	_____
759					
760 Pediatric/Special Needs Patient					
761 Head scans w/o Contrast	_____	x	1.25	=	_____
762 (includes dental CT examinations)					
763 Pediatric/Special Needs Patient					
764 Head Scans with Contrast	_____	x	1.50	=	_____
765 Pediatric/Special Needs Patient					
766 Head Scans w/o & with Contrast	_____	x	2.00	=	_____
767 Pediatric/Special Needs Patient					
768 Body Scans w/o Contrast	_____	x	1.75	=	_____
769 Pediatric/Special Needs Patient					
770 Body Scans with Contrast	_____	x	2.00	=	_____
771 Pediatric/Special Needs Patient					
772 Body Scans w/o & with Contrast	_____	x	3.00	=	_____
773					
774 TOTAL CT EQUIVALENTS					_____

775

## 776 Section 22. Documentation of projections

777

778 Sec. 22. An applicant required to project volumes under sections 3, 4 and 5 shall demonstrate the  
779 following, as applicable:

780 (1) An applicant required to project under Section 3 shall demonstrate that the projection is based on  
781 historical physician referrals that resulted in an actual scan for the most recent 12-month period  
782 immediately preceding the date of the application. Historical physician referrals will be verified with the  
783 data maintained by the Department through its "Annual Hospital statistical survey" and/or "Annual  
784 Freestanding Statistical Survey."

785

786 (2) An applicant required to project under Section 4 shall demonstrate that the projection is based on  
787 a combination of the following for the most recent 12-month period immediately preceding the date of the  
788 application:

789 (a) the number of dental procedures performed by the applicant, and

790 (b) the number of committed dental procedures performed by referring licensed dentists. Further,  
791 the applicant and the referring licensed dentists shall substantiate the numbers through the submission of  
792 HIPAA compliant billing records.  
793

794 (3) An applicant required to project under Section 5 shall demonstrate that the projection is based on  
795 historical utilization at the applicant's site for the most recent 12-month period immediately preceding the  
796 date of the application.  
797

798 (4) An applicant shall demonstrate that the projected number of referrals to be performed at the  
799 proposed site under subsections (1) and (2) are from an existing CT scanner service that is in compliance  
800 with the volume requirements applicable to that service, and will continue to be in compliance with the  
801 volume requirements applicable to that service subsequent to the initiation of the proposed CT scanner  
802 service by an applicant. **ONLY EXCESS CT EQUIVALENTS EQUAL TO OR GREATER THAN WHAT IS**  
803 **BEING COMMITTED PURSUANT TO THIS SUBSECTION MAY BE USED TO DOCUMENT**  
804 **PROJECTIONS UNDER SUBSECTION (1).** In demonstrating compliance with this subsection, an  
805 applicant shall provide each of the following:

806 (a) A written commitment from each referring physician that he or she will refer at least the volume of  
807 CT scans to be transferred to the proposed CT scanner service for no less than 3 years subsequent to  
808 the initiation of the CT scanner service proposed by an applicant.

809 (b) The number of referrals committed must have resulted in an actual CT scan of the patient at the  
810 existing CT scanner service from which referral will be transferred. The committing physician must make  
811 available HIPAA compliant audit material if needed upon Department request to verify referral sources  
812 and outcomes. Commitments must be verified by the most recent data set maintained by the Department  
813 through its "Annual Hospital Statistical Survey" and/or "Annual Freestanding Statistical Survey."

814 (c) The projected referrals are from an existing CT scanner service within a 75-mile radius for rural  
815 and micropolitan statistical area counties or 20-mile radius for metropolitan statistical area counties.  
816

### 817 **Section 23. Effect on prior CON review standards; comparative reviews**

818  
819 Sec. 23. (1) These CON review standards supersede and replace the CON Review Standards for  
820 Computed Tomography Scanner Services approved by the CON Commission on **March 11 APRIL 30,**  
821 **2008 and effective ~~May 5~~ JUNE 20, 2008.**  
822

823 (2) Projects reviewed under these standards shall not be subject to comparative review.  
824

### 825 **SECTION 24. HEALTH SERVICE AREAS**

826  
827 **SEC. 24. COUNTIES ASSIGNED TO EACH OF THE HEALTH SERVICE AREAS ARE AS**  
828 **FOLLOWS:**

829 <b>HSA</b>	830 <b>COUNTIES</b>		
831 <b>1 - SOUTHEAST</b>	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
835 <b>2 - MID-SOUTHERN</b>	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE
838 <b>3 - SOUTHWEST</b>	BARRY	CALHOUN	ST. JOSEPH
	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
842 <b>4 - WEST</b>	ALLEGAN	MASON	NEWAYGO

843	IONIA	MECOSTA	OCEANA
844	KENT	MONTCALM	OSCEOLA
845	LAKE	MUSKEGON	OTTAWA
846			

847	5 - GLS	GENESEE	LAPEER	SHIAWASSEE
848				
849	6 - EAST	ARENAC	HURON	ROSCOMMON
850		BAY	IOSCO	SAGINAW
851		CLARE	ISABELLA	SANILAC
852		GLADWIN	MIDLAND	TUSCOLA
853		GRATIOT	OGEMAW	
854				
855	7 - NORTHERN LOWER	ALCONA	CRAWFORD	MISSAUKEE
856		ALPENA	EMMET	MONTMORENCY
857		ANTRIM	GD TRAVERSE	OSCODA
858		BENZIE	KALKASKA	OTSEGO
859		CHARLEVOIX	LEELANAU	PRESQUE ISLE
860		CHEBOYGAN	MANISTEE	WEXFORD
861				
862	8 - UPPER PENINSULA	ALGER	GOGEBIC	MACKINAC
863		BARAGA	HOUGHTON	MARQUETTE
864		CHIPPEWA	IRON	MENOMINEE
865		DELTA	KEWEENAW	ONTONAGON
866		DICKINSON	LUCE	SCHOOLCRAFT

**APPENDIX A**

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**CON REVIEW STANDARDS  
FOR CT SCANNER SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

Amendment  
for Requirements for Hybrid Operating Room/  
Cardiac Catheterization Laboratories (OR/CCL)  
in the  
CON Review Standards for Cardiac Catheterization Services

*Draft language*

**New Section 7**

The language models similar requirements included in the Surgical Services standards.

**SECTION 7. REQUIREMENTS FOR A HYBRID OPERATING ROOM/CARDIAC CATHETERIZATION LABORATORY (OR/CCL)**

SEC. 8. 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 SERVICE WHICH IS IN FULL COMPLIANCE WITH THE CURRENT CON REVIEW STANDARDS FOR OPEN HEART SURGERY SERVICES.

(2) THE APPLICANT OPERATES A THERAPEUTIC CARDIAC CATHETERIZATION PROGRAM WHICH IS IN FULL COMPLIANCE WITH SECTION 4(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 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 4, IF APPLICABLE.

(5) THE APPLICANT MEETS THE APPLICABLE REQUIREMENTS OF THE CON REVIEW STANDARDS FOR CARDIAC CATHETERIZATION 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 ORCCLS WITHIN A SINGLE LICENSED FACILITY.

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

**CERTIFICATE OF NEED (CON) REVIEW STANDARDS**

**FOR MAGNETIC RESONANCE IMAGING (MRI) 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, expansion, replacement, relocation, or acquisition of MRI services and the delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, MRI is 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) "Acquisition of an existing MRI service or existing MRI unit(s)" means obtaining control or possession of an existing fixed or mobile MRI service or existing MRI unit(s) by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 13, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "MRI Service Utilization List," as of the date an application is deemed submitted by the Department.

(c) "Available MRI adjusted procedures" means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed submitted by the Department.

In the case of a mobile MRI unit, the term means the sum of all MRI adjusted procedures performed by the same mobile MRI unit at all of the host sites combined that is in excess of 7,000. For example, if a mobile MRI unit serves five host sites, the term means the sum of MRI adjusted procedures for all five host sites combined that is in excess of 7,000 MRI adjusted procedures.

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s).

(e) "Certificate of Need Commission" or "CON Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

(g) "Contrast MRI procedure" means an MRI procedure involving either of the following: (i) a procedure following use of a contrast agent or (ii) procedures performed both before and after the use of a contrast agent.

(h) "Dedicated pediatric MRI" means an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age

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

54 (j) "Doctor" means an individual licensed under Article 15 of the Code to engage in the practice of  
55 medicine, osteopathic medicine and surgery, chiropractic, dentistry, or podiatry.

56 (k) "Existing MRI service" means either the utilization of a CON-approved and operational MRI  
57 unit(s) at one site in the case of a fixed MRI service, and in the case of a mobile MRI service, the  
58 utilization of a CON-approved and operational mobile MRI unit(s) at each host site, on the date an  
59 application is submitted to the Department.

60 (l) "Existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI  
61 services.

62 (m) "Expand an existing fixed MRI service" means an increase in the number of fixed MRI units to  
63 be operated by the applicant.

64 (n) "Expand an existing mobile MRI service" means the addition of a mobile MRI unit that will be  
65 operated by a central service coordinator that is approved to operate one or more mobile MRI units as of  
66 the date an application is submitted to the Department.

67 (o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C.  
68 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
69 published in the Federal Register on August 14, 1995, or its replacement.

70 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 19.

71 (q) "Host site" means the site at which a mobile MRI unit is authorized by CON to provide MRI  
72 services.

73 (r) "Initiate a fixed MRI service" means begin operation of a fixed MRI service at a site that does  
74 not provide or is not CON approved to provide fixed MRI services as of the date an application is  
75 submitted to the Department. The term does not include the acquisition or relocation of an existing fixed  
76 MRI service or the renewal of a lease.

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

80 (t) "Initiate a mobile MRI service" means begin operation of a mobile MRI unit that serves two or  
81 more host sites.

82 The term does not include the acquisition of an existing mobile MRI service or the renewal of a  
83 lease.

84 (u) "Inpatient" means an MRI visit involving an individual who has been admitted to the licensed  
85 hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed  
86 hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI  
87 service.

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

90 (w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI  
91 technology during surgical and interventional procedures within a licensed operative environment.

92 (x) "Licensed hospital site" means the location of the hospital authorized by license and listed on  
93 that licensee's certificate of licensure.

94 (y) "Magnetic resonance imaging" or "MRI" means the analysis of the interaction that occurs  
95 between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional  
96 images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.

97 (z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been  
98 adjusted in accordance with the applicable provisions of Section 13.

99 (aa) "MRI database" means the database, maintained by the Department pursuant to Section 12 of  
100 these standards, that collects information about each MRI visit at MRI services located in Michigan.

101 (bb) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections  
102 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance  
103 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic  
104 radiology residency program, under a research protocol approved by an IRB. The capital and operating  
105 costs related to the research use are charged to a specific research account and not charged to or

106 collected from third-party payors or patients. The term does not include a procedure conducted by an  
107 MRI unit approved pursuant to Section 8(1).

108 (cc) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case  
109 of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI  
110 unit at each host site.

111 (dd) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines  
112 and related equipment necessary to produce the images and/or spectroscopic quantitative data from  
113 scans. The term does not include MRI simulators used solely for treatment planning purposes in  
114 conjunction with an MRT unit.

115 (ee) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI  
116 procedures.

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

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

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

127 (ii) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central  
128 service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of  
129 MRI services at each host site on a regularly scheduled basis.

130 (jj) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor  
131 and an applicant entity or an ownership relationship between a doctor and an entity that has an  
132 ownership relationship with an applicant entity.

133 (kk) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 9.

134 (ll) "Planning area" means

135 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius  
136 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a  
137 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area  
138 county.

139 (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the  
140 geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural  
141 or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the  
142 proposed site is in a rural or micropolitan statistical area county.

143 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section  
144 13(2)(d), the health service area in which all the proposed mobile host sites will be located.

145 (mm) "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to  
146 whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility,  
147 the attending doctor who is responsible for the house officer or resident that requested the MRI  
148 procedure.

149 (nn) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an  
150 existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.

151 (oo) "Relocation zone" means the geographic area that is within a 10-mile radius of the existing site  
152 of the MRI service or unit to be relocated.

153 (pp) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit  
154 that does not involve either replacement of the MRI unit, as defined in Section 2(1)(pp)(i), or (ii) a change  
155 in the parties to the lease.

156 (qq) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or  
157 replacement of, the magnet resulting in an applicant operating the same number and type (fixed or  
158 mobile) of MRI units before and after project completion or (ii) an equipment change other than a change

159 in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month  
 160 period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or  
 161 unit, and it does not include a host site that proposes to receive mobile MRI services from a different  
 162 central service coordinator if the requirements of Section 3(5) have been met.

163 (rr) "Research scan" means an MRI scan administered under a research protocol approved by the  
 164 applicant's IRB.

165 (ss) "Re-sedated patient" means a patient, either pediatric or adult, who fails the initial sedation  
 166 during the scan time and must be extracted from the unit to rescue the patient with additional sedation.

167 (tt) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
 168 statistical areas as those terms are defined under the "standards for defining metropolitan and  
 169 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of  
 170 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as  
 171 shown in Appendix A.

172 (uu) "Sedated patient" means a patient that meets all of the following:

173 (i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as  
 174 defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint  
 175 Commission on the Accreditation of Health Care Organizations, or an equivalent definition.

176 (ii) who is monitored by mechanical devices while in the magnet.

177 (iii) who requires observation while in the magnet by personnel, other than employees routinely  
 178 assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).

179 (vv) "Site" means

180 (i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a  
 181 location that is contiguous to the licensed hospital site or

182 (ii) in the case of a location that is not a licensed hospital site, a location at the same address or a  
 183 location that is contiguous to that address.

184 (ww) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the  
 185 following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),  
 186 developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric  
 187 disorders, and other conditions that make the patient unable to comply with the positional requirements of  
 188 the exam.

189 (xx) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or  
 190 mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is  
 191 approved by the Accreditation Council on Graduate Medical Education or American Osteopathic  
 192 Association, are assigned.

193 (yy) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as  
 194 defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 13.

195 (zz) "Upgrade an existing MRI unit" means any equipment change that

196 (i) does not involve a change in, or replacement of, the magnet; does not result in an increase in  
 197 the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile  
 198 MRI unit to a fixed MRI unit); and

199 (ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any  
 200 consecutive 24-month period.

201  
 202 (2) Terms defined in the Code have the same meanings when used in these standards.  
 203

### 204 **Section 3. Requirements to initiate an MRI service**

205  
 206 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the  
 207 following requirements, as applicable:

208  
 209 (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI  
 210 adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed  
 211 service/unit.

- 212  
213 (2) An applicant proposing to initiate a fixed MRI service that meets the following requirements  
214 shall not be required to be in compliance with subsection (1):  
215 (a) The applicant is currently an existing host site.  
216 (b) The applicant has received in aggregate, one of the following:  
217 (i) At least 6,000 MRI adjusted procedures.  
218 (ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:  
219 (A) Is located in a county that has no fixed MRI machines that are pending, approved by the  
220 Department, or operational at the time the application is deemed submitted.  
221 (B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.  
222 (iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:  
223 (A) The proposed site is a hospital licensed under Part 215 of the Code.  
224 (B) The applicant hospital operates an emergency room that provides 24-hour emergency care  
225 services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the  
226 Department, is available.  
227 (c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b)  
228 shall be utilized even if the aggregated data exceeds the minimum requirements.  
229 (d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within  
230 the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI  
231 unit at the same site as the existing host site.  
232 (e) The applicant shall cease operation as a host site and not become a host site for at least 12  
233 months from the date the fixed service and its unit becomes operational.  
234  
235 (3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI  
236 adjusted procedures from within the same planning area as the proposed service/unit, and the applicant  
237 shall meet the following:  
238 (a) Identify the proposed route schedule and procedures for handling emergency situations.  
239 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI  
240 service.  
241 (c) Identify a minimum of two (2) host sites for the proposed service.  
242  
243 (4) An applicant, whether the central service coordinator or the host site, proposing to initiate a  
244 host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:  
245 (a) 600 available MRI adjusted procedures, from within the same planning area as the proposed  
246 service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or  
247 (b) 400 available MRI adjusted procedures from within the same planning area for a proposed host  
248 site that is located in a rural or micropolitan statistical area county, and  
249 (c) The proposed host site has not received any mobile MRI service within the most recent 12-  
250 month period as of the date an application is submitted to the Department.  
251  
252 (5) An applicant proposing to add or change service on an existing mobile MRI service that meets  
253 the following requirements shall not be required to be in compliance with subsection (4):  
254 (a) The host site has received mobile MRI services from an existing mobile MRI unit within the  
255 most recent 12-month period as of the date an application is submitted to the Department.  
256 (b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI  
257 service.  
258  
259 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available  
260 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as  
261 applicable, are from the most recently published MRI lists as of the date an application is deemed  
262 submitted by the Department.  
263

264 **Section 4. Requirements to replace an existing MRI unit**

265

266 Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following  
267 requirements, as applicable:

268

269 (1) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most  
270 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
271 Department:

272 (a) Each existing mobile MRI unit on the network has performed at least an average of 5,500 MRI  
273 adjusted procedures per MRI unit.

274 (b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI  
275 adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the  
276 following:

277 (i) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000  
278 MRI adjusted procedures and is the only fixed MRI unit at the current site.

279 (ii) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000  
280 MRI adjusted procedures and is the only fixed MRI unit at the current site.

281 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
282 of 3,500 MRI adjusted procedures per MRI unit.

283

284 (2) Equipment that is replaced shall be removed from service and disposed of or rendered  
285 considerably inoperable on or before the date that the replacement equipment becomes operational.

286

287 (3) The replacement unit shall be located at the same site unless the requirements of the  
288 relocation section have been met.

289

290 (4) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a  
291 lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally  
292 accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;  
293 or the proposed replacement equipment offers a significant technological improvement which enhances  
294 quality of care, increases efficiency, and reduces operating costs.

295

296 **Section 5. Requirements to expand an existing MRI service**

297

298 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

299

300 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the  
301 most recently published MRI Service Utilization List as of the date of an application is deemed submitted  
302 by the Department:

303 (a) Each existing MRI unit on the network has performed at least an average of 9,000 MRI  
304 adjusted procedures per MRI unit.

305 (b) Each existing fixed MRI unit at the current site has performed at least an average of 11,000  
306 MRI adjusted procedures per MRI unit.

307 (c) Each existing dedicated pediatric MRI unit at the current site has performed at least an average  
308 of 3,500 MRI adjusted procedures per MRI unit.

309

310 (2) The additional fixed unit shall be located at the same site unless the requirements of the  
311 relocation section have been met.

312

313 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**

314

315 Sec. 6. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall  
316 demonstrate the following:

317 (a) The existing MRI service and its unit(s) to be relocated has been in operation for at least 36  
318 months as of the date an application is submitted to the Department.

319 (b) The proposed new site is in the relocation zone.

320 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of  
321 MRI adjusted procedures set forth in Section 12 based on the most recently published MRI Service  
322 Utilization List as of the date an application is deemed submitted by the Department.

323

324 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall  
325 demonstrate the following:

326 (a) The applicant currently operates the MRI service from which the unit will be relocated.

327 (b) The existing MRI service from which the MRI unit(s) to be relocated has been in operation for  
328 at least 36 months as of the date an application is submitted to the Department.

329 (c) The proposed new site is in the relocation zone.

330 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the  
331 applicable minimum number of MRI adjusted procedures set forth in Section 12 based on the most  
332 recently published MRI Service Utilization List as of the date an application is deemed submitted by the  
333 Department.

334 (e) For volume purposes, the new site shall remain associated to the original site for a minimum of  
335 three years.

336

### 337 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**

338

339 Sec 7. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s)  
340 shall demonstrate the following:

341 (a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after  
342 July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in  
343 compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.  
344 The MRI service shall be operating at the applicable volume requirements set forth in Section 12 of  
345 these standards in the second 12 months after the effective date of the acquisition, and annually  
346 thereafter.

347 (b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),  
348 except the first application approved pursuant to subsection (a), an applicant shall be required to  
349 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume  
350 requirements set forth in Section 12 of these standards applicable to an existing MRI service on the date  
351 the application is submitted to the Department.

352

353 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI  
354 service shall demonstrate that the proposed project meets all of the following:

355 (a) The project will not change the number of MRI units at the site of the MRI service being  
356 acquired, subject to the applicable requirements under Section 6(2), unless the applicant demonstrates  
357 that the project is in compliance with the requirements of the initiation or expansion Section, as  
358 applicable.

359 (b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired  
360 unless the applicant demonstrates that the requirements of the replacement section have been met.

361

### 362 **Section 8. Requirements to establish a dedicated research MRI unit**

363

364 Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the  
365 following:

366

367 (1) Submit copies of documentation demonstrating that the applicant operates a diagnostic  
368 radiology residency program approved by the Accreditation Council for Graduate Medical Education, the  
369 American Osteopathic Association, or an equivalent organization.

370  
 371 (2) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol  
 372 approved by the applicant's IRB.

373  
 374 (3) An applicant meeting the requirements of this section shall be exempt from meeting the  
 375 requirements of sections to initiate and replace.

376  
 377 **Section 9. Requirements to establish a dedicated pediatric MRI unit**

378  
 379 Sec. 9. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the  
 380 following:

381 (a) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges  
 382 (excluding normal newborns) in the most recent year of operation.

383 (b) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the  
 384 most recent year of operation.

385 (c) The applicant shall have an active medical staff that includes, but is not limited to, physicians  
 386 who are fellowship-trained in the following pediatric specialties:

387 (i) pediatric radiology (at least two)

388 (ii) pediatric anesthesiology

389 (iii) pediatric cardiology

390 (iv) pediatric critical care

391 (v) pediatric gastroenterology

392 (vi) pediatric hematology/oncology

393 (vii) pediatric neurology

394 (viii) pediatric neurosurgery

395 (ix) pediatric orthopedic surgery

396 (x) pediatric pathology

397 (xi) pediatric pulmonology

398 (xii) pediatric surgery

399 (xiii) neonatology

400 (d) The applicant shall have in operation the following pediatric specialty programs:

401 (i) pediatric bone marrow transplant program

402 (ii) established pediatric sedation program

403 (iii) pediatric open heart program

404

405 (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the  
 406 requirements of Section 5 of these standards.

407

408 **Section 10. ~~Pilot program~~ Requirements for approval—ALL applicants proposing to initiate,**  
 409 **replace, or acquire a hospital based IMRI**

410

411 Sec. 10. ~~As a pilot program, an AN~~ applicant proposing to initiate, replace, or acquire a hospital  
 412 based IMRI service shall demonstrate ~~that it meets all~~ EACH of the following, AS APPLICABLE TO THE  
 413 PROPOSED PROJECT.

414

415 (1) The proposed site is a licensed hospital under Part 215 of the Code.

416

417 (2) The proposed site has an existing fixed MRI service that has been operational for the previous  
 418 36 consecutive months and is meeting its minimum volume requirements.

419

420 (3) The proposed site has an existing and operational surgical service and is meeting its minimum  
 421 volume requirements pursuant to the CON Review Standards for Surgical Services.

422

423 | (4) The applicant ~~shall have experienced~~HAS ACHIEVED one of the following:  
 424 | (a) at least 1,500 oncology discharges in the most recent year of operation; or  
 425 | (b) at least 1,000 neurological surgeries in the most recent year of operation; or  
 426 | (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least  
 427 | 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

428 |  
 429 | (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating  
 430 | room allowing for transfer of the patient between the operating room and this adjoining room.

431 |  
 432 | (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this  
 433 | section unless the patient meets one of the following criteria:

434 | (a) the patient has been admitted to an inpatient unit; or  
 435 | (b) the patient is having the study performed on an outpatient basis, but is in need of general  
 436 | anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

437 |  
 438 | (7) The approved IMRI unit will not be subject to MRI volume requirements.

439 |  
 440 | (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need  
 441 | or to satisfy MRI CON review standards requirements.

442 |  
 443 | ~~(9) The provisions of Section 10 are part of a pilot program approved by the CON commission and  
 444 | shall expire and be of no further force and effect, and shall not be applicable to any application which has  
 445 | not been submitted by December 31, 2010.~~

#### 446 | **Section 11. Requirements for all applicants**

447 |  
 448 |  
 449 | Sec. 11. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
 450 | provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
 451 | to the Department within six (6) months from the offering of services if a CON is approved.

#### 452 | **Section 12. Project delivery requirements – terms of approval**

453 |  
 454 |  
 455 | Sec. 12. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall  
 456 | be delivered and maintained in compliance with the following:

457 | (a) Compliance with these standards.  
 458 | (b) Compliance with applicable safety and operating standards.  
 459 | (c) Compliance with the following quality assurance standards:  
 460 | (i) An applicant shall develop and maintain policies and procedures that establish protocols for  
 461 | assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI  
 462 | service.

463 | (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

464 | (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI  
 465 | team. At a minimum, the MRI team shall consist of the following professionals:

466 | (A) Physicians who shall be responsible for screening of patients to assure appropriate utilization  
 467 | of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a  
 468 | board-certified radiologist.

469 | (B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

470 | (C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual  
 471 | basis.

472 | (iv) An applicant shall document that the MRI team members have the following qualifications:

473 | (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the  
 474 | following:

475 | (1) The physician is licensed to practice medicine in the State of Michigan.

476 (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI  
 477 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council  
 478 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the  
 479 requirements of subdivision (i), (ii), or (iii):

480 (i) Board certification by the American Board of Radiology, the American Osteopathic Board of  
 481 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology  
 482 program completed by a physician in order to become board certified did not include at least two months  
 483 of MRI training, that physician shall document that he or she has had the equivalent of two months of  
 484 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited  
 485 by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

486 (ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate  
 487 Medical Education or the American Osteopathic Association, that included two years of training in cross-  
 488 sectional imaging and six months training in organ-specific imaging areas.

489 (iii) A practice in which at least one-third of total professional time, based on a full-time clinical  
 490 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

491 (3) The physician has completed and will complete a minimum of 40 hours every two years of  
 492 Category in Continuing Medical Education credits in topics directly involving MR imaging.

493 (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI  
 494 scans annually.

495 (B) An MRI technologist who is registered by the American Registry of Radiologic Technicians or  
 496 by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have  
 497 within 36 months of the effective date of these standards or the date a technologist is employed by an  
 498 MRI service, whichever is later, special certification in MRI. If a technologist does not have special  
 499 certification in MRI within either of the 3-year periods of time, all continuing education requirements shall  
 500 be in the area of MRI services.

501 (C) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For  
 502 purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the  
 503 qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the  
 504 American Board of Radiology, the American Board of Medical Physics, or the American Board of Science  
 505 in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence  
 506 that an MRI physicist/engineer is qualified appropriately.

507 (v) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical  
 508 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate  
 509 emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all  
 510 times when patients are undergoing scans.

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

513 (d) Compliance with the following terms of approval, as applicable:

514 (i) MRI units shall be operating at a minimum average annual utilization during the second 12  
 515 months of operation, and annually thereafter, as applicable:

516 (A) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),

517 (1) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)  
 518 and is the only fixed MRI unit at the current site,

519 (2) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)  
 520 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

521 (B) 5,500 MRI adjusted procedures per unit for mobile MRI services.

522 (C) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

523 (D) Each mobile host site in a rural or micropolitan statistical area county shall have provided at  
 524 least a total of 400 adjusted procedures during its second 12 months of operation, and annually  
 525 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or  
 526 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during

527 its second 12 months of operation and annually thereafter, from all mobile units providing services to the  
528 site.

529 (E) In meeting these requirements, an applicant shall not include any MRI adjusted procedures  
530 performed on an MRI unit used exclusively for research and approved pursuant to Section 8(1) or for an  
531 IMRI unit approved pursuant to Section 10.

532 (ii) The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan  
533 population, shall

534 (A) provide MRI services to all individuals based on the clinical indications of need for the service  
535 and not on ability to pay or source of payment.

536 (B) maintain information by source of payment to indicate the volume of care from each source  
537 provided annually.

538 (iii) The applicant shall participate in a data collection network established and administered by the  
539 Department or its designee. The data may include, but is not limited to, operating schedules,  
540 demographic and diagnostic information, and the volume of care provided to patients from all payor  
541 sources, as well as other data requested by the Department or its designee and approved by the  
542 Commission. The applicant shall provide the required data in a format established by the Department  
543 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which  
544 data are being reported to the Department. An applicant shall be considered in violation of this term of  
545 approval if the required data are not submitted to the Department within 30 days following the last day of  
546 the quarter for which data are being reported. The Department may elect to verify the data through  
547 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9,  
548 or Section 10 shall be reported separately.

549 For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is  
550 used and for what type of services, i.e., intra-operative or diagnostic.

551 (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA  
552 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

553 (e) The applicant shall provide the Department with a notice stating the first date on which the MRI  
554 unit became operational, and such notice shall be submitted to the Department consistent with applicable  
555 statute and promulgated rules.

556 (f) An applicant who is a central service coordinator shall notify the Department of any additions,  
557 deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the  
558 change(s) in host sites is made.

559  
560 (2) An applicant for an MRI unit approved under Section 8(1) shall agree that the services provided  
561 by the MRI unit are delivered in compliance with the following terms.

562 (a) The capital and operating costs relating to the research use of the MRI unit shall be charged  
563 only to a specific research account(s) and not to any patient or third-party payor.

564 (b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the  
565 applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other  
566 than Section 8.

567  
568 (3) The agreements and assurances required by this section shall be in the form of a certification  
569 agreed to by the applicant or its authorized agent.

570

### 571 **Section 13. MRI procedure adjustments**

572

573 Sec. 13. (1) The Department shall apply the following formula, as applicable, to determine the  
574 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

575 (a) The base value for each MRI procedure is 1.0.

576 (b) For each MRI visit involving a pediatric patient, 0.25 shall be added to the base value.

577 (c) For each MRI visit involving an inpatient, 0.50 shall be added to the base value.

578 (d) For each MRI procedure performed on a sedated patient, 0.75 shall be added to the base  
579 value.

- 580 (e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base  
581 value.
- 582 (f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base  
583 value.
- 584 (g) For each MRI visit that involves both a clinical and research scan on a single patient in a single  
585 visit, 0.25 shall be added to the base value.
- 586 (h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a  
587 procedure before use of a contrast agent, 0.35 shall be added to the base value.
- 588 (i) For each contrast MRI procedure involving a procedure before and after use of a contrast  
589 agent, 1.0 shall be added to the base value.
- 590 (j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.
- 591 (k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an  
592 MRI adjusted procedure.
- 593
- 594 (2) The Department shall apply not more than one of the adjustment factors set forth in this  
595 subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable  
596 provisions of subsection (1) that are performed by an existing MRI service or unit.
- 597 (a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted  
598 procedures shall be multiplied by a factor of 1.4.
- 599 (b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan  
600 statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a  
601 site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a  
602 site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be  
603 multiplied by a factor of 1.0.
- 604 (c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area  
605 counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.
- 606 (d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer  
607 fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be  
608 multiplied by a factor of 3.5.
- 609 (e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second,  
610 third, etc.) at the same site.
- 611
- 612 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of  
613 the results of subsections (1) and (2).
- 614

#### 615 **Section 14. Documentation of actual utilization**

616

617 Sec. 14. Documentation of the number of MRI procedures performed by an MRI unit shall be  
618 substantiated by the Department utilizing data submitted by the applicant in a format and media specified  
619 by the Department and as verified for the 12-month period reported on the most recently published "MRI  
620 Service Utilization List" as of the date an application is deemed submitted by the Department. The  
621 number of MRI procedures actually performed shall be documented by procedure records and not by  
622 application of the methodology required in Section 15. The Department may elect to verify the data  
623 through on-site review of appropriate records.

624

#### 625 **Section 15. Methodology for computing the number of available MRI adjusted procedures**

626

627 Sec. 15. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall  
628 be computed in accordance with the methodology set forth in this section. In applying the methodology,  
629 the following steps shall be taken in sequence, and data for the 12-month period reported on the most  
630 recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed  
631 submitted by the Department, shall be used:

632 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service  
633 as determined pursuant to Section 13.

634 (i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures  
635 performed on MRI units used exclusively for research and approved pursuant to Section 8(1) and  
636 dedicated pediatric MRI approved pursuant to Section 9 shall be excluded.

637 (ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures,  
638 from the host site routes utilized to meet the requirements of Section 3(2)(c), shall be excluded beginning  
639 at the time the application is submitted and for three years from the date the fixed MRI unit becomes  
640 operational.

641 (iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures  
642 utilized to meet the requirements of Section 5(1) shall be reduced by 8,000 and shall be excluded  
643 beginning at the time the application is submitted and for three years from the date the fixed MRI unit  
644 becomes operational.

645 (b) Identify the number of available MRI adjusted procedures, if any, for each existing MRI service  
646 as determined pursuant to Section 2(1)(c).

647 (c) Determine the number of available MRI adjusted procedures that each referring doctor may  
648 commit from each service to an application in accordance with the following:

649 (i) Divide the number of available MRI adjusted procedures identified in subsection (b) for each  
650 service by the number of actual MRI adjusted procedures identified in subsection (a) for that existing MRI  
651 service.

652 (ii) For each doctor referring to that existing service, multiply the number of actual MRI adjusted  
653 procedures that the referring doctor made to the existing MRI service by the applicable proportion  
654 obtained by the calculation in subdivision (c)(i).

655 (A) For each doctor, subtract any available adjusted procedures previously committed. The total  
656 for each doctor cannot be less than zero.

657 (B) The total number of available adjusted procedures for that service shall be the sum of the  
658 results of (A) above.

659 (iii) For each MRI service, the available MRI adjusted procedures resulting from the calculation in  
660 (c)(ii) above shall be sorted in descending order by the available MRI adjusted procedures for each  
661 doctor. Then any duplicate values shall be sorted in descending order by the doctors' license numbers  
662 (last 6 digits only).

663 (iv) Using the data produced in (c)(iii) above, sum the number of available adjusted procedures in  
664 descending order until the summation equals at least 75 percent of the total available adjusted  
665 procedures. This summation shall include the minimum number of doctors necessary to reach the 75  
666 percent level.

667 (v) For the doctors representing 75 percent of the total available adjusted procedures in (c)(iv)  
668 above, sum the available adjusted procedures.

669 (vi) For the doctors used in subsection (c)(v) above, divide the total number of available adjusted  
670 procedures identified in (c)(ii)(B) above by the sum of those available adjusted procedures produced in  
671 (c)(v) above.

672 (vii) For only those doctors identified in (c)(v) above, multiply the result of (c)(vi) above by the  
673 available adjusted procedures calculated in (c)(ii)(A) above.

674 (viii) The result shall be the "Available MRI Adjusted Procedures List."

675

676 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the  
677 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in  
678 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON  
679 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).  
680

681

682 **Section 16. Procedures and requirements for commitments of available MRI adjusted procedures**

683

683 Sec. 16. (1) If one or more host sites on a mobile MRI service are located within the planning area of  
684 the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile  
685 MRI service.  
686

687 (2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed  
688 data commitment on a form provided by the Department in response to the applicant's letter of intent for  
689 each doctor committing available MRI adjusted procedures to that application for a new MRI unit that  
690 requires doctor commitments.

691 (b) An applicant also shall submit, at the time the application is submitted to the Department, a  
692 computer file that lists, for each MRI service from which data are being committed to the same  
693 application, the name and license number of each doctor for whom a signed and dated data commitment  
694 form is submitted.

695 (i) The computer file shall be provided to the Department on mutually agreed upon media and in a  
696 format prescribed by the Department.

697 (ii) If the doctor commitments submitted on the Departmental forms do not agree with the data on  
698 the computer file, the applicant shall be allowed to correct only the computer file data which includes  
699 adding physician commitments that were submitted at the time of application.

700 (c) If the required documentation for the doctor commitments submitted under this subsection is  
701 not submitted with the application on the designated application date, the application will be deemed  
702 submitted on the first applicable designated application date after all required documentation is received  
703 by the Department.  
704

705 (3) The Department shall consider a signed and dated data commitment on a form provided by the  
706 Department in response to the applicant's letter of intent that meets the requirements of each of the  
707 following, as applicable:

708 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for  
709 each specified MRI service, calculated pursuant to Section 15, is being committed and specifies the CON  
710 application number for the MRI unit to which the data commitment is made. A doctor shall not be  
711 required to commit available MRI adjusted procedures from all MRI services to which his or her patients  
712 are referred for MRI services but only from those MRI services specified by the doctor in the data  
713 commitment form provided by the Department and submitted by the applicant in support of its application.

714 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.  
715 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This  
716 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a  
717 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.  
718 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,  
719 published in the Federal Register on August 14, 1995, or its replacement.

720 (c) A committing doctor certifies that he or she has not been provided, or received a promise of  
721 being provided, a financial incentive to commit any of his or her available MRI adjusted procedures to the  
722 application.  
723

724 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
725 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
726 service were used to support approval of an application for a new or additional MRI unit, pursuant to  
727 Section 3, for which a final decision to approve has been issued by the Director of the Department until  
728 either of the following occurs:

729 (i) The approved CON is withdrawn or expires.

730 (ii) The MRI service or unit to which the data were committed has been in operation for at least 36  
731 continuous months.

732 (b) The Department shall not consider a data commitment from a doctor for available MRI adjusted  
733 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI  
734 service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI

735 unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the  
736 Department until either of the following occurs:

737 (i) A final decision to disapprove an application is issued by the Director and the applicant does  
738 not appeal that disapproval or

739 (ii) If an appeal was made, either that appeal is withdrawn by the applicant or the committing  
740 doctor withdraws his or her data commitment pursuant to the requirements of subsection (8).

741  
742 (5) The Department shall not consider a data commitment from a committing doctor for available  
743 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data  
744 commitment, on a form provided by Department, for more than one (1) application for which a final  
745 decision has not been issued by the Department. If the Department determines that a doctor has  
746 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI  
747 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or  
748 additional mobile MRI unit pursuant to Section 3, the Department shall,

749 (a) if the applications were submitted on the same designated application date, notify all  
750 applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for  
751 available MRI adjusted procedures from the same MRI service and that the doctors' data from the same  
752 MRI service shall not be considered in the review of any of the pending applications submitted on the  
753 same designated application date until the doctor notifies the Department, in writing, of the one (1)  
754 application for which the data commitment shall be considered.

755 (b) if the applications were submitted on different designated application dates, consider the data  
756 commitment in the application submitted on the earliest designated application date and shall notify,  
757 simultaneously in writing, all applicants of applications submitted on designated application dates  
758 subsequent to the earliest date that one or more committing doctors have submitted data commitments  
759 for available MRI adjusted procedures from the same MRI service and that the doctors' data shall not be  
760 considered in the review of the application(s) submitted on the subsequent designated application  
761 date(s).

762  
763 (6) The Department shall not consider any data commitment submitted by an applicant after the  
764 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to  
765 subsection (5), that one or more committing doctors submitted data commitments for available MRI  
766 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data  
767 commitments will not be considered by the Department, the Department shall consider data commitments  
768 submitted after the date an application is deemed submitted only to the extent necessary to replace the  
769 data commitments not being considered pursuant to subsection (5).

770 (a) The applicant shall have 30 days to submit replacement of doctor commitments as identified by  
771 the Department in this Section.

772  
773 (7) In accordance with either of the following, the Department shall not consider a withdrawal of a  
774 signed data commitment:

775 (a) on or after the date an application is deemed submitted by the Department.

776 (b) after a proposed decision to approve an application has been issued by the Department.

777  
778 (8) The Department shall consider a withdrawal of a signed data commitment if a committing  
779 doctor submits a written notice to the Department, that specifies the CON application number and the  
780 specific MRI services for which a data commitment is being withdrawn, and if an applicant demonstrates  
781 that the requirements of subsection (7) also have been met.

782  
783 **Section 17. Lists published by the Department**

784  
785 Sec. 17. (1) On or before May 1 and November 1 of each year, the Department shall publish the  
786 following lists:

787 (a) A list, known as the "MRI Service Utilization List," of all MRI services in Michigan that includes  
788 at least the following for each MRI service:

- 789 (i) The number of actual MRI adjusted procedures;  
790 (ii) The number of available MRI adjusted procedures, if any; and  
791 (iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated  
792 pediatric.

793 (b) A list, known as the "Available MRI Adjusted Procedures List," that identifies each MRI service  
794 that has available MRI adjusted procedures and includes at least the following:

- 795 (i) The number of available MRI adjusted procedures;  
796 (ii) The name, address, and license number of each referring doctor, identified in Section  
797 15(1)(c)(v), whose patients received MRI services at that MRI service; and  
798 (iii) The number of available MRI adjusted procedures performed on patients referred by each  
799 referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This  
800 number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may  
801 have fractional portions of available MRI adjusted procedures.

802 (c) For the lists published pursuant to subsections (a) or (b), the May 1 list will report 12 months of  
803 data from the previous January 1 through December 31 reporting period, and the November 1 list will  
804 report 12 months of data from the previous July 1 through June 30 reporting period. Copies of both lists  
805 shall be available upon request.

806 (d) The Department shall not be required to publish a list that sorts MRI database information by  
807 referring doctor, only by MRI service.

808  
809 (2) When an MRI service begins to operate at a site at which MRI services previously were not  
810 provided, the Department shall include in the MRI database, data beginning with the second full quarter  
811 of operation of the new MRI service. Data from the start-up date to the start of the first full quarter will not  
812 be collected to allow a new MRI service sufficient time to develop its data reporting capability. Data from  
813 the first full quarter of operation will be submitted as test data but will not be reported in the lists published  
814 pursuant to this section.

815  
816 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported  
817 data in compliance with the requirements of Section 12, the Department shall indicate on both lists that  
818 the MRI service is in violation of the requirements set forth in Section 12, and no data will be shown for  
819 that service on either list.

820

## 821 **Section 18. Effect on prior CON Review Standards; Comparative reviews**

822

823 Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for  
824 MRI Services approved by the CON Commission on ~~September-DECEMBER 1015, 2009-2010~~ and  
825 effective ~~November-MARCH 511, 20092011~~.

826

827 (2) Projects reviewed under these standards shall not be subject to comparative review.

828

## 829 **Section 19. Health Service Areas**

830

831 Sec. 19. Counties assigned to each of the health service areas are as follows:

832

833 HSA	834 COUNTIES		
835 1	836 Livingston	837 Monroe	838 St. Clair
	839 Macomb	Oakland	Washtenaw
	Wayne		

839

840	2	Clinton	Hillsdale	Jackson
841		Eaton	Ingham	Lenawee
842	3	Barry	Calhoun	St. Joseph
844		Berrien	Cass	Van Buren
845		Branch	Kalamazoo	
846	4	Allegan	Mason	Newaygo
848		Ionia	Mecosta	Oceana
849		Kent	Montcalm	Osceola
850		Lake	Muskegon	Ottawa
851	5	Genesee	Lapeer	Shiawassee
853				
854	6	Arenac	Huron	Roscommon
855		Bay	Iosco	Saginaw
856		Clare	Isabella	Sanilac
857		Gladwin	Midland	Tuscola
858		Gratiot	Ogemaw	
859	7	Alcona	Crawford	Missaukee
861		Alpena	Emmet	Montmorency
862		Antrim	Gd Traverse	Oscoda
863		Benzie	Kalkaska	Otsego
864		Charlevoix	Leelanau	Presque Isle
865		Cheboygan	Manistee	Wexford
866	8	Alger	Gogebic	Mackinac
868		Baraga	Houghton	Marquette
869		Chippewa	Iron	Menominee
870		Delta	Keweenaw	Ontonagon
871		Dickinson	Luce	Schoolcraft

**APPENDIX A**

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**CON REVIEW STANDARDS**  
**FOR MRI SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**  
**MEGAVOLTAGE RADIATION THERAPY (MRT) SERVICES/UNITS**

(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 TO INITIATE, REPLACE, EXPAND, OR ACQUIRE AN MRT SERVICE and delivery of services for all projects approved and certificates of need issued under Part 222 of the Code that involve MRT services/units.~~

~~—(2) An MRT service~~S~~ AND unit~~S~~ is~~ARE~~ a covered clinical service for purposes of PURSUANT TO Part 222 of the Code. An MRT service/unit previously approved pursuant to Section 7 of these standards now seeking approval to operate pursuant to sections 4, 5, 6, 8, or 9 shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of an MRT service/unit. An MRT unit approved to operate as a special purpose MRT unit seeking approval to operate as a non-special MRT unit shall be considered as a person requesting CON approval to begin or expand, as applicable, operation of a non-special MRT service/unit.~~

~~—(3) The Department shall use THESE sections 4, 5, 6, 8, 9, and 10, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

~~—(4) The Department shall use Section 16, as applicable, in applying 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) "Acquisition of an existing MRT service or existing MRT unit(s)" means the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing MRT service or existing MRT unit(s).~~

~~—(b) "Begin operation of an MRT service" means the establishment of a non-special MRT unit at a geographic location where an MRT service is not currently provided. The term does not include the acquisition or relocation of an existing MRT service and/or unit(s) or the renewal of a lease.~~

~~—(c) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, and Iridium-192.~~

~~—(d) "Cancer treatment program" means 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: (i) access to consultative services from all major disciplines needed to develop a comprehensive treatment plan, (ii) a computer-based treatment planning system, (iii) medical radiation physicist involvement, (iv) MRT capability including electron beam capability, (v) treatment aid fabrication capability, (vi) brachytherapy, (vii) a multi-disciplinary cancer committee, (viii) a tumor registry, (ix) patient care evaluation studies, and (x) cancer prevention and education programs.~~

~~—(eA) "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.~~

55 ~~—(fB) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et~~  
 56 ~~seq. of the Michigan compiled Laws.~~

57 ~~—(g) "Complex treatment visit" means a treatment visit involving three or more treatment sites,~~  
 58 ~~tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom~~  
 59 ~~blocking.~~

60 ~~—(h) "Computer based treatment planning system" means a computer system capable of displaying~~  
 61 ~~radiation doses and dose distributions within a patient using anatomical data from that patient and using~~  
 62 ~~measured radiation output data from the specific unit used to treat the patient. The minimum software~~  
 63 ~~requirements for the treatment planning system are an external beam program, an irregular field routine,~~  
 64 ~~and a brachytherapy package.~~

65 ~~—(i) "Course of treatment" means the planned series of visits that compose a plan for treatment of one~~  
 66 ~~or more cancer sites for a single patient.~~

67 (jC) "Cyber knife" means a treatment device that is a frameless special stereotactic radiosurgery unit  
 68 that consists of three key components: (i) an advanced, lightweight linear accelerator (linac) (this device  
 69 is used to produce a high energy megavoltage of radiation), (ii) a robot which can point the linear  
 70 accelerator from a wide variety of angles, and (iii) several x-ray cameras (imaging devices) that are  
 71 combined with software to track patient position. The cameras obtain frequent pictures of the patient  
 72 during treatment and use this information to target the radiation beam emitted by the linear accelerator.

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

74 ~~—(l) "Dosimetrist" means a person who is familiar with the physical and geometric characteristics of~~  
 75 ~~the radiation equipment and radioactive sources commonly employed and who has the training and~~  
 76 ~~expertise necessary to measure and generate radiation dose distributions and calculations under the~~  
 77 ~~direction of a medical physicist and/or a radiation oncologist.~~

78 ~~—(m) "Driving miles" means the number of miles from the address of the proposed MRT service to the~~  
 79 ~~address of the closest existing MRT unit. Driving miles is the number of miles from address to address as~~  
 80 ~~identified by use of mapping software that is verifiable by the Department.~~

81 ~~—(n) "Duplication factor" means the number derived by subtracting the duplication rate from 1.~~

82 ~~—(o) "Duplication rate" means the percent of new cancer cases in each planning area determined by~~  
 83 ~~the Department, Vital Records and Health Data Development Section, that have been reported more than~~  
 84 ~~one time to the Michigan Cancer Surveillance Program.~~

85 (pE) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of  
 86 treatment visit, that reflects the relative average length of time one patient spends in one treatment visit in  
 87 an MRT unit. ~~Section 13 sets forth how ETVs shall be calculated.~~

88 (qF) "Existing MRT service" means a CON approved and operational facility and equipment  
 89 used to provide MRT services including but not limited to the simulator(s), block fabrication materials, and  
 90 all existing MRT units at a geographic location(s).

91 (rG) "Existing MRT unit" means a CON approved and operational equipment used to provide MRT  
 92 services.

93 ~~—(s) "Expand an existing MRT service" means adding one additional MRT unit to the number of~~  
 94 ~~existing MRT units.~~

95 ~~—(t) "Full time equivalent" or "FTE" means an individual(s) with normally scheduled working hours of~~  
 96 ~~40 hours per week.~~

97 (uH) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple  
 98 cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or  
 99 cerebrovascular system abnormalities.

100 ~~—(v) "Geographic location" means either (i) the geographic location of a licensed health facility as~~  
 101 ~~defined in the CON Review Standards applicable to the type of health facility or (ii) if the location is not a~~  
 102 ~~health facility as defined in Part 222 of the Code, a distinct geographic location separate from another~~  
 103 ~~location.~~

104 (wI) "Heavy particle accelerator" means a machine such as a cyclotron which produces beams of high  
 105 energy particles such as protons, neutrons, pions, carbon ions, or other heavy ions with masses greater  
 106 than that of an electron.

107 (xJ) "High MRT unit" or "HMRT unit" means a heavy particle accelerator or any other MRT unit  
 108 operating at an energy level equal to or greater than 30.0 million electron volts (megavolts or MEV).

- 109 ~~—(y) "Hospital MRT service" means an MRT service owned by a hospital or owned by a corporation~~  
 110 ~~that is itself wholly owned by hospital(s).~~
- 111 ~~—(z) "Image-guided radiation therapy" or "IGRT" means the use of in-room imaging to allow precise~~  
 112 ~~target localization using ultrasound, implanted fiducial markers or image reconstruction using kV or~~  
 113 ~~megavoltage beams. Two-dimensional port films using patient anatomy for localization do not constitute~~  
 114 ~~IGRT.~~
- 115 ~~—(aa) "Immediately available" means continuous availability of direct communication with the MRT unit~~  
 116 ~~in person or by radio, telephone, or telecommunication.~~
- 117 ~~(bbK) "Intensity modulated radiation therapy" or "IMRT" means a visit utilizing only the~~  
 118 ~~computer controlled multi-leaf collimator part of the CMS definition for IMRT.~~
- 119 ~~—(cc) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites,~~  
 120 ~~three or more fields to a single treatment site, or the use of special blocking.~~
- 121 ~~(ddL) "Intraoperative treatment visitMRT UNIT" OR "IORT UNIT" means AN MRT UNIT THAT~~  
 122 ~~IS DESIGNED TO EMIT ONLY ELECTRONS, LOCATED IN AN OPERATING ROOM IN THE~~  
 123 ~~SURGICAL DEPARTMENT OF A LICENSED HOSPITAL AND AVAILABLE FOR THE treatment visit~~  
 124 ~~where a dose of A PATIENT UNDERGOING A SURGICALPROCEDURE WITH megavoltage radiation is~~  
 125 ~~delivered to a surgically exposed neoplasm or cancerous organ/site using a dedicated unit.~~
- 126 ~~—(ee) "Institutional review board" or "IRB" means an institutional review board, as defined by Public Law~~  
 127 ~~93-348, that is regulated by Title 45 CFR 46.~~
- 128 ~~—(ff) "Isocenter" means the virtual point in space about which the MRT unit operates and is placed at~~  
 129 ~~the center of the tumor for the delivery of the radiation treatment.~~
- 130 ~~—(gg) "Licensed hospital site" means either: (i) in the case of a single site hospital, the location of the~~  
 131 ~~hospital authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a~~  
 132 ~~hospital with multiple sites, the location of each separate and distinct inpatient site as authorized by~~  
 133 ~~licensure.~~
- 134 ~~—(hh) "Licensed MRT unit" means an MRT unit that is licensed by the Nuclear Regulatory Commission~~  
 135 ~~(NRC) or registered by the Michigan Department of Community Health, Division of Health Facilities and~~  
 136 ~~Services, Radiation Safety Section.~~
- 137 ~~(iiM) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6~~  
 138 ~~and1396r-8 to 1396v.~~
- 139 ~~—(jj) "Medical radiation physicist" means an individual who is (i) board certified or board qualified by~~  
 140 ~~the American Board of Radiology in radiological physics or therapeutic radiological physics or (ii) board~~  
 141 ~~certified or board qualified by the American Board of Medical Physics in medical physics with special~~  
 142 ~~competence in radiation oncology physics.~~
- 143 ~~(kkN) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients~~  
 144 ~~with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is~~  
 145 ~~delivered by a MRT unit.~~
- 146 ~~—(ll) "MRT program" means one or more MRT services operated at one or more geographic locations~~  
 147 ~~under the same administrative unit.~~
- 148 ~~(mmO) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one~~  
 149 ~~geographic location.~~
- 150 ~~(nnP) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece~~  
 151 ~~of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts~~  
 152 ~~(megavolts or MEV) for the purpose of delivering doses of radiation to patients with cancer, other~~  
 153 ~~neoplasms, or cerebrovascular system abnormalities.~~
- 154 ~~—(oo) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as~~  
 155 ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~  
 156 ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~  
 157 ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~
- 158 ~~(ppQ) "Michigan Cancer Surveillance Program" means the program for the collection and~~  
 159 ~~analysis of information on cancer in Michigan operated by the Department, Vital Records and Health Data~~  
 160 ~~Development Section, mandated by Act 82 of 1984, being Section 333.2619 of the Michigan Compiled~~  
 161 ~~Laws.~~
- 162 ~~—(qq) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as~~  
 163 ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~

164 ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~  
165 ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~  
166 ~~—(rr) "Multi-disciplinary cancer committee" means a standing committee that (i) includes~~  
167 ~~representatives from the medical specialties or sub-specialties which refer patients to the MRT service;~~  
168 ~~representatives from the specialties of diagnostic radiology, radiation oncology, and pathology;~~  
169 ~~representatives from those who oversee the tumor registry; and representatives from administration,~~  
170 ~~nursing, social services, pharmacy, and rehabilitation; (ii) meets at least on a quarterly basis; and (iii) is~~  
171 ~~responsible for (a) establishing educational and problem-oriented multi-disciplinary, facility-wide cancer~~  
172 ~~conferences that include the major anatomic locations of cancer seen at the facility; (b) monitoring,~~  
173 ~~evaluating, and reporting to the medical staff and governing body on the quality of care provided to~~  
174 ~~patients with cancer; and (c) oversight of the applicant's tumor registry for quality control, staging, and~~  
175 ~~abstracting.~~  
176 (ssR) "New cancer case," means a person with any newly diagnosed cancer excluding basal,  
177 epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.  
178 (#S) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit  
179 meeting the definition of a special purpose MRT unit or an HMRT unit.  
180 —(uu) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit  
181 that is designed to emit only electrons, is located in an operating room in the surgical department of a  
182 licensed hospital, and is available for the treatment of a patient undergoing a surgical procedure with  
183 megavoltage radiation.  
184 —(vv) "Patient care evaluation studies" means a system of patient care evaluation, conducted at least  
185 twice annually, that documents the methods used to identify problems and the opportunities to improve  
186 patient care. Examples of patient care evaluation studies include nationwide patient care evaluation  
187 studies; hospital-wide quality assurance activities; and ongoing monitoring, evaluating, and action  
188 planning.  
189 (ww) "Planning area" means the groups of counties shown in Section 17.  
190 —(xx) "Relocation of an existing MRT service and/or MRT unit(s)" means a change in the geographic  
191 location within the same planning area.  
192 —(yy) "Replace/upgrade an existing MRT unit" means an equipment change that results in an applicant  
193 operating the same number of non-special and the same number and type of special purpose MRT units  
194 before and after the equipment change.  
195 —(zz) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
196 statistical areas as those terms are defined under the "standards for defining metropolitan and  
197 micropolitan statistical areas" by the statistical policy office of the office of information and regulatory  
198 affairs of the United States office of management and budget, 65 F.R., p. 82238 (December 27, 2000)  
199 and as shown in Appendix C.  
200 —(aaa) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment  
201 field, or parallel opposed fields with the use of no more than simple blocks.  
202 —(bbbI) "Simulation" means the precise mock-up of a patient treatment with an apparatus that  
203 uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and  
204 optical properties.  
205 (eeeU) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the  
206 following types of MRT units: (i) gamma knife, (ii) dedicated stereotactic radiosurgery unit, (iii) dedicated  
207 total body irradiator (TBI), (iv) an OR-based IORT unit, or (v) cyber knife.  
208 ~~—(ddd) "Stereotactic treatment visit" means a visit involving the use of a stereotactic guiding device with~~  
209 ~~radiotherapy for the destruction of a precisely defined intracranial and/or extracranial tumor or lesion.~~  
210 (eeeV) "Total body irradiator" or "TBI" means a specially modified dedicated cobalt unit certified  
211 as a total body irradiator by the Nuclear Regulatory Commission (NRC) or a permanently modified  
212 dedicated linear accelerator that uses a very wide beam of gamma rays or x-rays to irradiate the entire  
213 body simultaneously.  
214 (fffW) "Treatment site" means the anatomical location of the MRT treatment.  
215 (gggX) "Treatment visit" means one patient encounter during which MRT is administered. One  
216 treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same  
217 patient at different times of the same day shall be counted as a separate treatment visit.  
218

~~(hhh) "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.~~

~~—(iii)—"Very complex treatment visit" means those visits listed in Section 13 that involve special techniques in the performance of the MRT.~~

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

### Section 3. Modification of the Appendices

Sec. 3. ~~(1)~~ The Commission may modify the APPENDICES AS FOLLOWS.

(1) THE COMMISSION MAY MODIFY THE Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program AND presented ~~to the Commission~~ by the Department.

(2) The Commission may ~~periodically~~ modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data OBTAINED PROVIDED FROM THE DEPARTMENT ANNUAL SURVEY by OF MRT providers ~~as part of a Department survey~~ AND presented ~~to the Commission~~ by the Department.

(3) The Commission shall establish the effective date of the modifications made pursuant to subsections (1) or (2).

(4) Modifications made by the Commission pursuant to subsections (1) or (2) shall not require standard advisory committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to ~~become TAKE~~ effective.

### Section 4. Requirements ~~for approval— applicants proposing to~~ INITIATE begin operation of a AN MRT service other than an MRT service utilizing an HMRT unit

Sec. 4. ~~(1) INITIATE MEANS THE ESTABLISHMENT OF AN MRT SERVICE—An applicant proposing WHERE to begin operation of a AN MRT service, IS NOT CURRENTLY PROVIDED. —other than an THE TERM DOES NOT INCLUDE REPLACEMENT OF AN EXISTING— MRT service. AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE —utilizing an HMRT unit, shall demonstrate that 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 a minimum of 8,000 equivalent treatment visits ~~(ETVs)~~ for each proposed unit ~~results from application of the methodology described in Section 12, and,~~
- (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 ~~proposed APPLICANT MRT service~~ projects a minimum of 5,500 equivalent treatment visits ~~(ETVs)~~ for each proposed unit ~~based on the application of the methodology described in Section 12.~~
- (d) The proposed MRT unit is not a special purpose MRT unit.

272 (3) ~~All AN applicants PROPOSING TO INITIATE AN MRT SERVICE WITH AN HMRT UNIT under~~  
 273 ~~this section shall demonstrate, at the time the application is submitted to the Department, that the~~  
 274 ~~following staff, at a minimum, will be provided:~~

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

276 ~~(b) AnTHE applicant is a collaborative that consists of at least 40% of all Michigan-BASED hospital~~  
 277 ~~MRT services with more than 30,000 EQUIVALENT TREATMENT VISITS BASED ON THE MOST~~  
 278 ~~CURRENT DATA AVAILABLE TO THE DEPARTMENT. Hospital MRT service means an MRT service~~  
 279 ~~owned by a hospital or owned by a corporation that is itself wholly owned by hospital(s).~~

280 ~~(c) THE applicant shall include hospital MRT services from more than one planning area from ONE~~  
 281 ~~or both of the following:~~

282 ~~(i) HOSPITAL MRT SERVICES QUALIFIED The participating services under subsectionDIVISION~~  
 283 ~~(b).~~

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

285 ~~(d) EQUIVALENT TREATMENT VISITS FOR THIS SUBSECTION shall be those from THE MOST~~  
 286 ~~RECENT CON ANNUAL SURVEY.~~

287 ~~(e) An application under this section shall not be approved if it includes an MRT service described in~~  
 288 ~~subsectionsubdivision (i) or (ii) except as provided in subsections (iii) or (iv).~~

289 ~~(i) An MRT service that was part of another application under this sectionSUBSECTION.~~

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

292 ~~(iii) The prior application, or the approved CON, under this section were subsequently disapproved,~~  
 293 ~~OR withdrawn.~~

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

297 ~~(f) An application under this section shall not be approved if it includes any of the following:~~

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

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

305 ~~(g) An application under this section shall not be approved if it includes any of the following:~~

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

307 ~~(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT~~  
 308 ~~service described by subsection (i), unless the application under this section includes a commitment from~~  
 309 ~~the MRT service described in subsectionSUBDIVISION (i) to surrender the CON described in~~  
 310 ~~subsectionSUBDIVISION (i), and that commitment is fulfilled at the time the HMRT unit IS approved AND~~  
 311 ~~OPERATIONAL -under this SUBsection-is operational.~~

312 ~~(h) AnTHE applicant shall provide documentation of its process, policies and procedures, acceptable~~  
 313 ~~to the Department, which willTHAT allows any other interested entities to participate in the collaborative~~  
 314 ~~utilizingUTILIZATION OF anTHE HMRT unit.~~

315 ~~(i) AnTHE applicant shall provide an implementation plan, acceptable to the Department, for~~  
 316 ~~financing and operating the proposed-MRT service utilizing an HMRT unitTHAT includingES, but not~~  
 317 ~~limited to, how physician staff privileges, patient review, patient selection, and patient care management~~  
 318 ~~shall be determined.~~

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

321 ~~(k) AnTHE applicant shall demonstrate that the MRT service utilizing an HMRT unit will have~~  
 322 ~~simulation capabilities available for use in treatment planning.~~

323  
 324 ~~(4) APPLICANTS UNDER THIS SECTION SHALL DEMONSTRATE THE FOLLOWING STAFF~~  
 325 ~~WILL BE PROVIDED:~~  
 326

- 327     (a) ONE (1) FTE board-certified or board-qualified physician trained in radiation oncology,  
 328     (b) ONE (1) board-certified or board-qualified radiation physicist certified in therapeutic radiologic  
 329 physics,  
 330     (c) ONE (1) dosimetrist, ~~or physics assistant, a person who is familiar with the physical and~~  
 331 ~~geometric characteristics of the radiation equipment and radioactive sources commonly employed and~~  
 332 ~~who has the training and expertise necessary to measure and generate radiation dose distributions and~~  
 333 ~~calculations under the direction of a medical physicist and/or a radiation oncologist.~~  
 334     (d) TWO (2) FTE radiation ~~THERAPISTStherapy technologists~~ [registered or eligible by the American  
 335 Registry of Radiological Technologists (ARRT)], ~~and.~~  
 336     (e) ONE (1) program director who is a board-certified physician trained in radiation oncology who  
 337 may also be the physician required under ~~subsection SUBDIVISION (34)~~(a).  
 338

339 **Section 5. Requirements for approval ~~– applicants proposing to expand~~ replace an existing MRT**  
 340 **UNIT OR service other than an MRT service utilizing an HMRT unit**

341  
 342     Sec. 5. Replacement OF an existing MRT unit means an equipment change that results in a NEW  
 343 SERIAL NUMBER OR REQUIRING THE ISSUANCE OF A NEW RADIATION SAFETY CERTIFICATE  
 344 FROM THE STATE OF MICHIGAN RADIATION SAFETY SECTION. REPLACEMENT ALSO MEANS  
 345 THE RELOCATION OF AN MRT SERVICE OR UNIT TO A NEW SITE. REPLACEMENT DOES NOT  
 346 INCLUDE AMN UPGRADE TO AN EXISTING MRT UNIT WITH THE ADDITION OR MODIFICATION OF  
 347 EQUIPMENT OR SOFTWARE; THE REPLACEMENT COMPONENTS; OR CHANGE FOR THE  
 348 PURPOSE OF MAINTAINING OR IMPROVING ITS EFFICIENCY, EFFECTIVENESS, AND/OR  
 349 FUNCTIONALITY. An applicant requesting to replace an existing MRT unit(s) OR MRT SERVICE, shall  
 350 demonstrate the following, as applicable TO THE PROPOSED PROJECT.  
 351

- 352     (1) An applicant PROPOSING to replace an existing MRT unit(S) shall demonstrate the following:  
 353     (a) THE REPLACEMENT UNIT(S) IS THE SAME TYPE AS THE MRT UNIT(S) TO BE REPLACED.  
 354     (b) THE MRT UNIT(S) TO BE REPLACED IS FULLY DEPRECIATED ACCORDING TO  
 355 GENERALLY ACCEPTED ACCOUNTING PRINCIPLES OR EITHER OF THE FOLLOWING:  
 356         (I) THE EXISTING MRT UNIT(S) POSES A THREAT TO THE SAFETY OF THE PATIENTS.  
 357         (II) THE REPLACEMENT MRT UNIT(S) OFFERS TECHNOLOGICAL IMPROVEMENTS THAT  
 358 ENHANCE QUALITY OF CARE, INCREASED EFFICIENCY, AND A REDUCTION IN OPERATING  
 359 COSTS AND PATIENT CHARGES.  
 360     (C) THE APPLICANT AGREES THAT THE UNIT(S) TO BE REPLACED WILL BE REMOVED FROM  
 361 SERVICE ON OR BEFORE BEGINNING OPERATION OF THE REPLACEMENT UNIT(S).  
 362  
 363     (2) An applicant PROPOSING to replace an existing MRT service TO A NEW SITE shall  
 364 demonstrate the following:  
 365     (A) THE PROPOSED SITE IS WITHIN THE SAME PLANNING AREA AS THE EXISTING MRT  
 366 SERVICE SITE.  
 367     (B) THE EXISTING MRT UNIT(S) SHALL BE OPERATING AT THE FOLLOWING VOLUMES, AS  
 368 APPLICABLE TO THE PROPOSED PROJECT:  
 369         (I) NON-SPECIAL MRT UNIT(S) AT 8,000 EQUIVALENT TREATMENT VISITS PER UNIT OR  
 370 5,500 FOR A UNIT APPROVED UNDER SECTION 4(2).  
 371         (II) HMRT UNIT(S) AT 8,000 EQUIVALENT TREATMENT VISITS PER UNIT.  
 372         (III) SPECIAL PURPOSE UNIT(S) AT 1,000 EQUIVALENT TREATMENT VISITS PER UNIT.  
 373  
 374     (3) An applicant PROPOSING to replace AN MRT unit(S) OF AN EXISTING MRT SERVICE TO A  
 375 NEW SITE shall demonstrate the following:  
 376     (a) THE APPLICANT IS THE SAME LEGAL ENTITY AS THE EXISTING MRT SERVICE.  
 377     (b) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE  
 378 EXISTING MRT SERVICE FOR A MINIMUM OF THREE YEARS.  
 379     (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 4(4).

(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.

~~— Sec. 5. (1) An applicant proposing to expand an existing MRT service, other than an MRT service utilizing an HMRT unit, with an additional non-special MRT unit shall demonstrate:~~

~~— (a) an average of 10,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units, and~~

~~— (b) the additional unit shall be located at the same site, unless the requirements of section 9(2) also have been met.~~

~~— (2) An applicant proposing to expand an existing MRT service, other than an MRT service utilizing an HMRT unit, with a special purpose MRT unit shall demonstrate each of the following, as applicable:~~

~~— (a) An average of 8,000 ETVs was performed in the most recent 12-month period on each of the applicant's non-special MRT units at the location where the special purpose unit is to be located.~~

~~— (b) An applicant proposing to expand by adding a dedicated total body irradiator shall have either (i) a valid CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program. Documentation of the written agreement shall be included in the application at the time it is submitted to the Department.~~

~~— (c) An applicant proposing to expand by adding and operating a dedicated stereotactic radiosurgery unit (including a gamma knife and cyber knife) shall demonstrate that (i) the applicant has, at the time the application is filed, a contractual relationship with a board-eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and (ii) on-site 3-dimensional imaging and 3-dimensional treatment planning capabilities.~~

~~— (d) An applicant proposing to expand by adding an operating room based intraoperative MRT unit shall demonstrate that (i) the hospital at which the OR-based IORT unit will be located meets the CON review standards for surgical facilities if the application involves the replacement of or an increase in the number of operating rooms and (ii) the OR-based IORT unit to be installed is a linear accelerator with only electron beam capabilities.~~

**Section 6. Requirements for approval ~~— applicants proposing to replace/upgrade~~ EXPAND an existing MRT ~~unit(s) other than an MRT service~~ utilizing an HMRT unit**

Sec. 6. 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.:

(a1) 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.

(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-

434 eligible or board-certified neurosurgeon(s) trained in stereotactic radiosurgery and -on-site 3-dimensional  
 435 imaging and 3-dimensional treatment planning capabilities.

436 (d) An applicant proposing to ADD AN intraoperative MRT unit IN AN EXISTING OR PROPOSED  
 437 hospital operating room SHALL DEMONSTRATE THAT the unit is a linear accelerator with only electron  
 438 beam capabilities.

439 ~~Sec. 6. An applicant requesting to replace/upgrade an existing MRT unit(s), other than an HMRT unit,~~  
 440 ~~shall demonstrate each of the following, as applicable.~~

441  
 442 ~~—(1) An applicant requesting to replace/upgrade an existing non-special MRT unit which is the only~~  
 443 ~~unit at that geographic location, shall demonstrate each of the following:~~

444 ~~—(a) The unit performed at least 5,500 ETVs in the most recent 12-month period.~~

445 ~~—(b) The replacement unit will be located at the same geographic location as the unit to be replaced,~~  
 446 ~~unless the applicant demonstrates that the requirements of Section 9 have been met.~~

447  
 448 ~~—(2) An applicant requesting to replace/upgrade an existing non-special MRT unit at a MRT service~~  
 449 ~~which is the only MRT service in the planning area shall demonstrate each of the following:~~

450 ~~—(a) Each unit at the geographic location of the unit to be replaced operated at an average of at least~~  
 451 ~~5,500 ETVs in the most recent 12-month period.~~

452 ~~—(b) The replacement unit will be located at the same geographic location as the unit to be replaced,~~  
 453 ~~unless the applicant demonstrates that the requirements of Section 9 have been met.~~

454  
 455  
 456 ~~—(3) An applicant, other than an applicant meeting all of the applicable requirements of subsection (1)~~  
 457 ~~or (2), requesting to replace/upgrade a non-special MRT unit shall demonstrate each of the following:~~

458 ~~—(a) Each non-special unit at the geographic location of the unit to be replaced operated at a total of at~~  
 459 ~~least 13,000 ETVs for two units and an additional 5,500 ETVs for each additional unit (i.e., 13,000 ETVs +~~  
 460 ~~5,500 ETVs = 18,500 ETVs for three units, 13,000 ETVs + 5,500 etvs + 5,500 ETVs = 24,000 ETVs for~~  
 461 ~~four units, etc.) in the most recent 12-month period.~~

462 ~~—(b) The replacement unit will be located at the same geographic location as the unit to be replaced,~~  
 463 ~~unless the applicant demonstrates that the requirements of Section 9 have been met.~~

464  
 465 ~~—(4) An applicant requesting to replace/upgrade an existing special-purpose unit shall demonstrate~~  
 466 ~~each of the following, as applicable:~~

467 ~~—(a) The special-purpose unit to be replaced operated at an average of 1,000 ETVs for each OR-~~  
 468 ~~based IORT unit, gamma knife, cyber knife, dedicated stereotactic radiosurgery unit, or dedicated total~~  
 469 ~~body irradiator during the most recent 12-month period.~~

470 ~~—(b) The replacement special-purpose unit will be located at the same geographic location as the~~  
 471 ~~special-purpose unit to be replaced, unless the applicant demonstrates that the applicable requirements~~  
 472 ~~of sections 5 and 9 have been met.~~

473 ~~—(c) An applicant proposing to replace a dedicated total body irradiator shall have either (i) a valid~~  
 474 ~~CON to operate a bone marrow transplantation program or (ii) a written agreement to provide total body~~  
 475 ~~irradiation services to a hospital that has a valid CON to operate a bone marrow transplantation program.~~

476  
 477 ~~—(5) An applicant under this section shall demonstrate that the MRT unit proposed to be~~  
 478 ~~replaced/upgraded is fully depreciated according to generally accepted accounting principles; that the~~  
 479 ~~existing unit clearly poses a threat to the safety of the public; or that the proposed replacement unit offers~~  
 480 ~~technological improvements which enhance quality of care, increase efficiency, and/or reduce operating~~  
 481 ~~costs and patient charges.~~

482  
 483 ~~—(6) Equipment that is replaced shall be removed from service and disposed of or rendered~~  
 484 ~~considerably inoperable within 30 days of the replacement equipment becoming operational.~~

485  
 486 **Section 7. Requirements for approval – applicants proposing to use MRT units exclusively for**  
 487 **research**  
 488

489 ~~— Sec. 7. (1) An applicant proposing a MRT unit to be used exclusively for research shall demonstrate~~  
 490 ~~each of the following:~~

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

493 ~~— (b) The MRT unit shall operate under a protocol approved by the applicant's IRB.~~

494 ~~— (c) The applicant agrees to operate the unit in accordance with the terms of approval in Section~~  
 495 ~~16(1)(c)(v), (viii), (xiii); 16(2); 16(4); and 16(5).~~

496  
 497 ~~— (2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the~~  
 498 ~~requirements and terms of sections 4, 5; 6; and 16(1)(c)(i), (ii), (iii), (iv), (vi), (vii), (ix), (x), (xi), and (xii) of~~  
 499 ~~these standards.~~

500  
 501 ~~— (3) Equipment that is replaced shall be removed from service and disposed of or rendered~~  
 502 ~~considerably inoperable within 30 days of the replacement equipment becoming operational.~~

503  
 504 **Section 87. Requirements for approval – applicants proposing to acquire an existing MRT service**  
 505 **or an existing MRT unit(s) other than an MRT service utilizing an HMRT unit**

506  
 507 ~~Sec. 87. (1) Acquiring an existing MRT service means OBTAINING POSSESSION AND CONTROL~~  
 508 ~~BY CONTRACT, OWNERSHIP, LEASE, or ANOTHER comparable arrangement AND RENEWAL OF~~  
 509 ~~LEASE FOR an existing MRT UNIT(S). An applicant proposing to acquire an existing MRT service and~~  
 510 ~~its MRT unit(s), other than an MRT service utilizing an HMRT unit, shall demonstrate that it meets all of~~  
 511 ~~the following, AS APPLICABLE TO THE PROPOSED PROJECT.~~

512  
 513 ~~(1) FOR THE FIRST APPLICATION PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE,~~  
 514 ~~OTHER THAN THE RENEWAL OF A LEASE, ON OR AFTER <INSERT EFFECTIVE DATE OF~~  
 515 ~~STANDARDS>, THE EXISTING MRT SERVICE SHALL NOT BE REQUIRED TO BE IN COMPLIANCE~~  
 516 ~~WITH THE APPLICABLE VOLUME REQUIREMENTS SET FORTH IN THIS SECTION.~~

517  
 518 ~~(2) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE SHALL~~  
 519 ~~DEMONSTRATE THE FOLLOWING:~~

520 ~~(a) THE EXISTING MRT UNIT(S) SHALL BE OPERATING AT THE FOLLOWING VOLUMES, AS~~  
 521 ~~APPLICABLE TO THE PROPOSED PROJECT:~~~~The project is limited solely to the acquisition of an~~  
 522 ~~existing MRT service and its MRT unit(s).~~

523 ~~(b) The project will not change the number or type (special, non-special) of MRT units at the~~  
 524 ~~geographic location of the MRT service being acquired unless the applicant demonstrates that the project~~  
 525 ~~is in compliance with the requirements of Section 4 or 5, as applicable.~~

526 ~~(c) The project will not result in the replacement/upgrade of the MRT unit(s) to be acquired unless~~  
 527 ~~the applicant demonstrates that the requirements of Section 6, as applicable, have been met.~~

528 ~~(I) NON-SPECIAL MRT UNIT(S) AT 8,000 EQUIVALENT TREATMENT VISITS PER UNIT OR~~  
 529 ~~5,500 FOR A UNIT APPROVED UNDER SUBDIVISION 4(2).~~

530 ~~(II) HMRT UNIT(S) AT 8,000 EQUIVALENT TREATMENT VISITS PER UNIT.~~

531 ~~(III) SPECIAL PURPOSE UNIT(S) AT 1,000 EQUIVALENT TREATMENT VISITS PER UNIT.~~

532  
 533 ~~(3) AN APPLICANT PROPOSING TO RENEW A LEASE FOR AN EXISTING MRT UNIT SHALL~~  
 534 ~~DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE THAN REPLACING~~  
 535 ~~THE EQUIPMENT.~~

536  
 537 ~~(2) An applicant proposing to acquire an existing MRT unit(s) of an existing MRT service, other than~~  
 538 ~~an MRT service utilizing an HMRT unit, shall demonstrate that it meets all of the following:~~

539 ~~(a) The project is limited solely to the acquisition of an existing MRT unit(s) of an existing MRT~~  
 540 ~~service.~~

541 ~~(b) The project will not change the number or type (special, non-special) of MRT units at the~~  
 542 ~~geographic location of the MRT service being acquired unless the applicant demonstrates that the project~~  
 543 ~~is in compliance with the requirements of Section 4 or 5, as applicable.~~

544 ~~—(c) The project will not result in the replacement/upgrade of an existing MRT unit(s) to be acquired~~  
 545 ~~unless the applicant demonstrates that the requirements of Section 6, as applicable, also have been met.~~  
 546 ~~—(d) The requirements of Section 4(3) have been met.~~

### 547 **Section 8. Requirements for A DEDICATED RESEARCH MRT unit(s)**

548 ~~Sec. 8. An applicant proposing TO ADD A DEDICATED RESEARCH MRT unit shall demonstrate the~~  
 549 ~~following:~~

550 ~~\_(a1) THE APPLICANT IS AN EXISTING MRT SERVICE.~~

551 ~~\_(2) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH MRT UNIT(S) WILL BE USED~~  
 552 ~~PRIMARILY (70% OR MORE OF TREATMENTS) FOR RESEARCH PURPOSES.~~

553 ~~\_(3) The DEDICATED RESEARCH MRT unit(S) shall operate under a protocol approved by the~~  
 554 ~~applicant's INSTITUTIONAL REVIEW BOARD (IRB), AS DEFINED BY PUBLIC LAW 93-348 AND~~  
 555 ~~REGULATED BY TITLE 45 CFR 46..~~

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

558 ~~\_(5) THE PROPOSED SITE CAN HAVE NO MORE THAN TWO DEDICATED RESEARCH MRT~~  
 559 ~~UNITS.~~

### 560 **Section 9. Requirements for ~~MEDICAID PARTICIPATION approval – applicants proposing to~~** 561 **~~relocate an existing MRT service and/or MRT unit(s) other than an MRT service utilizing an HMRT~~** 562 **~~unit~~**

563 ~~Sec. 9. An applicant shall provide verification of Medicaid participation. An applicant that is a new~~  
 564 ~~provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided~~  
 565 ~~to the Department within six (6) months from the offering of services, if a CON is approved.~~

566 ~~\_(1) An applicant proposing to relocate an existing MRT service and its MRT unit(s), other than an MRT~~  
 567 ~~service utilizing an HMRT unit, shall demonstrate that it meets all of the following:~~

568 ~~—(a) The relocation of the existing MRT service and its MRT unit(s) will not change the number or type~~  
 569 ~~(special, non-special) of MRT units in the planning area, unless subsections (c) and/or (d), as applicable,~~  
 570 ~~have been met.~~

571 ~~—(b) The new geographic location will be in the same planning area as the existing geographic~~  
 572 ~~location.~~

573 ~~—(c) The project will not result in the replacement/upgrade of the existing MRT unit(s) to be relocated~~  
 574 ~~unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.~~

575 ~~—(d) The project will not result in the expansion of an existing MRT service unless the applicant~~  
 576 ~~demonstrates that the requirements of Section 5, as applicable, have been met.~~

577 ~~—(2) An applicant proposing to relocate an MRT unit(s) of an existing MRT service, other than an MRT~~  
 578 ~~service utilizing an HMRT unit, shall demonstrate that it meets all of the following:~~

579 ~~—(a) The relocation of the MRT unit(s) will not change the number or type (special, non-special) of~~  
 580 ~~MRT units in the planning area, unless subsections (c) and/or (d), as applicable, have been met.~~

581 ~~—(b) The new geographic location will be in the same planning area as the existing geographic~~  
 582 ~~location.~~

583 ~~—(c) The project will not result in the replacement/upgrade of the existing MRT (unit)s to be relocated~~  
 584 ~~unless the applicant demonstrates that the requirements of Section 6, as applicable, have been met.~~

585 ~~—(d) The project will not result in the expansion of an existing MRT service unless the applicant~~  
 586 ~~demonstrates that the requirements of Section 5, as applicable, have been met.~~

587 ~~—(e) For volume purposes, the new site shall remain associated to the original site for a minimum of~~  
 588 ~~three years.~~

599 ~~—(f) For a micropolitan statistical area or rural county, each existing MRT unit at the geographic~~  
 600 ~~location of the MRT unit to be relocated operated at an average of at least 5,500 ETVs in the most recent~~  
 601 ~~12-month period. For a metropolitan statistical area county, each existing MRT unit at the geographic~~  
 602 ~~location of the MRT unit to be relocated operated at an average of at least 8,000 ETVs in the most recent~~  
 603 ~~12-month period.~~

604 ~~—(g) The requirements of Section 4(3) have been met.~~

605 ~~—(h) A special purpose unit cannot be relocated to a site that does not have an existing non-special~~  
 606 ~~purpose unit.~~

607  
 608 **Section 10. Requirements for approval—~~applicants proposing to initiate an MRT service utilizing~~**  
 609 **~~an HMRT unit~~ METHODOLOGY FOR PROJECTING EQUIVALENT TREATMENT VISITS**  
 610

611 ~~Sec. -10. The~~ AN applicant being reviewed under Section 4 shall apply the methodology set forth in  
 612 this section in computing the projected number of equivalent treatment visits.

613  
 614 (1) Identify the number of new cancer cases documented in accord with the requirements of ~~UNDER~~  
 615 Section 4513.

616  
 617 (2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor  
 618 identified in Appendix A, for the planning area in which the proposed unit will be located.

619  
 620 (3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the  
 621 estimated number of courses of MRT.

622  
 623 (4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number  
 624 of treatment visits.

625  
 626 (5) Determine the number of estimated simple, intermediate, complex, and IMRT treatment visits by  
 627 multiplying the total estimated number of treatment visits produced in subsection (4) by the percent  
 628 allocations for each category as set forth in Appendix B.

629  
 630 (6) Multiply the estimated number of treatment visits in the simple category produced in subsection  
 631 (5) by 1.0.

632  
 633 (7) Multiply the estimated number of treatment visits in the intermediate category produced in  
 634 subsection (5) by 1.1.

635  
 636 (8) Multiply the estimated number of treatment visits in the complex category produced in subsection  
 637 (5) by 1.25.

638  
 639 (9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5)  
 640 by 2.50.

641  
 642 (10) Sum the numbers produced in subsections (6) through (9) to determine the total number of  
 643 estimated EQUIVALENT TREATMENT VISITS.

644 ~~The use of an HMRT unit represents emerging cancer treatment technology and consequently provides a~~  
 645 ~~mixture of both treatment and research uses. This section of the CON Review Standards for MRT~~  
 646 ~~Services/Units recognizes the unique nature of this technology.~~

647 ~~—(1) An applicant proposing to initiate an MRT service utilizing an HMRT unit shall demonstrate each~~  
 648 ~~of the following:~~

649 ~~—(a) An applicant is a single legal entity authorized to do business in the State of Michigan.~~

650 ~~—(b) An applicant is a collaborative that consists of at least 40% of all Michigan hospital MRT services~~  
 651 ~~with more than 30,000 ETVs.~~

652 ~~—(c) An applicant shall include hospital MRT services from more than one planning area from either or~~  
 653 ~~both of the following:~~

- 654 ~~—(i) The participating services under subsection (b).~~  
655 ~~—(ii) Hospital MRT services with the highest number of ETVs in a planning area.~~  
656 ~~—(d) For the purposes of this section, ETVs shall be those from the April 30, 2008 list (revised)~~  
657 ~~published by the Department. The Department shall update the list every three years thereafter.~~  
658 ~~—(e) An application under this section shall not be approved if it includes an MRT service described in~~  
659 ~~subsection (i) or (ii) except as provided in subsections (iii) or (iv).~~  
660 ~~—(i) An MRT service that was part of another application under this section.~~  
661 ~~—(ii) An MRT service owned by, under common control of, or has a common parent, as an MRT~~  
662 ~~service under subsection (i).~~  
663 ~~—(iii) The prior application, or the approved CON, under this section were subsequently disapproved,~~  
664 ~~withdrawn.~~  
665 ~~—(iv) The application under this section includes a commitment from the MRT service described in~~  
666 ~~subsection (i) to surrender the CON, or application, described in subsection (i) and that commitment is~~  
667 ~~fulfilled at the time the application under this section is approved.~~  
668 ~~—(f) An application under this section shall not be approved if it includes any of the following:~~  
669 ~~—(i) An MRT service that is approved but not operational, or that has a pending application, for a~~  
670 ~~heavy particle accelerator.~~  
671 ~~—(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT~~  
672 ~~service described by subsection (i), unless the application under this section includes a commitment from~~  
673 ~~the MRT service described in subsection (i) to surrender the CON, or application, described in subsection~~  
674 ~~(i) and that commitment is fulfilled at the time the application under this section is approved.~~  
675 ~~—(g) An application under this section shall not be approved if it includes any of the following:~~  
676 ~~—(i) An MRT service that is approved for a heavy particle accelerator that is operational.~~  
677 ~~—(ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT~~  
678 ~~service described by subsection (i), unless the application under this section includes a commitment from~~  
679 ~~the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that~~  
680 ~~commitment is fulfilled at the time the HMRT unit approved under this section is operational.~~  
681 ~~—(h) An applicant shall provide documentation of its process, policies and procedures, acceptable to~~  
682 ~~the Department, which will allow any other interested entities to participate in the collaborative utilizing an~~  
683 ~~HMRT unit.~~  
684 ~~—(i) An applicant shall provide an implementation plan, acceptable to the Department, for financing~~  
685 ~~and operating the proposed MRT service utilizing an HMRT unit including, but not limited to, how~~  
686 ~~physician staff privileges, patient review, patient selection, and patient care management shall be~~  
687 ~~determined.~~  
688 ~~—(j) An applicant shall indicate that its proposed HMRT unit will be available to both adult and~~  
689 ~~pediatric patients.~~  
690 ~~—(k) An applicant shall demonstrate that the MRT service utilizing an HMRT unit will have simulation~~  
691 ~~capabilities available for use in treatment planning.~~  
692  
693 ~~—(2) An applicant proposing to initiate an mrt service utilizing an hmrt unit shall also demonstrate~~  
694 ~~compliance with the requirements of section 4(3).~~

#### **Section 11. Requirements for approval— all applicants**

~~—Sec. 11. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services, if a CON is approved.~~

#### **Section 12. Methodology for computing the projected number of equivalent treatment visits**

~~—Sec. 12. The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits (ETVs).~~

~~—(1) Identify the number of new cancer cases documented in accord with the requirements of Section 45.~~

- 709  
710 ~~—(2) Multiply the number of new cancer cases identified in subsection (1) by the duplication factor~~  
711 ~~identified in Appendix A, for the planning area in which the proposed unit will be located.~~  
712  
713 ~~—(3) Multiply the number of new cancer cases produced in subsection (2) by 0.55 to determine the~~  
714 ~~estimated number of courses of MRT.~~  
715  
716 ~~—(4) Multiply the estimated number of courses of MRT by 20 to determine the total estimated number~~  
717 ~~of treatment visits.~~  
718  
719 ~~—(5) Determine the number of estimated simple, intermediate, complex, and IMRT treatment visits by~~  
720 ~~multiplying the total estimated number of treatment visits produced in subsection (4) by the percent~~  
721 ~~allocations for each category as set forth in Appendix B.~~  
722  
723 ~~—(6) Multiply the estimated number of treatment visits in the simple category produced in subsection~~  
724 ~~(5) by 1.0.~~  
725  
726 ~~—(7) Multiply the estimated number of treatment visits in the intermediate category produced in~~  
727 ~~subsection (5) by 1.1.~~  
728  
729 ~~—(8) Multiply the estimated number of treatment visits in the complex category produced in subsection~~  
730 ~~(5) by 1.25.~~  
731  
732 ~~—(9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5)~~  
733 ~~by 2.5.~~  
734  
735 ~~—(10) Sum the numbers produced in subsections (6) through (9) to determine the total number of~~  
736 ~~estimated ETVs.~~

737  
738 **Section 4311. Equivalent treatment visits**

739  
740 Sec. 4311. ~~For purposes of these standards, equivalent~~ Equivalent treatment visits shall be  
741 calculated as follows:

742  
743 (1) For the time period specified in the applicable section(s) ~~of these standards~~, assign each actual  
744 treatment visit provided to one applicable treatment visit category set forth in Table 1.

745  
746 (2) The number of treatment visits for each category in the time period specified in the applicable  
747 section(s) of these standards shall be multiplied by the corresponding ETV-EQUIVALENT TREATMENT  
748 VISITS weight in Table 1 to determine the number of equivalent treatment visits for that category for that  
749 time period.

750  
751 (3) The number of EQUIVALENT TREATMENT VISITs for each category determined pursuant to  
752 subsection (2) shall be summed to determine the total EQUIVALENT TREATMENT VISITs for the time  
753 period specified in the applicable section(s) of these standards.

754

**TABLE 1**  
**Equivalent Treatments**

Treatment Visit Category	Non-Special Visit Weight	Special Visit Weight
Simple	1.00	
Intermediate	1.10	
Complex	1.25	
IMRT	<del>2.50</del> 2.00	
<del>Very Complex:</del>		
Total Body Irradiation	8.00	<del>5.00</del> 8.00
HMRT <del>Unit</del> THERAPY		5.00
Stereotactic radio-surgery/radio-therapy* (non-gamma knife and cyber knife**)	8.00	8.00
Gamma Knife**		8.00
<del>Dedicated OR-Based</del> IORT		20.00

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

\*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 additional EQUIVALENT TREATMENT VISITs.

755

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

758

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

761

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

765

766 (7) "IMRT TREATMENT VISIT" means a visit utilizing only the computer controlled multi-leaf  
767 collimator part of the CMS definition for IMRT.

768

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

771

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

774

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

777

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

780

#### 781 **Section 4412. Commitment of new cancer cases**

782

783 Sec. 4412. (1)–An applicant proposing to use USING new cancer cases shall TO demonstrate NEED  
784 SHALL MEET all of the following:

785  
786 (a1) Each entity contributing new cancer case data provides, ~~as part of the application at the time it is~~  
787 ~~submitted to the Department,~~ a signed governing body resolution that states that the number of new  
788 cancer cases committed to the application shall not be used in support of any other application for an  
789 MRT unit(s) for the duration of the MRT service for which the data are being committed.

790  
791 (b2) The ~~geographic~~ locations of all entities contributing new cancer case data are in the same  
792 planning area as the proposed MRT service.

793  
794 (23) An entity currently operating or approved to operate ~~a~~ AN MRT service shall not contribute new  
795 cancer cases to initiate any MRT service.

796  
797 **Section 4513. Documentation of new cancer case data**

798  
799 Sec. 4513. (1) An applicant ~~required to document volumes of new cancer cases~~ shall submit, ~~as part~~  
800 ~~of its application,~~ documentation from the MICHIGAN CANCER SURVEILLANCE PROGRAM, WITHIN  
801 THE Department, Vital Records and Health Data Development Section, verifying the number of new  
802 cancer cases provided in support of the application for the most recent calendar year for which verifiable  
803 data is available ~~from the State Registrar.~~

804 ~~—(2)—~~ New cancer case data supporting an application ~~under these standards~~ shall be submitted to the  
805 Michigan Cancer Surveillance Program using a format and media specified in instructions from the State  
806 Registrar ~~DEPARTMENT.~~

807  
808 **Section 4614. Project delivery requirements – terms of approval for all applicants**

809  
810 Sec. 4614. (1) ~~An applicant shall agree that, if approved, THE MRT services,~~ INCLUDING ALL  
811 EXISTING AND APPROVED MRT UNITS, shall be delivered in compliance with the following ~~applicable~~  
812 ~~terms of CON approval for each geographical location where the applicant operates an MRT unit:~~

813  
814 (a1) Compliance with these standards.

815 ~~—(b)—~~ ~~Compliance with applicable safety and operating standards.~~

816  
817 (e2) Compliance with the following quality assurance standards:

818 (i)(A) An applicant shall assure that -the MRT service is staffed AND operated by physicians and/or  
819 radiation THERAPISTS qualified by training and experience to operate the unit safely and effectively.  
820 The Department shall consider it prima facie evidence if the applicant requires the equipment to be  
821 operated by a physician who is board certified or board qualified in either radiation oncology or  
822 therapeutic radiology, and/or a radiation therapy-THERAPIST certified by the American Registry of  
823 Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists  
824 (ARCRT). The applicant may ALSO submit, and the Department may accept, other evidence. AN  
825 APPLICANT APPROVED TO OPERATE a dedicated stereotactic radiosurgery unit or a gamma knife  
826 HAS ON THE ACTIVE MEDICAL STAFF A neurosurgeon(s) trained in THE SPECIAL type OF MRT unit  
827 being operated.

828 (B) AN APPLICANT shall HAVE THE FOLLOWING STAFF:

829 (I) ONE (1) FULL-TIME EQUIVALENT (FTE) board-certified or board- qualified physician trained in  
830 radiation oncology for each 250 patients treated with MRT annually,

831 ~~—(bII)—~~ ONE (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic  
832 radiologic physics, immediately available during hours of operation,

833 (eIII) ONE (1) dosimetrist or physics assistant for every 300 patients treated with MRT annually,

834 (dIV) TWO (2) FTE-radiation therapy technologists THERAPISTS [registered or eligible by the American  
835 Registry of Radiological Technologists (ARRT)], for every MRT unit per shift of operation (not including  
836 supervisory time), and

837 (eV) ONE (1) FTE program director who is a board-certified physician trained in radiation oncology  
838 who may also be the physician required under subsection (iii)(a). 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 radiation oncology and/or therapeutic radiology.~~

~~The non-special MRT units and HMRT units approved pursuant to these standards shall be operating at a minimum average volume of 8,000 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. The following types of special purpose MRT units: OR-based IORT unit, gamma knife, dedicated stereotactic radiosurgery unit and dedicated total body irradiator approved pursuant to these standards shall be operating at a minimum average volume of 1,000 ETVs per special purpose unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.~~

~~(B) The non-special MRT units and HMRT units approved pursuant to Section 4(2) of these standards shall be operating at a minimum average volume of 5,500 ETVs per unit annually by the end of the third full year of operation, and annually thereafter. In meeting this requirement, the applicant shall not include any treatment visits conducted by MRT units approved exclusively for research pursuant to Section 7.~~

~~—(ii) An applicant shall establish a mechanism to assure that (a) the MRT service is staffed so that the MRT unit is operated by physicians and/or radiation therapy technologists qualified by training and experience to operate the unit safely and effectively. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence of a satisfactory quality assurance mechanism as to the operation of the unit 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 therapy technologist certified by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT). However, the applicant may submit and the Department may accept other evidence that the applicant has established and operates a satisfactory quality assurance mechanism to assure that the MRT unit is appropriately staffed, and (b) for the MRT service/program operating a dedicated stereotactic radiosurgery unit or a gamma knife, a neurosurgeon(s) trained in each type of special MRT unit being operated is on the active medical staff of the applicant organization.~~

~~—(iii) At a minimum, the following staff shall be provided: (a) 1 FTE board-certified or board-qualified physician trained in radiation oncology for each 250 patients treated with MRT annually, (b) 1 board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation, (c) 1 dosimetrist or physics assistant for every 300 patients treated with MRT annually, (d) 2 FTE radiation therapy technologists [registered or eligible by the American Registry of Radiological Technologists (ARRT)] for every MRT unit per shift of operation (not including supervisory time), and (e) 1 FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (iii)(a). For purposes of evaluating this subsection, the departmentDepartment 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.~~

~~—(ivC) 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).~~

~~(vD) The AN applicant shall have equipment and supplies within the megavoltage therapy unit/facility to handle clinical emergencies that might occur in the unit. MRT facility staff Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the MRT unit at all times when patients are treated. A physician shall be on-site in or immediately available to the MRT unit at all times when patients are treated.~~

~~(viE) An applicant shall operate a cancer treatment program. For purposes of evaluating this subsection,†The Department shall consider it prima facie evidence of meeting this requirement 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~~

894 involvement, MRT capability including electron beam capability, treatment aid fabrication capability,  
 895 brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care evaluation studies,  
 896 and cancer prevention and education programs. The applicant may ALSO submit, and the Department  
 897 may accept, other evidence. Patient care evaluation studies means a system of patient care evaluation,  
 898 conducted at least twice annually, that documents the methods used to identify problems and the  
 899 opportunities to improve patient care. Tumor registry means a manual or computerized data base  
 900 containing information about all malignancies and only those that are diagnosed and/or treated at the  
 901 applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as  
 902 required pursuant to Public Act 82 of 1984, as amended.

903 ~~(viiF)~~ A-THE MRT service will have simulation capability at the same -location.

904 ~~(viiiG)~~ An applicant shall participate in the Michigan Cancer Surveillance Program.

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

907 (I) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source  
 908 of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant  
 909 approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or  
 910 an HMRT unit, shall meet any requirements specified by THE STATE OF MICHIGAN Radiation Safety  
 911 Section.

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

916 (K) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA  
 917 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

918

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

920 ~~—(ix)—An applicant required to document new cancer cases shall agree to pay the State Registrar's~~  
 921 ~~costs for verification of the new cancer case data.~~

922 ~~(x)A~~ The applicant shall accept referrals for MRT services from all appropriately licensed health care  
 923 practitioners.

924 ~~(xiB)~~ The applicant, ~~t~~To assure that the MRT SERVICE AND ITS unit(S) will be utilized by all segments  
 925 of the Michigan population, THE APPLICANT shall:

926 \_(aI) \_not deny MRT services to any individual based on ability to pay or source of payment,

927 \_(bII) \_provide MRT services to an individual based on the clinical indications of need for the service,  
 928 and

929 \_(eIII) \_maintain information by payor and non-paying sources to indicate the volume of care from each  
 930 source provided annually. Compliance with selective contracting requirements shall not be construed as  
 931 a violation of this term.

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

934

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

936 (A) Non-special MRT units and HMRT units shall be operating at a minimum average volume of  
 937 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and  
 938 annually thereafter. ALL special purpose MRT units shall be operating at a minimum average volume of  
 939 1,000 EQUIVALENT TREATMENT VISITs per special purpose unit by the end of the third full year of  
 940 operation, and annually thereafter. AN applicant shall not include any ~~t~~treatments conducted ~~by~~ON A  
 941 DEDICATED RESEARCH MRT unit.

942 (B) Non-special MRT units and HMRT units approved pursuant to Section 4(2) of these standards  
 943 shall be operating at a minimum average volume of 5,500 EQUIVALENT TREATMENT VISITs per unit by  
 944 the end of the third full year of operation, and annually thereafter. AN applicant shall not include any  
 945 treatments conducted ON A DEDICATED RESEARCH MRT unit.

946 (C) AN APPLICANT IS NOT REQUIRED TO BE IN COMPLIANCE WITH SUBDIVISIONS (4)(A) OR  
 947 (B) IF THE APPLICANT IS REPLACING AN MRT UNIT UNDER SUBSECTION 5(1).

948 ~~\_(AD) The AN~~ applicant shall participate in a data collection network established and administered by  
 949 the Department or its designee. The data may include, but is not limited to, annual budget and cost  
 950 information, operating schedules, through-put schedules, demographic and diagnostic information, and  
 951 the volume of care provided to patients from all payor sources and other data requested by the  
 952 Department ~~or its designee, and approved by the CON Commission. The applicant shall provide the~~  
 953 ~~required data Data on a separate basis for each separate and distinct geographic location or unit, and~~  
 954 ~~separately for non-special MRT units and each DATA SHALL BE PROVIDED BY EACH~~ type of special  
 955 ~~purpose~~ MRT unit, ~~as required by the Department;~~ in a format established by the Department; and in a  
 956 mutually agreed upon media. The Department may elect to verify the data through on-site review of  
 957 appropriate records.

958 (E) SERVICES PROVIDED ON A DEDICATED RESEARCH MRT UNIT SHALL BE DELIVERED IN  
 959 COMPLIANCE WITH THE FOLLOWING TERMS:

960 (I) Capital and operating costs FOR research TREATMENT VISITS shall be charged only to a  
 961 specific research account(s) and not to any patient or third-party payor.

962 (BII) If the applicant intends to include THE DEDICATED research treatment visits conducted by a  
 963 MRT unit other than an MRT unit approved exclusively for research pursuant to Section 7 in its utilization  
 964 statistics, the applicant shall NOT BE USED submit to the Department a copy of the research protocol  
 965 FOR ANY PURPOSES OTHER THAN with evidence of approval AS APPROVED by the IRB. The  
 966 applicant shall submit this at the time the applicant intends to include research procedures in its utilization  
 967 statistics.

968 (III) The applicant shall not report to the Department any treatments ON A DEDICATED RESEARCH  
 969 RESEARCH visits conducted by an MRT UNIT SHALL NOT BE USED FOR ANY VOLUME  
 970 PURPOSES unit approved pursuant to Section 7.

971 —(xiii) The applicant shall provide the Department with a notice stating the first date on which the MRT  
 972 service and its unit(s) became operational, and such notice shall be submitted to the Department  
 973 consistent with applicable statute and promulgated rules.

974 —(xiv) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which  
 975 it was approved and to seek approval under a separate CON application to operate the unit as a non-  
 976 special MRT unit.

977 —(xv) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source  
 978 of radiation shall obtain and maintain Nuclear Regulatory Commission certification as a total body  
 979 irradiator. An applicant approved to operate a dedicated total body irradiator that is a permanently  
 980 modified linear accelerator, or an HMRT unit, shall meet any requirements specified by the Department,  
 981 Division of Health Facilities and Services, Radiation Safety Section.

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

984  
 985 —(2) An applicant for an MRT unit under Section 7 shall agree that the services provided by the MRT  
 986 unit approved pursuant to Section 7 shall be delivered in compliance with the following terms of CON  
 987 approval:

988 —(a) The capital and operating costs relating to the research use of the MRT unit approved pursuant to  
 989 Section 7 shall be charged only to a specific research account(s) and not to any patient or third-party  
 990 payor.

991 —(b) The MRT unit approved pursuant to Section 7 shall not be used for any purposes other than as  
 992 approved by the IRB unless the applicant has obtained CON approval for the MRT unit pursuant to Part  
 993 222 and these standards, other than Section 7.

994  
 995 —(3) An applicant for an MRT service utilizing an HMRT unit approved under Section 10 shall agree to  
 996 deliver the service in compliance with the following additional terms:

997 —(a) All patients treated shall be evaluated for potential enrollment in research studies focusing on the  
 998 applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer conditions. The  
 999 number of patients treated, number enrolled in research studies, and the types of cancer conditions  
 1000 involved, shall be provided to the Department as part of the CON Annual Survey.

1001 ~~—(b) Upon completion of any study, and authorization by study sponsor, the findings and summary of~~  
 1002 ~~any research studies, consistent with patient confidentiality, shall be provided to the Department by the~~  
 1003 ~~applicant.~~

1004 ~~—(c) The MRT service utilizing an HMRT unit shall provide the Department, on an annual basis,~~  
 1005 ~~following the initiation of the service, with updates to the information provided and approved by the~~  
 1006 ~~Department pursuant to subsections 10(1)(h), (i), (j), (k), and 10(2).~~

1007 ~~—(d) On an annual basis, following the initiation of the service, the Department will assess the~~  
 1008 ~~affordability of the project by evaluating the “Hospital Cost Report” and any other applicable information~~  
 1009 ~~supplied to the Centers of Medicare and Medicaid Services (CMS) and the Michigan Medical Services~~  
 1010 ~~Administration (MSA).~~

1011 ~~—(e) Upon review, by the Department, of the information submitted under subsections (c) and (d)~~  
 1012 ~~above, and the Department’s finding that the service has not fulfilled project delivery requirements, the~~  
 1013 ~~Department may order changes with regard to the provision of the HMRT service to assure fulfillment of~~  
 1014 ~~project delivery requirements. The Department may elect to verify the information and data through on-~~  
 1015 ~~site review of appropriate records.~~

1016  
 1017 ~~—(4) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA~~  
 1018 ~~368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

1019  
 1020 (5) The applicable agreements and assurances required by this section shall be in the form of a  
 1021 certification agreed to by the applicant or its authorized agent.

1022  
 1023 **Section 15. Effect on prior CON review standards; comparative reviews**

1024  
 1025 Sec. 15. PROPOSED PROJECTS reviewed UNDER THESE standards SHALL NOT BE SUBJECT  
 1026 TO COMPARATIVE REVIEW. THESE STANDARDS supersede and replace the CON Review Standards  
 1027 for Megavoltage Radiation Therapy (MRT) Services/Units approved by the CON Commission on  
 1028 December 13, 2005SEPTEMBER 16, 2008 and effective January 30, 2006NOVEMBER 13, 2008.

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**Section 17. Planning areas**  
**APPENDIX A**

**DUPLICATION RATES AND FACTORS**

The following Duplication Rates and Factors are effective <INSERT EFFECTIVE DATE> and remain in effect until otherwise changed by the Commission. Duplication factor means the number derived by subtracting the duplication rate from 1. Duplication rate means the percent of new cancer cases in each planning area determined by the Department, Vital Records and Health Data Development Section, that have been reported more than one time to the Michigan Cancer Surveillance Program.

<u>PLANNING AREA</u>	<u>DUPLICATION RATE</u>	<u>DUPLICATION FACTOR</u>
<u>1</u>	<u>0.123-21085</u>	<u>0.877-78945</u>
<u>2</u>	<u>0.152-23517</u>	<u>0.848-76483</u>
<u>3</u>	<u>0.113-41219</u>	<u>0.887-74336</u>
<u>4</u>	<u>0.162-25664</u>	<u>0.838-74336</u>
<u>5</u>	<u>0.167-21849</u>	<u>0.8330-78151</u>
<u>6</u>	<u>0.270-34615</u>	<u>0.730-65385</u>
<u>7</u>	<u>0.126-21865</u>	<u>0.874-78135</u>
<u>8</u>	<u>0.193-42314</u>	<u>0.807-87686</u>

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APPENDIX BDISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective <INSERT EFFECTIVE DATE> ~~December 11, 2007~~ and remains in effect until otherwise changed by the Commission.

<u>Treatment Visit Category</u>	<u>Statewide Percent</u>
<u>Simple</u>	<u>0.74-6%</u>
<u>Intermediate</u>	<u>0.18%</u>
<u>Complex</u>	<u>52.273-4%</u>
<u>IMRT</u>	<u>47.024-2%</u>

Source: 200610 Annual Hospital Statistical CON Survey

**APPENDIX C**

1058  
1059  
1060 ~~— Sec. 17. Counties assigned to each planning area are as follows:~~

1061	<del>PLANNING AREA</del>	<del>COUNTIES</del>	<del>COUNTIES</del>
1062	<del>—1</del>	<del>Livingston Macomb Wayne</del>	<del>Monroe Oakland St. Clair Washtenaw</del>
1063	<del>—2</del>	<del>Clinton Eaton</del>	<del>Hillsdale Ingham Jackson Lenawee</del>
	<del>—3</del>	<del>Barry Berrien Branch</del>	<del>Calhoun Cass Kalamazoo St. Joseph Van Buren</del>
	<del>—4</del>	<del>Allegan Ionia Kent Lake</del>	<del>Mason Mecosta Montcalm Muskegon Newaygo Oceana Osceola Ottawa</del>
	<del>—5</del>	<del>Genesee</del>	<del>Lapeer Shiawassee</del>
1064	<del>—6</del>	<del>Arenac Bay Clare Gladwin Gratiot</del>	<del>Huron Iosco Isabella Midland Ogemaw Roscommon Saginaw Sanilac Tuscola</del>
	<del>—7</del>	<del>Alcona Alpena Antrim Benzie Charlevoix Cheboygan</del>	<del>Crawford Emmet Gd. Traverse Kalkaska Leelanau Manistee Missaukee Montmorency Oscoda Otsego Presque Isle Wexford</del>
	<del>—8</del>	<del>Alger Baraga Chippewa Delta Dickinson</del>	<del>Gogebic Houghton Iron Keweenaw Luce Mackinac Marquette Menominee Ontonagon Schoolcraft</del>

1065  
1066 **Section 18. Effect on prior CON review standards; comparative reviews**

1067  
1068 ~~— Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for~~  
1069 ~~Megavoltage Radiation Therapy (MRT) Services/Units approved by the CON Commission on December~~  
1070 ~~13, 2005 and effective January 30, 2006.~~

1071  
1072 ~~— (2) Projects reviewed under these standards shall not be subject to comparative review.~~

APPENDIX ADUPLICATION RATES AND FACTORS

The following Duplication Rates and Factors are effective December 11, 2007 ~~<INSERT EFFECTIVE DATE>~~ and remain in effect until otherwise changed by the Commission.

<b>PLANNING AREA</b>	<b>DUPLICATION RATE</b>	<b>DUPLICATION FACTOR</b>
1	<del>0.210850.123</del>	<del>0.789150.877</del>
2	<del>0.235170.152</del>	<del>0.764830.848</del>
3	<del>0.112190.113</del>	<del>0.887810.887</del>
4	<del>0.256640.162</del>	<del>0.743360.838</del>
5	<del>0.218490.167</del>	<del>0.781510.8330</del>
6	<del>0.346150.270</del>	<del>0.653850.730</del>
7	<del>0.218650.126</del>	<del>0.781350.874</del>
8	<del>0.123140.193</del>	<del>0.876860.807</del>

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APPENDIX BDISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective December 11, 2007 and remains in effect until otherwise changed by the Commission.

<u>Treatment —Visit Category</u>	<u>Statewide Percent</u>
Simple	1.60.7%
Intermediate	.80.1%
Complex	73.452.2%
IMRT	24.247.0%

Source: 2006 Annual Hospital Statistical Survey

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1101APPENDIX CCON REVIEW STANDARDS  
FOR MRT SERVICES PLANNING AREAS BY COUNTY

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

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

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Source:

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

**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. ~~(1)~~ These standards are requirements for the approval OF THE INITIATION, REPLACEMENT, EXPANSION, OR ACQUISITION OF PET SCANNER SERVICES, and THE delivery of THESE services for all projects approved and Certificates of Need issued under Part 222 of the Code ~~that involve PET scanner services.~~

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

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

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

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

**Section 2. Definitions**

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

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

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

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

~~— (d) "Anatomical site" means the physical area that can be imaged by a single PET scan.~~

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

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

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

~~(h)~~ (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.

~~— (i) "Cyclotron" means an apparatus for accelerating charged particles to high energies by means~~

54 of electromagnetic fields.

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

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

63 ~~(lC)~~ "Department" means the ~~state agency known as the~~ Michigan Department of Community  
 64 Health (MDCH).

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

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

73 ~~(oD)~~ "Existing PET scanner" means an ~~CON-approved and~~ operational PET scanner used to  
 74 provide PET services on the date an application is submitted to the Department.

75 ~~(pE)~~ "Existing PET scanner service" means an ~~CON-approved and~~ operational ~~PET scanner(s)~~  
 76 ~~SERVICE used to provide~~ providing PET ~~SCANNER~~ services at one site in the case of a fixed PET  
 77 service or at each host site in the case of a mobile PET service on the date an application is submitted to  
 78 the Department.

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

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

85 ~~\_\_\_\_\_ (s) "FDG" means 2-{fluorine-18} fluoro-2-deoxy-D-glucose radiopharmaceuticals.~~

86 ~~(tF)~~ "Health service area" or "HSA" means the groups of counties listed in ~~Section 22~~ APPENDIX A.

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

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

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

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

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

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

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

105 ~~(bbJ)~~ "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan  
 106 Health and Hospital Association or successor organization. The data base consists of inpatient

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

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

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

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

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

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

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

123 ~~—(iiO) "PET data unit" means the result of the methodology as used in Section 1712.~~

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

126 ~~(kkPQO) "PET procedure" means the acquisition of a single image or image sequence involving a single  
127 injection of tracer.~~

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

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

137 ~~(nnSTR) "PET scanner services" or "PET services" means either the CON-approved utilization of a PET  
138 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  
139 service.~~

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

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

143 ~~—(qq) "Radiopharmaceutical" means a radioactive pharmaceutical used for diagnostic or therapeutic  
144 purposes.~~

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

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

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

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

156 ~~—(vv) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
157 statistical areas as those terms are defined under the "standards for defining metropolitan and  
158 micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of  
159 the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as~~

- 160 shown in Appendix A.
- 161 (~~wwwUVS~~) "SPECT" means single photon emission computed tomography.
- 162 ~~—(xx) "Static PET scan" means any PET scan that is not dynamic.~~
- 163 ~~—(yy) "Tracer" means a radiopharmaceutical developed for use in PET scanner services which allows~~
- 164 ~~the quantification and/or qualitative images of chemistry, metabolism, and/or perfusion in vivo.~~
- 165 ~~—(zz) "Transmission scan" means transmission computed tomography using a sealed radioactive~~
- 166 ~~photon source or x-ray tube photon source applied to the attenuation correction of the emission scan~~
- 167 ~~data.~~
- 168 ~~—(aaa) "Upgrade an existing PET scanner" means any equipment change that:~~
- 169 ~~—(i) does not involve a change in, or replacement of, the scanner;~~
- 170 ~~—(ii) does not result in an increase in the number of PET scanners;~~
- 171 ~~—(iii) does not result in a change in the type of PET scanner (e.g., changing a mobile PET scanner to~~
- 172 ~~a fixed PET scanner) or a change in manufacturer; and~~
- 173 ~~—(iv) involves a capital expenditure of less than \$500,000 in any consecutive 24-month period.~~
- 174
- 175 (2) The definitions in Part 222 shall apply to these standards.
- 176

### 177 **Section 3. Requirements ~~for approval for all fixed services and mobile host sites~~ TO INITIATE A**

### 178 **PET SCANNER SERVICE**

179

180 Sec. 3. ~~(1)~~ An applicant proposing to ~~provide~~ INITIATE PET scanner services shall ~~provide~~

181 DEMONSTRATE the following ~~services and medical specialties, AS APPLICABLE TO THE PROPOSED~~

182 PROJECT:

183

#### 184 (1) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE PROVIDES THE

#### 185 FOLLOWING SERVICES AND SPECIALTIES:

- 186 (a) nuclear medicine services AS DOCUMENTED BY A CERTIFICATE FROM THE US NUCLEAR
- 187 REGULATORY COMMISSION, ~~as documented on the certificate issued by the Department of~~
- 188 Environmental Quality,
- 189 (b) single photon emission computed tomography (SPECT) services,
- 190 (c) computed tomography (CT) scanning services,
- 191 (d) magnetic resonance imaging (MRI) services,
- 192 (e) cardiac catheterization services,
- 193 (f) open heart surgery,
- 194 (g) thoracic surgery,
- 195 (h) cardiology,
- 196 (i) oncology,
- 197 (j) radiation oncology,
- 198 (k) neurology,
- 199 (l) neurosurgery, and
- 200 (m) psychiatry.
- 201

202 (2) If the applicant PROPOSED SITE does not provide any of the services listed in this subsection

203 (1) at the same site at which the proposed PET scanner service will be located ON-SITE, the applicant

204 shall include in the application PROVIDE written contracts or agreements with a hospital(s) located within

205 the same planning area OR 25-MILES RADIUS OF THE PROPOSED SITE for the services not provided

206 at the proposed PET scanner service site.

207

#### 208 (3) THE APPLICANT SHALL DEMONSTRATE THE PROPOSED SITE HAS AN ON-SITE

#### 209 SOURCE OF RADIOPHARMACEUTICALS.

210

211 ~~—(24)~~ If ~~a~~ THE proposed ~~PET scanner service~~ SITE does not ~~involve~~ PROVIDE an on-site source of

212 ~~radiopharmaceuticals, an~~ THE applicant ~~must~~ SHALL provide ~~in the application~~ a written contract or

213 agreement that demonstrates ~~that~~ a reliable supply of radiopharmaceuticals ~~will be available to the~~  
 214 ~~proposed PET scanner service.~~

215  
 216 (54) AN APPLICANT PROPOSING TO INITIATE A FIXED PET SCANNER SERVICE WITH ITS  
 217 FIRST PET SCANNER SHALL PROJECT 2,600 PET DATA UNITS OR SHALL DEMONSTRATE ALL  
 218 OF THE FOLLOWING:

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

221 (B) THE APPLICANT HAS PERFORMED:

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

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

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

230  
 231 (65) AN APPLICANT PROPOSING TO INITIATE A MOBILE PET SCANNER SERVICE WITH ITS  
 232 FIRST MOBILE PET SCANNER SHALL PROJECT 2,100 PET DATA UNITS.

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

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

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

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

243  
 244 (76) AN APPLICANT PROPOSING TO INITIATE A HOST SITE ON A PROPOSED OR EXISTING  
 245 MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING:

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

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

249 (C) THE APPLICANT HAS NOT INITIATED FIXED PET SCANNER SERVICES UNDER  
 250 SUBSECTION 3(54) WITHIN THE MOST RECENT 12-MONTH PERIOD AS OF THE DATE THE  
 251 APPLICATION IS SUBMITTED TO THE DEPARTMENT.

252 (D) AN APPLICANT INITIATING A HOST SITE IN HSA 8 ON A MOBILE PET SCANNER  
 253 SERVICE THAT OPERATES PREDOMINANTLY OUTSIDE OF MICHIGAN SHALL DEMONSTRATE  
 254 240 PET DATA UNITS FROM PLANNING AREA 6.

255  
 256 (87) AN APPLICANT PROPOSING TO INITIATE PET SCANNER SERVICES AS AN EXISTING  
 257 HOST SITE ON A DIFFERENT MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THE  
 258 FOLLOWING:

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

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

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

266 **Section 4. Requirements for approval for applicants proposing to initiate TO REPLACE AN**  
 267 **EXISTING PET scanner-service(S) OR PET SCANNER SERVICE**

268  
 269 Sec. 4. REPLACING A PET SCANNER(S) MEANS A CHANGE IN THE SCANNER EQUIPMENT  
 270 OR RELOCATION OF THE SERVICE TO A NEW SITE. AN UPGRADE TO SOFTWARE OR  
 271 COMPONENTS OF AN EXISTING SCANNER DOES NOT CONSTITUTE REPLACEMENT OF A PET  
 272 SCANNER. AN APPLICANT PROPOSING TO REPLACE AN EXISTING PET SCANNER(S) OR PET  
 273 SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE  
 274 PROPOSED PROJECT. (1) An applicant proposing to initiate a fixed PET scanner(S) service shall project  
 275 an operating level of at least 2,600 PET data units for each proposed PET scanner based on the  
 276 methodology used in Section 17.

277  
 278 (2) An applicant proposing to REPLACE a PET scanner(S) shall DEMONSTRATE EACH OF THE  
 279 FOLLOWING. An applicant proposing to initiate a mobile PET scanner service shall project 2,100 PET  
 280 data units for each proposed mobile PET scanner based on the methodology used in Section 17:

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

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

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

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

299 (3C) Initiation of a mobile PET host site does not include the provision of mobile PET services at a  
 300 host site if the applicant, whether the host site or the central service coordinator, demonstrates or  
 301 provides, as applicable, each of the following: THE APPLICANT AGREES THAT THE PET SCANNER(S)  
 302 TO BE REPLACED WILL BE REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION  
 303 OF THE REPLACEMENT SCANNER(S).

304  
 305 (a2) The host site has received mobile PET services from an existing approved mobile PET unit  
 306 within the most recent 12-month period as of the date the application is submitted to the Department. AN  
 307 APPLICANT PROPOSING TO REPLACE A FIXED PET SCANNER SERVICE TO A NEW SITE SHALL  
 308 DEMONSTRATE THE FOLLOWING:-:

309 (bA) The addition of a host site to a mobile PET scanner service will not increase the number of PET  
 310 units operated by the central service coordinator or by any other person. PROPOSED SITE IS WITHIN A  
 311 10-MILE RADIUS OF THE EXISTING SITE FOR A METROPOLITAN STATISTICAL AREA COUNTY OR  
 312 A 25-MILE RADIUS FOR A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

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

316 (dC) A signed certification whereby the host site has agreed and assured that it will provide PET  
 317 services in accordance with the terms for approval set forth in Section 14 and 15. The applicant also  
 318 shall provide a current route schedule for the mobile PET scanner service THE EXISTING FIXED PET

319 SCANNER SERVICE HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE OF  
 320 THE APPLICATION SUBMITTED TO THE DEPARTMENT.

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

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

327  
 328 ~~— (4) An applicant that meets all of the following requirements shall not be required to be in~~  
 329 ~~compliance with subsection (1):~~

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

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

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

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

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

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

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

341  
 342 **Section 5. Requirements ~~for approval for applicants proposing to expand a PET scanner service~~**

343  
 344 Sec. 5. (1) An applicant proposing to increase EXPAND A the number of fixed PET scanner SERVICE  
 345 (second, third, etc.) shall demonstrate the following, AS APPLICABLE TO THE PROPOSED PROJECT.:  
 346 THIS SECTION DOES NOT APPLY TO DEDICATED RESEARCH, DEDICATED PEDIATRIC, OR  
 347 POSITRON EMISSION MAMMOGRAPHY (PEM) SCANNERS.

348  
 349  
 350 (a1) For aAn applicant in a metropolitan statistical area county, all of the applicant's approved fixed  
 351 PET scanners have performed an average of at least 5,500 PET equivalents per PET scanner during the  
 352 most recent 12-month period for which the Department has verifiable data. PROPOSING TO ADD A  
 353 FIXED PET SCANNER(S) TO AN EXISTING FIXED PET SCANNER SERVICE SHALL DEMONSTRATE  
 354 THE FOLLOWING.:

355 (bA) For an applicant in a rural or micropolitan statistical area county, all of the applicant's approved  
 356 fixed pet scanners have performed an average of at least 5,000 pet equivalents per pet scanner  
 357 during 1,900 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED FIXED PET  
 358 SCANNER(S) IN the most recent 12-month period for which the department has verifiable  
 359 data. VERIFIABLE BY THE DEPARTMENT FOR AN APPLICANT IN A METROPOLITAN STATISTICAL  
 360 AREA COUNTY, OR

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

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

368  
 369 (2) An applicant proposing to increase ADD the number of A mobile PET scanner(s) TO AN  
 370 EXISTING MOBILE PET SCANNER SERVICE (second, third, etc.) shall demonstrate the following:

371 (a) 2,000 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED MOBILE

SCANNER(S)

~~For an applicant serving at least one existing host site in a metropolitan statistical area county, all of the applicant's approved mobile PET scanners on a mobile route have performed an average of at least 5,000 PET equivalents per PET scanner during IN the most recent 12-month period VERIFIABLE BY for which the Department has verifiable data. FOR AN APPLICANT SERVING AT LEAST ONE EXISTING HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR~~

~~(b) 1,800 PET EQUIVALENTS WERE PERFORMED PER EXISTING AND APPROVED SCANNER(S). For an applicant serving only host sites in rural or micropolitan statistical area counties, all of the applicant's approved mobile PET scanners on a mobile route have performed an average of at least 4,500 PET equivalents per PET scanner during IN the most recent 12-month period VERIFIABLE for which BY the Department has verifiable data. 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 meets ALSO RECEIVES MOBILE PET SCANNER SERVICES SHALL DEMONSTRATE all of the following requirements shall not be required to be in compliance with subsection (1):~~

~~(a) The applicant is proposing CURRENTLY A HOST SITE BEING SERVED BY ONE OR MORE to initiate a mobile PET scanner services.~~

~~(b) The applicant is currently a fixed PET scanner service HAS PERFORMED:~~

~~(c) The applicant has demonstrated the following: AN AVERAGE OF 1,900 PET EQUIVALENTS FOR THE HOST SITE AND EACH OF THE EXISTING AND APPROVED FIXED SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE DEPARTMENT FOR A HOST SITE IN A METROPOLITAN STATISTICAL AREA COUNTY, OR~~

~~(i) For a/an applicant in a metropolitan statistical area county, all of the applicant's approved fixed AVERAGE OF 1,700 PET scanners EQUIVALENTS have performed an average of at least 5,500 PET equivalents FOR THE HOST SITE AND EACH OF THE EXISTING AND APPROVED FIXED per PET scanners scanners during IN the most recent 12-month period for which VERIFIABLE BY the Department has verifiable data FOR A HOST SITE IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.~~

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

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

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

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

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

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

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

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

~~Sec. 6. (1) An applicant proposing to replace an existing fixed 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 shall demonstrate that all of the applicant's approved and operating fixed OR MOBILE PET scanners. AN APPLICANT PROPOSING TO ACQUIRE A have performed an average of at least~~

425 ~~4,500~~ PET SCANNER SERVICE equivalents SHALL DEMONSTRATE THE FOLLOWING, AS  
 426 APPLICABLE TO THE PROPOSED PROJECT per PET scanner during the most recent 12-month period  
 427 for which the Department has verifiable data.

428  
 429 ~~(21) FOR THE FIRST~~ An applicant APPLICATION proposing to ~~replace~~ ACQUIRE an existing  
 430 FIXED, mobile, OR HOST SITE PET scanner ~~(s) SERVICE, OTHER THAN A RENEWAL OF LEASE,~~  
 431 ~~shall demonstrate that all of the applicant's approved and operating mobile PET scanners on~~ OR AFTER  
 432 <INSERT EFFECTIVE DATE OF STANDARDS>, ~~THE EXISTING~~ a mobile route have performed an  
 433 average of at least 3,000 PET equivalents per PET scanner ~~SERVICE AND ITS SCANNER(S) SHALL~~  
 434 NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE APPLICABLE VOLUME REQUIREMENTS  
 435 SET FORTH IN THIS SECTION during the most recent 12-month period for which the Department has  
 436 verifiable data.

437  
 438 ~~(32) An exemption~~ APPLICANT to subsections (1) and (2) may be made by the Department, if an  
 439 applicant demonstrates to the satisfaction of the Department, the following: PROPOSING TO ACQUIRE  
 440 AN EXISTING FIXED OR MOBILE PET SCANNER SERVICE SHALL DEMONSTRATE THAT THE  
 441 EXISTING FIXED OR MOBILE SCANNER(S) PERFORMED AN AVERAGE OF 500 PET  
 442 EQUIVALENTS PER SCANNER IN THE MOST RECENT 12-MONTH PERIOD VERIFIABLE BY THE  
 443 DEPARTMENT.

444  
 445 ~~(a3) The existing PET scanner is technologically incapable of performing the applicable minimum~~  
 446 ~~number of PET equivalents. An applicant proposing a~~ TO ~~replacement~~ ACQUIRE AN EXISTING HOST  
 447 SITE under this subsection shall ~~provide documentation~~ DEMONSTRATE, satisfactory to ~~THAT~~ the  
 448 Department, from a person or an organization with recognized professional expertise regarding that type  
 449 of equipment, other than the applicant or a representative of a manufacturer or vendor of that type of  
 450 equipment, indicating the number of PET equivalents the ~~existing~~ HOST SITE HAS equipment is  
 451 ~~technologically capable of performing~~ PERFORMED: 50 PET EQUIVALENTS. The applicant also shall  
 452 provide documentation, satisfactory to the Department, that the number of PET equivalents performed  
 453 during IN the most recent 12-month period, for which VERIFIABLE BY the Department has verifiable  
 454 data, was the number the equipment is technologically capable of performing.

455  
 456 (4) An applicant proposing to RENEW A LEASE FOR AN EXISTING FIXED OR MOBILE ~~replace a~~  
 457 ~~PET scanner(s), whether fixed or mobile,~~ shall demonstrate THAT THE RENEWAL OF THE LEASE IS  
 458 MORE COST EFFECTIVE THAN REPLACING THE SCANNER(S).

459 ~~— (a) the equipment to be replaced is fully depreciated according to generally accepted accounting~~  
 460 ~~principles or~~

461 ~~— (b) either of the following:~~

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

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

467  
 468 ~~— (5) An applicant that meets all of the following requirements shall not be required to be in~~  
 469 ~~compliance with subsections (1), (2), (3) and (4):~~

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

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

473  
 474 ~~— (6) In the case of a fixed PET scanner, the proposed PET scanner will be located at the same site~~  
 475 ~~as the applicant's existing fixed PET scanner to be replaced. If the proposed scanner will not be located~~  
 476 ~~at the same site, the applicant must meet the requirements to relocate a PET scanner at the proposed~~  
 477 ~~site, in accordance with Section 9.~~

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**Section 7. Requirements for approval for applicants proposing to acquire an existing DEDICATED RESEARCH FIXED PET scanner**

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

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

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

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

(e4) The project PROPOSED SITE CAN HAVE NO MORE THAN THREE DEDICATED RESEARCH FIXED will not result in the replacement of the PET scanners scanners APPROVED UNDER THIS to be acquired unless the applicant demonstrates that the requirements of Section 6 also have been met.

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

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

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

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

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

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

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

(dB) AT LEAST 5,000 PEDIATRIC (< 18 YEARS OLD) SURGERIES, All PET scanners to be acquired are listed on the Department Inventory of PET Scanners on the date the application is submitted to the Department. AND

531 ~~(eC) AT LEAST 50 NEW PEDIATRIC CANCER CASES ON ITS CANCER REGISTRY~~The applicant  
 532 ~~agrees to operate the PET scanner service in accordance with all applicable project delivery~~  
 533 ~~requirements set forth in Section 14.~~

534  
 535 (3) THE APPLICANT SHALL HAVE AN ACTIVE MEDICAL STAFF AT THE TIME THE  
 536 APPLICATION IS SUBMITTED TO THE DEPARTMENT THAT INCLUDES PHYSICIANS WHO ARE  
 537 FELLOWSHIP-TRAINED IN THE FOLLOWING PEDIATRIC SPECIALTIES:

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

539 (B) ANESTHESIOLOGY

540 (C) CARDIOLOGY

541 (D) CRITICAL CARE

542 (E) GASTROENTEROLOGY

543 (F) HEMATOLOGY/ONCOLOGY

544 (G) NEUROLOGY

545 (H) NEUROSURGERY

546 (I) ORTHOPEDIC SURGERY

547 (J) PATHOLOGY

548 (K) PULMONOLOGY

549 (L) SURGERY

550 (M) NEONATOLOGY

551  
 552 (4) THE APPLICANT SHALL HAVE IN OPERATION THE FOLLOWING PEDIATRIC SPECIALTY  
 553 PROGRAMS AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

554  
 555 (A) BONE MARROW TRANSPLANT PROGRAM

556 (B) SEDATION PROGRAM

557 (C) OPEN HEART PROGRAM

558  
 559 (5) THE APPLICANT MEETS THE REQUIREMENTS OF SECTION 3(1) THROUGH 3(4) IF THE  
 560 APPLICANT IS INITIATING A PET SCANNER SERVICE WITH A DEDICATED PEDIATRIC FIXED PET  
 561 SCANNER.

562  
 563 (6) THE PROPOSED SITE CAN HAVE NO MORE THAN TWO DEDICATED PEDIATRIC FIXED  
 564 PET SCANNERS APPROVED UNDER THIS SECTION.

565  
 566 **Section 9. Requirements for ~~approval for applicants proposing to relocate an existing PET A~~**  
 567 **~~POSITRON EMISSION MAMMOGRAPHY (PEM) scanner service or its unit(s)~~**

568  
 569 Sec. 9. AN APPLICANT PROPOSING TO ADD A PEM SCANNER SERVICE TO AN EXISTING  
 570 PET SCANNER SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE  
 571 PROPOSED PROJECT:

572  
 573 (1) AN APPLICANT PROPOSING TO ADD A FIXED PEM SCANNER TO AN EXISTING FIXED  
 574 PET SCANNER SITE SHALL DEMONSTRATE THE FOLLOWING:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~\_\_\_\_\_ (e) The proposed project will not result in the replacement of the PET scanner(s) of the service to be relocated unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.~~

637 ~~\_\_\_\_\_ (f) The applicant agrees to operate the PET service and all its units in accordance with all~~  
 638 ~~applicable project delivery requirements set forth in Section 15 of these standards.~~

639  
 640 ~~\_\_\_\_\_ (2) An applicant proposing to relocate a PET scanner of an existing PET service shall demonstrate~~  
 641 ~~that it meets all of the following:~~

642 ~~\_\_\_\_\_ (a) The PET scanner to be relocated is a fixed PET scanner.~~

643 ~~\_\_\_\_\_ (b) The existing fixed PET service from which the PET scanner is to be relocated has been in~~  
 644 ~~operation for at least 36 months as of the date of the application submitted to the Department.~~

645 ~~\_\_\_\_\_ (c) The proposed new site for the PET scanner to be relocated is in the relocation zone.~~

646 ~~\_\_\_\_\_ (d) The proposed project will not result in the replacement of the PET scanner(s) to be relocated~~  
 647 ~~unless the applicant demonstrates that the requirements of Section 6, as applicable, have also been met.~~

648 ~~\_\_\_\_\_ (e) The applicant agrees to operate the PET scanner at the proposed site in accordance with all~~  
 649 ~~applicable project delivery requirements set forth in Section 15.~~

650  
 651 **Section 10. Requirements for approval for applicants proposing a dedicated research fixed PET**  
 652 **scanner**MEDICAID PARTICIPATION

653  
 654 ~~Sec. 10. (1) An applicant proposing to operate a fixed PET scanner (whether new or replacement) to be~~  
 655 ~~used exclusively for research shall demonstrate each of the following~~PROVIDE VERIFICATION OF  
 656 MEDICAID PARTICIPATION. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTLY  
 657 ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE  
 658 PROVIDED TO THE DEPARTMENT WITHIN (6) MONTHS FROM THE OFFERING OF SERVICES IF A  
 659 CON IS APPROVED.;

660  
 661 **Section 11. PROJECT DELIVERY Requirements for approval for applicants proposing to establish**  
 662 **a dedicated pediatric PET scanner**AND TERMS OF APPROVAL FOR ALL APPLICANTS

663  
 664 ~~Sec. 11. (1) An applicant proposing to establish a dedicated pediatric PET scanner(s) shall~~ AGREE  
 665 THAT, IF APPROVED, demonstrate all of the followingPET SCANNER SERVICES SHALL BE  
 666 DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF APPROVAL.;

667  
 668 ~~\_\_\_\_\_ (a1) The applicant shall experience at least 7,000 pediatric (< 18 years old) discharges, excluding~~  
 669 ~~normal newborns, in the most recent year of operation~~COMPLIANCE WITH THESE STANDARDS.

670  
 671 ~~\_\_\_\_\_ (b2) The applicant shall experience at least 5,000 pediatric (< 18 years old) surgeries in the most~~  
 672 ~~recent year of operation~~COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE  
 673 REQUIREMENTS.;

674 ~~(c) The applicant shall experience at least 50 new pediatric cancer cases on its cancer registry in~~  
 675 ~~the most recent year of operation~~A PET SCANNER SERVICE SHALL BE STAFFED SO THAT  
 676 SCREENING OF REQUESTS FOR AND INTERPRETATION OF PET PROCEDURES WILL BE  
 677 CARRIED OUT BY A PHYSICIAN(S) WITH APPROPRIATE TRAINING AND FAMILIARITY WITH THE  
 678 APPROPRIATE DIAGNOSTIC USE AND INTERPRETATION OF CROSS-SECTIONAL IMAGES OF  
 679 THE ANATOMICAL REGION(S) TO BE EXAMINED. FOR PURPOSES OF EVALUATING THIS  
 680 SUBSECTION, THE DEPARTMENT SHALL CONSIDER IT PRIMA FACIE EVIDENCE AS TO THE  
 681 TRAINING OF THE PHYSICIAN(S) IF THE PHYSICIAN IS BOARD CERTIFIED OR BOARD QUALIFIED  
 682 IN NUCLEAR MEDICINE OR NUCLEAR RADIOLOGY. HOWEVER, AN APPLICANT MAY SUBMIT,  
 683 AND THE DEPARTMENT MAY ACCEPT, OTHER EVIDENCE THAT THE PHYSICIAN(S) IS QUALIFIED  
 684 TO OPERATE THE PET SERVICE/SCANNER. THE PHYSICIAN(S) MUST BE ON-SITE OR  
 685 AVAILABLE THROUGH TELECOMMUNICATION CAPABILITIES TO PARTICIPATE IN THE  
 686 SCREENING OF PATIENTS FOR PET PROCEDURES AND TO PROVIDE OTHER CONSULTATION  
 687 SERVICES.

688 ~~(d) The applicant shall have an active medical staff at the time the application is submitted to the~~  
 689 ~~Department that~~PET SCANNER SERVICE SHALL includes, but is not limited to, physicians who are

690 ~~fellows~~ PERSONNEL, EMPLOYED DIRECTLY OR ON A  
 691 CONTRACTUAL BASIS: A TECHNOLOGIST WITH TRAINING IN PET SCANNING AND A PHYSICIST.  
 692 THE PHYSICIST MUST BE BOARD CERTIFIED OR ELIGIBLE FOR CERTIFICATION BY THE  
 693 AMERICAN BOARD OF RADIOLOGY OR AN EQUIVALENT ORGANIZATION.

694 ~~(i) pediatric radiology (at least two staff members)~~

695 ~~— (ii) pediatric anesthesiology~~

696 ~~— (iii) pediatric cardiology~~

697 ~~— (iv) pediatric critical care~~

698 ~~— (v) pediatric gastroenterology~~

699 ~~— (vi) pediatric hematology/oncology~~

700 ~~— (vii) pediatric neurology~~

701 ~~— (viii) pediatric neurosurgery~~

702 ~~— (ix) pediatric orthopedic surgery~~

703 ~~— (x) pediatric pathology~~

704 ~~— (xi) pediatric pulmonology~~

705 ~~— (xii) pediatric surgery~~

706 ~~— (xiii) neonatology~~

707 ~~(eC) The applicant shall have in operation the following pediatric specialty programs at the time the~~  
 708 ~~application is submitted to~~ PET SCANNER SERVICE SHALL HAVE A PHYSICIAN ON-SITE OR  
 709 IMMEDIATELY AVAILABLE TO THE PET SCANNER SERVICE AT ALL TIMES WHEN PATIENTS ARE  
 710 UNDERGOING PET PROCEDURES ~~the Department.~~

711 ~~(i) pediatric bone marrow transplant program~~

712 ~~— (ii) established pediatric sedation program~~

713 ~~— (iii) pediatric open heart program~~

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

716

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

720 ~~(3A) The dedicated pediatric PET scanner SERVICE shall be excluded~~ ACCEPT REFERRALS FOR  
 721 PET SCANNER SERVICES from the adult count for ALL APPROPRIATELY LICENSED  
 722 PRACTITIONERS ~~the facility.~~

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

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

728 (D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE PET SCANNER SERVICE  
 729 SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL  
 730 333.16221; MSA 14.15 (16221).

731

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

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

741 (B) THE PET SCANNER SERVICE SHALL PARTICIPATE IN A DATA COLLECTION SYSTEM  
 742 ESTABLISHED AND ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE. THE DATA MAY

743 INCLUDE, BUT ARE NOT LIMITED TO, CLINICAL SCAN DATA, ANNUAL BUDGET AND COST  
 744 INFORMATION, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, DEMOGRAPHIC AND  
 745 DIAGNOSTIC INFORMATION, AND THE VOLUME OF CARE PROVIDED TO PATIENTS FROM ALL  
 746 PAYOR SOURCES. THE APPLICANT SHALL PROVIDE THE REQUIRED DATA ON A SEPARATE  
 747 BASIS FOR EACH SEPARATE AND DISTINCT SITE, PET SCANNER, OR PET SCANNER SERVICE  
 748 AS REQUIRED BY THE DEPARTMENT, IN A FORMAT ESTABLISHED BY THE DEPARTMENT. THE  
 749 DEPARTMENT MAY ELECT TO VERIFY THE DATA THROUGH ON-SITE REVIEW OF APPROPRIATE  
 750 RECORDS.

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

754  
 755 (5) COMPLIANCE WITH THE FOLLOWING DEDICATED RESEARCH PET SCANNER  
 756 REQUIREMENTS, IF APPLICABLE:

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

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

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

764  
 765 (6) COMPLIANCE WITH THE FOLLOWING DEDICATED PEDIATRIC PET SCANNER  
 766 REQUIREMENTS, IF APPLICABLE:

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

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

771  
 772 (7) COMPLIANCE WITH THE FOLLOWING PEM SCANNER REQUIREMENTS, IF APPLICABLE:

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

775  
 776 (8) COMPLIANCE WITH THE FOLLOWING MOBILE PET SCANNER REQUIREMENTS, IF  
 777 APPLICABLE:

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

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

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

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

791  
 792 (9) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE  
 793 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

794  
 795 **Section 12. ~~Additional requirements~~METHODOLOGY for ~~mobile~~COMPUTING THE PROJECTED**

796 | **PET service**DATA UNITS

797

798 | Sec. 12. ~~(1) An applicant proposing to begin operation of a mobile PET service shall demonstrate all~~  
 799 | ~~of the following~~BEING REVIEWED UNDER SECTION 3 SHALL APPLY THE METHODOLOGY SET  
 800 | FORTH IN THIS SECTION IN COMPUTING THE PROJECTED NUMBER OF PET DATA UNITS:

801

802 | (a1) A separate CON application has been submitted by the central service coordinator and each  
 803 | proposed host siteIDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW CANCER CASES  
 804 | DOCUMENTED IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 13.

805 | ~~(bA) A proposed regular route schedule, the procedures for handling emergency situations, and~~  
 806 | ~~copies of all proposed contracts related to the mobile PET service have been included in the CON~~  
 807 | ~~application~~COMBINE THE NUMBER OF CANCER CASES FOR LUNG (SITE CODES C340-C349),  
 808 | ESOPHAGUS (SITE CODES C150-C159), COLORECTAL (SITE CODES C180-C209), LYMPHOMA  
 809 | (MORPHOLOGY CODES (9590-9729), MELANOMA (MORPHOLOGY CODES 8720-8790), AND HEAD  
 810 | & NECK [SITE CODES C000-C148, C300-C329, C410, C411, C470 OR C490 EXCLUDING C440-C444  
 811 | (SKIN OF HEAD AND NECK), AND ADDITIONAL CODES APPROVED BY NATIONAL COVERAGE  
 812 | DETERMINATION]. USE THE NAME "COMBINED" FOR THIS GROUPING.

813 | ~~(eB) The requirements of sections 3, 4, 5, and 6, as applicable, have been met.~~ MULTIPLY THE  
 814 | NUMBER RESULTING FROM THE CALCULATION IN "COMBINED" CANCER CASES IDENTIFIED IN  
 815 | SUBSECTION (1)(B) BY 0.8, WHICH IS THE ESTIMATED PROBABILITY THAT A "COMBINED"  
 816 | CANCER CASE WILL REQUIRE A PET SCAN.

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

820

821 | ~~(2) An applicant proposing to become a host site on an existing mobile PET scanner service shall~~  
 822 | ~~demonstrate that it meets all of the following:~~ IDENTIFY THE NUMBER OF DIAGNOSIS-SPECIFIC NEW  
 823 | CANCER CASES DOCUMENTED IN ACCORD WITH THE REQUIREMENTS OF SECTION 13.

824 | ~~(a) Approval of the application will not result in an increase in the number of mobile PET scanners~~  
 825 | ~~listed on the "Department Inventory of PET Scanners" unless the requirements of Section 5 have been~~  
 826 | ~~met.~~ MULTIPLY THE NUMBER OF BREAST CANCER CASES (SITE CODES C500-C509) BY 0.25,  
 827 | WHICH IS THE ESTIMATED PROBABILITY THAT A BREAST CANCER CASE WILL REQUIRE A PET  
 828 | SCAN.

829 | ~~(b) A proposed regular route schedule, the procedures for handling emergency situations, and~~  
 830 | ~~copies of all proposed contracts related to the mobile PET scanner have been included in the CON~~  
 831 | ~~application.~~ MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (2)(B)  
 832 | BY 1.0, WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT  
 833 | REQUIRING A PET SCAN.

834

835 | (3) MULTIPLY THE NUMBER OF DIAGNOSTIC CARDIAC CATHETERIZATION CASES  
 836 | IDENTIFIED IN ACCORD WITH THE REQUIREMENTS OF SECTION 15 BY 0.1, WHICH IS THE  
 837 | ESTIMATED PROBABILITY THAT A PATIENT HAVING A DIAGNOSTIC CARDIAC  
 838 | CATHETERIZATION WILL REQUIRE A PET SCAN.

839

840 | (4) MULTIPLY THE NUMBER OF INTRACTABLE EPILEPSY CASES (ICD-9-CM CODES 345.01,  
 841 | 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, OR 345.91) IDENTIFIED IN ACCORD WITH THE  
 842 | REQUIREMENTS OF SECTION 16 BY 1.0, WHICH IS THE ESTIMATED PROBABILITY THAT A  
 843 | PATIENT HAVING AN INTRACTABLE EPILEPSY PROCEDURE WILL REQUIRE A PET SCAN.  
 844 | MULTIPLY THE NUMBER RESULTING FROM THE CALCULATION IN SUBSECTION (3) BY 1.0,  
 845 | WHICH IS THE ESTIMATED NUMBER OF PET SCANS NEEDED FOR EACH PATIENT REQUIRING A  
 846 | PET SCAN.

847

848 | (5) SUM THE NUMBERS RESULTING FROM THE CALCULATIONS IN SUBSECTIONS (1)

849 THROUGH (4) TO DETERMINE THE TOTAL NUMBER OF PROJECTED PET DATA UNITS.

850  
851 (6) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 3.0  
852 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 6 TO DETERMINE THE  
853 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

854  
855 (7) MULTIPLY THE RESULT CALCULATED IN SUBSECTION (5) ABOVE BY A FACTOR OF 2.0  
856 IF THE APPLICANT IS PROPOSING TO SERVE ONLY PLANNING AREA 5 TO DETERMINE THE  
857 TOTAL NUMBER OF PROJECTED PET DATA UNITS.

858  
859 **Section 13. ~~Requirements for approval for all applicants~~ COMMITMENT OF DIAGNOSIS-SPECIFIC**  
860 **NEW CANCER CASES**

861  
862 ~~Sec. 13. An applicant shall provide verification of Medicaid participation at the time the application is~~  
863 ~~submitted to the Department. If the required documentation is not submitted with the application on the~~  
864 ~~designated application date, the application will be deemed filed on the first applicable designated~~  
865 ~~application date after all required documentation is received by the Department.~~ AN APPLICANT  
866 PROPOSING TO USE DIAGNOSIS-SPECIFIC NEW CANCER CASES SHALL DEMONSTRATE ALL OF  
867 THE FOLLOWING:

868  
869 (1) ONLY THOSE CANCER DIAGNOSES IDENTIFIED IN SECTION 12(1) AND 12(2) SHALL BE  
870 INCLUDED.

871  
872 (2) EACH ENTITY CONTRIBUTING DIAGNOSIS SPECIFIC NEW CANCER CASE DATA  
873 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE  
874 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF  
875 DIAGNOSIS-SPECIFIC CANCER CASES BEING COMMITTED TO THE APPLICATION AND THAT  
876 STATES NO CURRENT OR FUTURE DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA WILL BE  
877 USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET UNIT FOR A PERIOD OF FIVE (5)  
878 YEARS FROM THE DATE OF START OF OPERATIONS OF THE APPROVED PET SCANNER  
879 SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED DOCUMENTATION FOR  
880 THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE DESIGNATED  
881 APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST APPLICABLE  
882 DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS RECEIVED BY  
883 THE DEPARTMENT.

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

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

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

896  
897 (3) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER  
898 SERVICE SHALL CONTRIBUTE DIAGNOSIS-SPECIFIC NEW CANCER CASES.

899  
900 (4) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSIS-SPECIFIC  
901 NEW CANCER CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING

902 THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR  
 903 AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN ISSUED UNLESS  
 904 THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE  
 905 SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT  
 906 CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY  
 907 COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA,  
 908 THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL  
 909 OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE  
 910 SIGNATURE.

911  
 912 **Section -14. ~~Project delivery requirements and terms of approval for all applicants~~**  
 913 **DOCUMENTATION OF DIAGNOSIS-SPECIFIC NEW CANCER CASE DATA**  
 914

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

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

- 930 ~~— (a) Compliance with these standards.~~  
 931 ~~— (b) Compliance with applicable safety and operating standards.~~  
 932 ~~— (c) Compliance with the following quality assurance standards:~~  
 933 ~~— (i) The approved PET scanner shall be operating at the applicable required volumes specified in~~  
 934 ~~these standards. In meeting this requirement, an applicant shall not include any patient visits conducted~~  
 935 ~~by dedicated research PET scanners.~~  
 936 ~~— (ii) An applicant shall establish and maintain (A) a standing medical staff and governing body (or~~  
 937 ~~its equivalent) requirement that provides for the medical and administrative control of the ordering and~~  
 938 ~~utilization of PET patient visits and (B) a formal program of utilization review and quality assurance.~~  
 939 ~~These responsibilities may be assigned to an existing body of the applicant, as appropriate.~~  
 940 ~~— (iii) A PET service, whether fixed or mobile, shall be staffed so that screening of requests for PET~~  
 941 ~~procedures and/or interpretation of PET procedures will be carried out by a physician(s) with appropriate~~  
 942 ~~training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of~~  
 943 ~~the anatomical region(s) to be examined. For purposes of evaluating this subsection, the Department~~  
 944 ~~shall consider it prima facie evidence as to the training of the physician(s) if the physician is board~~  
 945 ~~certified or board qualified in nuclear medicine or nuclear radiology. However, an applicant may submit,~~  
 946 ~~and the Department may accept, other evidence that the physician(s) is qualified to operate the PET~~  
 947 ~~service/scanner. The physician(s) must be on-site or available through telecommunication capabilities to~~  
 948 ~~participate in the screening of patients for PET procedures and to provide other consultation services.~~  
 949 ~~— (iv) An applicant shall establish a PET service team. A PET service team shall be responsible for~~  
 950 ~~(A) developing criteria for procedure performance, (B) developing protocols for procedure performance,~~  
 951 ~~(C) developing a clinical data base for utilization review and quality assurance purposes, (D) transmitting~~  
 952 ~~requested data to the Department, (E) screening of patients to assure appropriate utilization of the PET~~  
 953 ~~scanner, (F) taking and interpreting scans, and (G) coordinating PET activity at a PET host site(s) for a~~  
 954 ~~mobile pet service(s)/scanner(s).~~

955 ~~— (v) At a minimum, the PET service team shall include the following personnel, employed directly by~~  
 956 ~~the applicant or on a contractual basis: (A) a team leader, (B) technologists with training in PET~~  
 957 ~~scanning, (C) radiation safety personnel, and (D) a physicist(s). The physicist(s) must be board certified~~  
 958 ~~or eligible for certification by the American Board of Radiology or an equivalent organization. Other~~  
 959 ~~personnel that may be appropriate members of the PET service team, depending on the type of operation~~  
 960 ~~and PET procedures performed, include but are not limited to nurses, computer technicians, radio-~~  
 961 ~~chemists, radio-chemistry technicians, radio-pharmacists, and instrument maintenance technicians. If the~~  
 962 ~~team leader is not a physician, the PET service team also shall include a physician with appropriate~~  
 963 ~~training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of~~  
 964 ~~the anatomical region(s) to be examined.~~

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

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

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

974 ~~— (d) Compliance with the following requirements:~~

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

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

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

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

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

1000 ~~— (v) The applicant shall provide the Department with a notice stating the first date on which the PET~~  
 1001 ~~scanner became operational, and such notice shall be submitted to the Department consistent with~~  
 1002 ~~applicable statute and promulgated rules.~~

1004 ~~— (2) An applicant for a dedicated research PET scanner under Section 10 shall agree that the~~  
 1005 ~~services provided by the PET scanner approved pursuant to Section 10 shall be delivered in compliance~~  
 1006 ~~with the following terms of CON approval:~~

1007 ~~— (a) The capital and operating costs relating to the dedicated research PET scanner approved~~

1008 ~~pursuant to Section 8 shall be charged only to a specific research account(s) and not to any patient or~~  
 1009 ~~third-party payer.~~

1010 ~~— (b) The dedicated research PET scanner approved pursuant to Section 10 shall not be used for~~  
 1011 ~~any purposes other than as approved by the Institutional Review Board unless the applicant has obtained~~  
 1012 ~~CON approval for the PET scanner pursuant to Part 222 and these standards, other than Section 10.~~

1013  
 1014 ~~— (3) The operation of and referral of patients to the PET service shall be in conformance with 1978~~  
 1015 ~~PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

1016  
 1017 ~~— (4) The agreements and assurances required by this section shall be in the form of a certification~~  
 1018 ~~authorized by the governing body of the applicant or its authorized agent.~~

1019  
 1020 **Section 15. ~~Project delivery requirements and additional terms of approval for applicants~~**  
 1021 **~~involving mobile PET services~~COMMITMENT AND DOCUMENTATION OF DIAGNOSTIC CARDIAC**  
 1022 **CATHETERIZATION DATA**

1023  
 1024 Sec. 15. AN APPLICANT PROPOSING TO USE DIAGNOSTIC CARDIAC CATHETERIZATION  
 1025 DATA SHALL DEMONSTRATE ALL OF THE FOLLOWING:

1026  
 1027 (1) EACH ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA  
 1028 PROVIDES, AS PART OF THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE  
 1029 DEPARTMENT, A SIGNED GOVERNING BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF  
 1030 DIAGNOSTIC CARDIAC CATHETERIZATION CASES (SESSIONS) COMMITTED TO THE  
 1031 APPLICATION AND THAT STATES NO CURRENT OR FUTURE DIAGNOSTIC CARDIAC  
 1032 CATHETERIZATION DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET  
 1033 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH DATA ARE BEING COMMITTED  
 1034 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE  
 1035 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED  
 1036 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE  
 1037 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST  
 1038 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS  
 1039 RECEIVED BY THE DEPARTMENT.

1040 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY  
 1041 CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA IS IN THE SAME PLANNING  
 1042 AREA AS THE PROPOSED PET UNIT/SERVICE.

1043 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH  
 1044 ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IN THE  
 1045 PLANNING AREA(S) FOR WHICH THE PROPOSED PET SERVICE CONTAINS A PROPOSED HOST  
 1046 SITE OR WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND  
 1047 MICROPOLITAN STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN  
 1048 STATISTICAL AREA COUNTIES.

1049 (C) NO ENTITY CONTRIBUTING DIAGNOSTIC CARDIAC CATHETERIZATION DATA HAS  
 1050 PREVIOUSLY COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS  
 1051 THAN FIVE (5) YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1052 (D) THE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA IS FROM THE MOST  
 1053 RECENTLY COMPLETED REPORT(S) OF THE ANNUAL SURVEY PRODUCED BY THE  
 1054 DEPARTMENT, AND THE CONTRIBUTING ENTITY HAS CON APPROVAL TO PROVIDE  
 1055 DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES.

1056  
 1057 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A PET SCANNER  
 1058 SERVICE SHALL CONTRIBUTE DIAGNOSTIC CARDIAC CATHETERIZATION CASE DATA.

1059  
 1060 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF DIAGNOSTIC CARDIAC

CATHETERIZATION CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A PROPOSED DECISION TO APPROVE THE APPLICATION HAS BEEN DENIED UNLESS THE APPLICATION IS DENIED, WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA, THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.

~~(1) In addition to the provisions of Section 14, an applicant for a mobile PET services shall agree that the services provided by the mobile PET scanner(s) shall be delivered in compliance with the following terms of CON approval:~~

~~— (a) The central service coordinator for a mobile PET service, with an approved CON, shall notify the administrative unit of the Department of Community Health responsible for administering the CON program 30 days prior to dropping an existing host site.~~

~~— (b) Each host site must have at least one physician who is board certified or board eligible in nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for (i) establishing patient examination and infusion protocol and (ii) providing for the interpretation of scans performed by the mobile PET service/scanner.~~

~~— (c) Each mobile PET scanner service shall have an operations committee with members representing each host site, the central service coordinator, and the medical director. This committee shall oversee the effective and efficient use of the PET scanner, establish the regular route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile PET scanner service on at least a quarterly basis.~~

~~— (d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile PET scanner equipment as well as the vehicle transporting the equipment. In addition, to preserve image quality and minimize PET scanner downtime, calibration checks shall be performed on the PET scanner unit at least once each work day or in accordance with the manufacturer's requirements. Routine maintenance services shall be provided on a regularly scheduled basis, at least once a week or in accordance with the manufacturer's requirements, during hours not normally used for patient procedures.~~

~~— (e) Each host site shall provide a properly prepared parking pad, for the mobile PET scanner unit, of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor). Each host site also must provide the capability for processing the film and maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.~~

~~— (f) A mobile PET scanner service shall operate under a contractual agreement that includes the provision of PET services at each host site on a regularly scheduled basis.~~

~~— (g) The volume of utilization at each host site shall be reported to the Department by the central service coordinator under the terms of Section 14(1)(d)(iii).~~

~~(2) The agreements and assurances required by this section shall be in the form of a certification authorized by the owner or the governing body of the applicant or its authorized agent.~~

**Section 16. Determination of PET equivalents COMMITMENT AND DOCUMENTATION OF INTRACTABLE EPILEPSY DATA**

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

1114  
 1115 (1) EACH ENTITY CONTRIBUTING INTRACTABLE EPILEPSY DATA PROVIDES, AS PART OF  
 1116 THE APPLICATION AT THE TIME IT IS SUBMITTED TO THE DEPARTMENT, A SIGNED GOVERNING  
 1117 BODY RESOLUTION THAT IDENTIFIES THE NUMBER OF INTRACTABLE EPILEPSY CASES  
 1118 COMMITTED TO THE APPLICATION AND THAT STATES NO CURRENT OR FUTURE INTRACTABLE  
 1119 EPILEPSY CASE DATA WILL BE USED IN SUPPORT OF ANY OTHER APPLICATION FOR A PET  
 1120 UNIT FOR THE DURATION OF THE PET SERVICE FOR WHICH THE DATA ARE BEING COMMITTED  
 1121 FOR A PERIOD OF FIVE (5) YEARS FROM THE DATE OF START OF OPERATIONS OF THE  
 1122 APPROVED PET SERVICE FOR WHICH DATA ARE BEING COMMITTED. IF THE REQUIRED  
 1123 DOCUMENTATION FOR THIS SUBSECTION IS NOT SUBMITTED WITH THE APPLICATION ON THE  
 1124 DESIGNATED APPLICATION DATE, THE APPLICATION WILL BE DEEMED FILED ON THE FIRST  
 1125 APPLICABLE DESIGNATED APPLICATION DATE AFTER ALL REQUIRED DOCUMENTATION IS  
 1126 RECEIVED BY THE DEPARTMENT.

1127 (A) FOR FIXED PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH ENTITY  
 1128 CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IS IN THE SAME PLANNING AREA AS THE  
 1129 PROPOSED PET UNIT/SERVICE.

1130 (B) FOR MOBILE PET SCANNER SERVICES, THE GEOGRAPHIC LOCATION OF EACH  
 1131 ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA IN THE PLANNING AREA(S) FOR  
 1132 WHICH THE PROPOSED PET SCANNER SERVICE CONTAINS A PROPOSED HOST SITE OR  
 1133 WITHIN A 75-MILE RADIUS OF THE PROPOSED HOST SITE FOR RURAL AND MICROPOLITAN  
 1134 STATISTICAL AREA COUNTIES OR 25-MILE RADIUS FOR METROPOLITAN STATISTICAL AREA  
 1135 COUNTIES.

1136 (C) NO ENTITY CONTRIBUTING INTRACTABLE EPILEPSY CASE DATA HAS PREVIOUSLY  
 1137 COMMITTED OR IS COMMITTING DATA TO ANOTHER SERVICE THAT IS LESS THAN FIVE (5)  
 1138 YEARS FROM THE START OF OPERATIONS OF THAT SERVICE.

1139 (D) THE INTRACTABLE EPILEPSY CASE DATA IS FROM THE MOST RECENT MICHIGAN  
 1140 INPATIENT DATA BASE (MIDB) AVAILABLE TO THE DEPARTMENT.

1141  
 1142 (2) NO ENTITY CURRENTLY OPERATING OR APPROVED TO OPERATE A SCANNER SHALL  
 1143 CONTRIBUTE INTRACTABLE EPILEPSY CASE DATA.

1144  
 1145 (3) THE DEPARTMENT MAY NOT CONSIDER A WITHDRAWAL OF INTRACTABLE EPILEPSY  
 1146 CASE DATA DURING THE 120-DAY APPLICATION REVIEW CYCLE FOLLOWING THE DATE ON  
 1147 WHICH THE DEPARTMENT REVIEW OF THE APPLICATION COMMENCES OR AFTER A  
 1148 PROPOSED DECISION TO APPROVE THE APPLICATION UNLESS THE APPLICATION IS DENIED,  
 1149 WITHDRAWN, OR EXPIRED. THE WITHDRAWAL MUST BE SUBMITTED TO THE DEPARTMENT IN  
 1150 THE FORM OF A GOVERNING BODY RESOLUTION THAT CONTAINS THE SPECIFIC CON  
 1151 APPLICATION NUMBER TO WHICH THE DATA WERE ORIGINALLY COMMITTED, THE LEGAL  
 1152 APPLICANT ENTITY, THE COMMITTING ENTITY, THE TYPE OF DATA, THE DATE OF THE  
 1153 MEETING IN WHICH THE GOVERNING BODY AUTHORIZED THE WITHDRAWAL OF THE DATA,  
 1154 THE GOVERNING BODY PRESIDENT'S SIGNATURE, AND THE DATE OF THE SIGNATURE.

1155  
 1156  
 1157 ~~For purposes of these standards, PET equivalents shall be calculated as follows:~~

1158 ~~(a) Each actual patient visit performed during the time period specified in the applicable section(s)~~  
 1159 ~~of these standards shall be assigned a number of PET equivalents based on the sum of the applicable~~  
 1160 ~~values set forth in subsections (i) through (vii).~~

1161 ~~(i) A single patient visit \_\_\_\_\_ 1.0~~

1162 ~~(ii) Number of chemically different tracers~~  
 1163 ~~used during a single patient visit.~~

1164 ~~1 tracers = 0~~

1165 ~~>2 tracers = 0.8~~

1166 ~~(iii) Number of tracer injections performed~~

- 1167 ~~\_\_\_\_\_ during a single patient visit.~~  
 1168 ~~\_\_\_\_\_ 1 tracer injection = 0~~  
 1169 ~~\_\_\_\_\_ 2 tracer injections = 0.3~~  
 1170 ~~\_\_\_\_\_ >3 tracer injections = 0.6~~  
 1171 ~~\_\_\_\_\_ (iv) Dynamic scan(s) performed during a single \_\_\_\_\_ 0.5~~  
 1172 ~~\_\_\_\_\_ patient visit.~~  
 1173 ~~\_\_\_\_\_ (v) Number of bed positions used during a single~~  
 1174 ~~\_\_\_\_\_ patient visit.~~  
 1175 ~~\_\_\_\_\_ 1 bed position = 0~~  
 1176 ~~\_\_\_\_\_ >2 bed positions = 0.2 for each additional position~~  
 1177 ~~\_\_\_\_\_ (vi) Arterial sampling performed during a single \_\_\_\_\_ 0.5~~  
 1178 ~~\_\_\_\_\_ patient visit.~~  
 1179 ~~\_\_\_\_\_ (vii) Transmission scan \_\_\_\_\_ .1 per bed position~~  
 1180 ~~\_\_\_\_\_ **Total PET Equivalents for a Single Patient Visit**~~  
 1181 ~~\_\_\_\_\_ (b) For each pediatric patient visit, the PET equivalent(s) determined pursuant to subdivision (a)~~  
 1182 ~~shall be multiplied as follows:~~  
 1183 ~~\_\_\_\_\_ patient ≤ 5 years of age multiply by 4.0~~  
 1184 ~~\_\_\_\_\_ patient >5≤10 years of age multiply by 3.0~~  
 1185 ~~\_\_\_\_\_ patient >10≤17 years of age multiply by 2.0~~  
 1186 ~~\_\_\_\_\_ (c) For each radiation therapy patient visit, the PET equivalent(s) determined pursuant to~~  
 1187 ~~subdivision (a) shall be multiplied by 1.5.~~  
 1188 ~~\_\_\_\_\_ (d) The PET equivalents for each patient visit determined pursuant to subdivisions (a), (b) and (c)~~  
 1189 ~~shall be summed to determine the total PET equivalents for the time period specified in the applicable~~  
 1190 ~~section(s) of these standards.~~  
 1191 ~~**SECTION 17. METHODOLOGY FOR COMPUTING PET EQUIVALENTS**~~  
 1192 ~~\_\_\_\_\_~~  
 1193 ~~\_\_\_\_\_ Sec. 17. For purposes of these standards, PET equivalents shall be calculated as follows:~~  
 1194 ~~\_\_\_\_\_~~

<b>TABLE1</b>	
<b>PET EQUIVALENTS</b>	
<b>Scan Category</b>	<b>Weight</b>
Simple <sup>1</sup>	<u>0.75</u>
Standard <sup>2</sup>	<u>1.0</u>
Complex <sup>3</sup>	<u>1.5</u>
<sup>1</sup> BRAIN AND SINGLE CARDIAC SCANS.	
<sup>2</sup> MID-SKULL TO MID-THIGH SCANS.	
<sup>3</sup> 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.	

- 1195 ~~\_\_\_\_\_~~  
 1196 ~~\_\_\_\_\_ **Section 4718. Methodology for computing the projected number of PET data units**~~  
 1197 ~~\_\_\_\_\_ **DEPARTMENT INVENTORY OF PET SCANNERS**~~  
 1198 ~~\_\_\_\_\_~~  
 1199 ~~\_\_\_\_\_ Sec. 4718. THE DEPARTMENT SHALL MAINTAIN AND PUBLICLY POST ON ITS WEB SITE A~~  
 1200 ~~\_\_\_\_\_ LIST OF PET SCANNER SERVICES ANNUALLY.~~  
 1201 ~~\_\_\_\_\_ The applicant being reviewed under Section 4 shall apply the methodology set forth in this section in~~  
 1202 ~~\_\_\_\_\_ computing the projected number of PET data units.~~  
 1203 ~~\_\_\_\_\_~~  
 1204 ~~\_\_\_\_\_ (1)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the~~  
 1205 ~~\_\_\_\_\_ requirements of Section 18.~~  
 1206 ~~\_\_\_\_\_ (b) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes~~

1207 C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes 9590-9729), melanoma  
 1208 (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411,  
 1209 C470 OR C490 excluding C440-C444 (skin of head and neck), and additional codes approved by  
 1210 National Coverage Determination]. Use the name "combined" for this grouping.

1211 — (c) Multiply the number resulting from the calculation in "combined" cancer cases identified in  
 1212 subsection (1)(b) by 0.8, which is the estimated probability that a "combined" cancer case will require a  
 1213 PET scan.

1214 — (d) Multiply the number resulting from the calculation in subsection (1)(c) by 2.5, which is the  
 1215 estimated number of PET scans needed for each patient requiring a PET scan.

1216  
 1217 — (2)(a) Identify the number of diagnosis specific new cancer cases documented in accord with the  
 1218 requirements of Section 18.

1219 — (b) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the  
 1220 estimated probability that a breast cancer case will require a PET scan.

1221 — (c) Multiply the number resulting from the calculation in subsection (2)(b) by 1.0, which is the  
 1222 estimated number of PET scans needed for each patient requiring a PET scan.

1223  
 1224 — (3)(a) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the  
 1225 requirements of Section 20 by 0.1, which is the estimated probability that a patient having a diagnostic  
 1226 cardiac catheterization will require a PET scan.

1227 — (b) Multiply the number resulting from the calculation in subsection (3)(a) by 1.0, which is the  
 1228 estimated number of PET scans needed for each patient requiring a PET scan.

1229  
 1230 (4)(a)(b) Multiply the number resulting from the calculation in subsection (4)(a) by 1.0, which is the  
 1231 estimated number of PET scans needed for each patient requiring a PET scan.

1232  
 1233 — (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the  
 1234 total number of projected PET data units.

1235  
 1236 — (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is  
 1237 proposing to serve only Planning Area 6 to determine the total number of projected PET data units.

1238  
 1239 — (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is  
 1240 proposing to serve only Planning Area 5 to determine the total number of projected PET data units.

1241

1242

1243 **Section 1819. Commitment of diagnosis specific new cancer cases COMPARATIVE REVIEWS;**  
 1244 **EFFECT ON PRIOR PLANNING POLICIES**

1245

1246 Sec. 1819. PROPOSED PROJECTS REVIEWED UNDER THESE STANDARDS SHALL NOT BE  
 1247 SUBJECT TO COMPARATIVE REVIEW. THESE CON REVIEW STANDARDS SUPERSEDE AND  
 1248 REPLACE THE CON STANDARDS FOR PET SCANNER SERVICES APPROVED BY THE CON  
 1249 COMMISSION ON DECEMBER 12, 2006 AND EFFECTIVE MARCH 8, 2007.

1250

1251 ~~(1) An applicant proposing to use diagnosis specific new cancer cases shall demonstrate all of the~~  
 1252 ~~following:~~

1253 ~~— (a) Only those cancer diagnoses identified in Section 17(1) and 17(2) shall be included.~~

1254 ~~— (b) Each entity contributing diagnosis specific new cancer case data provides, as part of the~~  
 1255 ~~application at the time it is submitted to the Department, a signed governing body resolution that identifies~~  
 1256 ~~the number of diagnosis specific cancer cases being committed to the application and that states no~~  
 1257 ~~current or future diagnosis specific new cancer case data will be used in support of any other application~~  
 1258 ~~for a PET unit for a period of five (5) years from the date of start of operations of the approved PET~~  
 1259 ~~service for which data are being committed. If the required documentation for this subsection is not~~

1260 submitted with the application on the designated application date, the application will be deemed filed on  
 1261 the first applicable designated application date after all required documentation is received by the  
 1262 Department.

1263 ~~—(c) For fixed PET scanner services, the geographic location of each entity contributing diagnosis  
 1264 specific new cancer case data is in the same planning area as the proposed PET service.~~

1265 ~~—(d) For mobile PET scanner services, the geographic location of each entity contributing diagnosis  
 1266 specific new cancer case data in the planning area(s) for which the proposed PET service contains a  
 1267 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical  
 1268 area counties or 25-mile radius for metropolitan statistical area counties.~~

1269 ~~—(e) No entity contributing diagnosis specific new cancer case data has previously committed or is  
 1270 committing data to another service that is less than five (5) years from the start of operations of that  
 1271 service and is listed on the "Department Inventory of Pet Scanners."~~

1272  
 1273 ~~—(2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed  
 1274 on the "Department Inventory of PET Scanners" shall contribute diagnosis specific new cancer cases.~~

1275  
 1276 ~~—(3)(a) The Department may not consider a withdrawal of diagnosis specific new cancer case data  
 1277 during the 120-day application review cycle following the date on which the Department review of the  
 1278 application commences or after a proposed decision to approve the application has been issued unless  
 1279 the application is denied, withdrawn, or expired.~~

1280 ~~—(b) The withdrawal must be submitted to the Department in the form of a governing body resolution  
 1281 that contains the specific CON application number to which the data were originally committed, the legal  
 1282 applicant entity, the committing entity, the type of data, the date of the meeting in which the governing  
 1283 body authorized the withdrawal of the data, the governing body president's signature, and the date of the  
 1284 signature.~~

#### 1285 **Section 19. Documentation of diagnosis specific new cancer case data**

1286 ~~—Sec. 19. (1) An applicant required to document volumes of diagnosis specific new cancer cases  
 1287 shall submit, as part of its application at the time it is submitted to the Department, documentation from  
 1288 the Division for Vital Records and Health Statistics verifying the number of diagnosis specific new cancer  
 1289 cases provided in support of the application for the most recent calendar year for which verifiable data are  
 1290 available from the State Registrar. If the required documentation for this subsection is not submitted with  
 1291 the application on the designated application date, the application will be deemed filed on the first  
 1292 applicable designated application date after all required documentation is received by the Department.~~

1293  
 1294 ~~—(2) Diagnosis specific new cancer case data supporting an application under these standards shall  
 1295 be submitted to the Division for Vital Records and Health Statistics using a format and media specified in  
 1296 instructions from the Department of Community Health.~~

#### 1297 **Section 20. Commitment and documentation of diagnostic cardiac catheterization data**

1298  
 1299  
 1300 ~~—Sec. 20. (1) An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate  
 1301 all of the following:~~

1302 ~~—(a) Each entity contributing diagnostic cardiac catheterization data [pursuant to Section 17(3)(a)]  
 1303 provides, as part of the application at the time it is submitted to the Department, a signed governing body  
 1304 resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to  
 1305 the application and that states no current or future diagnostic cardiac catheterization data will be used in  
 1306 support of any other application for a PET unit for the duration of the PET service for which data are  
 1307 being committed for a period of five (5) years from the date of start of operations of the approved PET  
 1308 service for which data are being committed. If the required documentation for this subsection is not  
 1309 submitted with the application on the designated application date, the application will be deemed filed on  
 1310 the first applicable designated application date after all required documentation is received by the  
 1311  
 1312~~

1313 Department.

1314 ~~—— (b) For fixed PET scanner services, the geographic location of each entity contributing diagnostic~~  
 1315 ~~cardiac catheterization data is in the same planning area as the proposed PET unit/service.~~

1316 ~~—— (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~  
 1317 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~  
 1318 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~  
 1319 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1320 ~~—— (d) No entity contributing diagnostic cardiac catheterization data has previously committed or is~~  
 1321 ~~committing data to another service that is less than five (5) years from the start of operations of that~~  
 1322 ~~service and is listed on the "Department Inventory of Pet Scanners."~~

1323 ~~—— (e) The diagnostic cardiac catheterization case data is from the most recently completed report(s)~~  
 1324 ~~of the "Annual Hospital Statistical Questionnaire" produced by the Department, and the contributing entity~~  
 1325 ~~has CON Approval to provide diagnostic cardiac catheterization services.~~

1326 ~~—— (2) No entity currently operating or approved to operate a PET scanner, whether fixed or mobile,~~  
 1327 ~~listed on the "Department Inventory of PET Scanners" shall contribute diagnostic cardiac catheterization~~  
 1328 ~~case data.~~

1329 ~~—— (3)(a) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data~~  
 1330 ~~during the 120-day application review cycle following the date on which the Department review of the~~  
 1331 ~~application commences or after a proposed decision to approve the application has been denied unless~~  
 1332 ~~the application is denied, withdrawn, or expired.~~

1333 ~~—— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~  
 1334 ~~that contains the specific CON application number to which the data were originally committed, the legal~~  
 1335 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~  
 1336 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~  
 1337 ~~signature.~~

1340

1341 **Section 21. Commitment and documentation of intractable epilepsy data**

1342 ~~—— Sec. 21. (1) An applicant proposing to use intractable epilepsy cases shall demonstrate all of the~~  
 1343 ~~following:~~

1344 ~~—— (a) Each entity contributing intractable epilepsy data [pursuant to Section 17(4)(a)] provides, as~~  
 1345 ~~part of the application at the time it is submitted to the Department, a signed governing body resolution~~  
 1346 ~~that identifies the number of intractable epilepsy cases committed to the application and that states no~~  
 1347 ~~current or future intractable epilepsy case data will be used in support of any other application for a PET~~  
 1348 ~~unit for the duration of the PET service for which the data are being committed for a period of five (5)~~  
 1349 ~~years from the date of start of operations of the approved PET service for which data are being~~  
 1350 ~~committed. If the required documentation for this subsection is not submitted with the application on the~~  
 1351 ~~designated application date, the application will be deemed filed on the first applicable designated~~  
 1352 ~~application date after all required documentation is received by the Department.~~

1353 ~~—— (b) For fixed PET scanner services, the geographic location of each entity contributing intractable~~  
 1354 ~~epilepsy case data is in the same planning area as the proposed PET unit/service.~~

1355 ~~—— (c) For mobile PET scanner services, the geographic location of each entity contributing diagnosis~~  
 1356 ~~specific new cancer case data in the planning area(s) for which the proposed PET service contains a~~  
 1357 ~~proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical~~  
 1358 ~~area counties or 25-mile radius for metropolitan statistical area counties.~~

1359 ~~—— (d) No entity contributing intractable epilepsy case data has previously committed or is committing~~  
 1360 ~~data to another service that is less than five (5) years from the start of operations of that service and is~~  
 1361 ~~listed on the "Department Inventory of Pet Scanners."~~

1362 ~~—— (e) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base~~  
 1363 ~~(MIDB) available to the Department.~~

1365

1366 ~~—— (2) No entity currently operating or approved to operate a scanner, whether fixed or mobile, listed~~  
1367 ~~on the "Department Inventory of Pet Scanners" shall contribute intractable epilepsy case data.~~

1368  
1369 ~~—— (3)(a) The Department may not consider a withdrawal of intractable epilepsy case data during the~~  
1370 ~~120-day application review cycle following the date on which the Department review of the application~~  
1371 ~~commences or after a proposed decision to approve the application unless the application is denied,~~  
1372 ~~withdrawn, or expired.~~

1373 ~~—— (b) The withdrawal must be submitted to the Department in the form of a governing body resolution~~  
1374 ~~that contains the specific CON application number to which the data were originally committed, the legal~~  
1375 ~~applicant entity, the committing entity, the type of data, the date of the meeting in which the governing~~  
1376 ~~body authorized the withdrawal of the data, the governing body president's signature, and the date of the~~  
1377 ~~signature.~~

1378 | **Section 22. Health Service Areas** **APPENDIX A**

1379

1380 | **Sec. 22.** Counties assigned to each health service area are as follows:

1381

1382 **HEALTH SERVICE AREA****COUNTIES**

1383

1384	1	Livingston	Monroe	St. Clair
1385		Macomb	Oakland	Washtenaw
1386		Wayne		

1387

1388	2	Clinton	Hillsdale	Jackson
1389		Eaton	Ingham	Lenawee

1390

1391	3	Barry	Calhoun	St. Joseph
1392		Berrien	Cass	Van Buren
1393		Branch	Kalamazoo	

1394

1395	4	Allegan	Mason	Newaygo
1396		Ionia	Mecosta	Oceana
1397		Kent	Montcalm	Osceola
1398		Lake	Muskegon	Ottawa

1399

1400	5	Genesee	Lapeer	Shiawassee
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1401

1402	6	Arenac	Huron	Roscommon
1403		Bay	Iosco	Saginaw
1404		Clare	Isabella	Sanilac
1405		Gladwin	Midland	Tuscola
1406		Gratiot	Ogemaw	

1407

1408	7	Alcona	Crawford	Missaukee
1409		Alpena	Emmet	Montmorency
1410		Antrim	Gd Traverse	Oscoda
1411		Benzie	Kalkaska	Otsego
1412		Charlevoix	Leelanau	Presque Isle
1413		Cheboygan	Manistee	Wexford

1414

1415	8	Alger	Gogebic	Mackinac
1416		Baraga	Houghton	Marquette
1417		Chippewa	Iron	Menominee
1418		Delta	Keweenaw	Ontonagon
1419		Dickinson	Luce	Schoolcraft

1420

1421

1422	<b>Section 23. Planning Areas</b>			<b>APPENDIX B</b>
1423	<b>Section 23. COUNTIES BY</b> Health service areas assigned to each planning area are as follows:			
1424				
1425				
1426				
1427	<b>PLANNING AREA 1</b>	<b>COUNTIES</b>		
1428				
1429	HSA 1	Livingston	Monroe	St. Clair
1430		Macomb	Oakland	Washtenaw
1431		Wayne		
1432				
1433	<b>PLANNING AREA 2</b>			
1434				
1435	HSA 2	Clinton	Hillsdale	Jackson
1436		Eaton	Ingham	Lenawee
1437	HSA 3	Barry	Calhoun	St. Joseph
1438		Berrien	Cass	Van Buren
1439		Branch	Kalamazoo	
1440				
1441	<b>PLANNING AREA 3</b>			
1442				
1443	HSA 4	Allegan	Mason	Newaygo
1444		Ionia	Mecosta	Oceana
1445		Kent	Montcalm	Osceola
1446		Lake	Muskegon	Ottawa
1447				
1448	<b>PLANNING AREA 4</b>			
1449				
1450	HSA 5	Genesee	Lapeer	Shiawassee
1451	HSA 6	Arenac	Huron	Roscommon
1452		Bay	Iosco	Saginaw
1453		Clare	Isabella	Sanilac
1454		Gladwin	Midland	Tuscola
1455		Gratiot	Ogemaw	
1456				
1457	<b>PLANNING AREA 5</b>			
1458				
1459	HSA 7	Alcona	Crawford	Missaukee
1460		Alpena	Emmet	Montmorency
1461		Antrim	Gd Traverse	Oscoda
1462		Benzie	Kalkaska	Otsego
1463		Charlevoix	Leelanau	Presque Isle
1464		Cheboygan	Manistee	Wexford
1465				
1466	<b>PLANNING AREA 6</b>			
1467				
1468	HSA 8	Alger	Gogebic	Mackinac
1469		Baraga	Houghton	Marquette
1470		Chippewa	Iron	Menominee
1471		Delta	Keweenaw	Ontonagon
1472		Dickinson	Luce	Schoolcraft

**APPENDIX AC**

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**CON REVIEW STANDARDS**  
**FOR PET SCANNER SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

**CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR SURGICAL SERVICES**

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

**Section 1. Applicability**

Sec. 1. ~~(1)~~ These standards are requirements for THE approval and delivery of services for all projects approved and Certificates of Need issued OF THE INITIATION, REPLACEMENT, EXPANSION, OR ACQUISITION OF A SURGICAL SERVICE PROVIDED IN A SURGICAL FACILITY AND THE DELIVERY OF THESE SERVICES under Part 222 of the Code ~~that involve the initiation, expansion, replacement, relocation, or acquisition of surgical services provided in a surgical facility.~~

~~(2)~~ PURSUANT TO PART 222 OF THE CODE, Surgical Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under Part 215 of the Code and offering inpatient or outpatient surgical services are covered clinical services ~~for purposes of Part 222 of the Code.~~

~~(3)~~ A "freestanding surgical outpatient facility" is a health facility for purposes of Part 222 of the Code.

~~(4)~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, and 11, as applicable,~~ THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws. ~~AND~~

~~(5)~~ ~~The Department shall use Section 10, as applicable, in applying~~ 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)~~ "Acquisition of a surgical service" means a project involving the issuance of a new license for a hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing surgical service.

~~(bA)~~ "Ambulatory surgical center" or "ASC" means any distinct entity certified by Medicare as an ASC under the provisions of Title 42, Part 416, ~~that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.~~

~~(cB)~~ "Burn care" means surgical services provided to burn patients in a licensed hospital site that has been verified as meeting the "Guidelines for Development and Operation of Burn Centers" issued by the American Burn Association in March 1988, or equivalent standards for a burn center.

~~(dC)~~ "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.

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

~~(fE)~~ "Cystoscopy" means direct visual examination of the urinary tract with a cystoscope.

~~(gF)~~ "Cystoscopy case" means a single visit to an operating room during which one or more cystoscopic procedures are performed.

~~(hG)~~ "Dedicated endoscopy or cystoscopy operating room" means a room used exclusively for endoscopy or cystoscopy cases.

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

- 54 | (j) "Emergency Room" means a designated area in a licensed hospital and recognized by the  
 55 | Department as having met the staffing and equipment requirements for the treatment of emergency  
 56 | patients.
- 57 | (k) "Endoscopy" means visual inspection of any portion of the body by means of an endoscope.
- 58 | (l) "Endoscopy case" means a single visit to an operating room during which one or more endoscopic  
 59 | procedures are performed.
- 60 | (m) "Existing surgical service" means a surgical facility that, on the date an application is submitted to  
 61 | the Department, is part of a licensed hospital site, a licensed freestanding surgical outpatient facility, or a  
 62 | certified ASC.
- 63 | ~~(n) "Expand a surgical service" means the addition of one or more operating rooms at an existing  
 64 | surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR to a  
 65 | non-dedicated OR.~~
- 66 | ~~(o) "Freestanding surgical outpatient facility" or "FSOF" means a health facility licensed under Part 208  
 67 | of the Code. It does not include a surgical outpatient facility owned and operated as a part of a licensed  
 68 | hospital site. A freestanding surgical outpatient facility is a health facility for purposes of Part 222 of the  
 69 | Code.~~
- 70 | (p) "Hospital" means a health facility licensed under Part 215 of the Code.
- 71 | (q) "Hours of use" means the actual time in hours, and parts thereof, an operating room is used to  
 72 | provide surgical services. It is the time from when a patient enters an operating room until that same patient  
 73 | leaves that same room. It excludes any pre- or post-operative room set-up or clean-up preparations, or any  
 74 | time a patient spends in pre- or post-operative areas including a recovery room.
- 75 | ~~(r) "Initiate a surgical service" means to begin operation of a surgical facility at a site that has not  
 76 | offered surgical services within the 12-month period immediately preceding the date an application is  
 77 | submitted to the Department. The term does not include the relocation of a surgical service or one or more  
 78 | operating rooms meeting the requirements of Section 7.~~
- 79 | (s) "Licensed hospital site" means either:  
 80 | (i) in the case of a single site hospital, the location of the hospital authorized by license and listed on  
 81 | that licensee's certificate of licensure or  
 82 | (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient site  
 83 | as authorized by licensure.
- 84 | (t) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6  
 85 | and 1396r-8 to 1396v.
- 86 | (u) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as  
 87 | that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by  
 88 | the statistical policy office of the office of information and regulatory affairs of the United States office of  
 89 | management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 90 | (v) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as  
 91 | that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by  
 92 | the statistical policy office of the office of information and regulatory affairs of the United States office of  
 93 | management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
- 94 | (w) "Offer" means to perform surgical services.
- 95 | (x) "Operating room" or "OR" means a room in a surgical facility constructed and equipped to perform  
 96 | surgical cases and located on a sterile corridor. The term also includes a room constructed and equipped to  
 97 | perform surgical cases on a nonsterile corridor if the room is located in an FSOF or ASC that is used  
 98 | exclusively for endoscopy or cystoscopy cases. This term does not include procedure rooms.
- 99 | (y) "Operating suite," for purposes of these standards, means an area in a surgical facility that is  
 100 | dedicated to the provision of surgery. An operating suite includes operating rooms, pre- and post-operative  
 101 | patient areas, clean and soiled utility and linen areas, and other support areas associated with the provision  
 102 | of surgery.
- 103 | (z) "Outpatient surgery" means the provision of surgical services performed in a hospital, FSOF, or  
 104 | ASC, requiring anesthesia or a period of post-operative observation, or both, to patients whose admission to  
 105 | a hospital for an overnight stay is not anticipated as being medically necessary.

106 | (~~aaX~~) "Procedure room" means a room in a surgical facility constructed and equipped to perform surgical  
 107 | procedures and not located on a sterile corridor.

108 | ~~—(bb) "Relocate a surgical service or one or more operating rooms" means changing the geographic  
 109 | location of an existing surgical facility or one or more operating rooms to a different location currently  
 110 | offering surgical services within the relocation zone.~~

111 | ~~—(cc) "Relocation zone," for purposes of these standards, means a site that is within a 10-mile radius of  
 112 | the site at which an existing surgical service is located if an existing surgical service is located in a  
 113 | metropolitan statistical area county, or a 20-mile radius if an existing surgical service is located in a rural or  
 114 | micropolitan statistical area county.~~

115 | (~~ddY~~) "Renovate an existing surgical service or one or more operating rooms" means a project that:

116 | (i) involves the renovation, remodeling, or modernization of an operating suite of a hospital, FSOF, or  
 117 | ASC;

118 | (ii) does not involve new construction;

119 | (iii) does not involve a change in the physical location within the surgical facility at the same site; and

120 | (iv) does not result in an increase in the number of operating rooms at an existing surgical facility.

121 | Renovation of an existing surgical service or one or more operating rooms may involve a change in the  
 122 | number of square feet allocated to an operating suite. The renovation of an existing surgical service or one  
 123 | or more operating rooms shall not be considered the initiation, expansion, replacement, ~~relocation,~~ or  
 124 | acquisition of a surgical service or one or more operating rooms.

125 | ~~—(ee) "Replace a surgical service or one or more operating rooms" means the development of new space  
 126 | (whether through new construction, purchase, lease or similar arrangement) to house one or more operating  
 127 | rooms currently operated by an applicant at the same site as the operating room(s) to be replaced. This  
 128 | term also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term does not  
 129 | include the renovation of an existing surgical service or one or more operating rooms.~~

130 | (~~ffZ~~) "Rural county" means a county not located in a metropolitan statistical area or micropolitan  
 131 | statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan  
 132 | statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United  
 133 | States Office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in  
 134 | Appendix A.

135 | (~~ggAA~~) "Sterile corridor" means an area of a surgical facility designated primarily for surgical cases and  
 136 | surgical support staff. Access to this corridor is controlled and the corridor is not used by the general public  
 137 | or personnel of the surgical facility whose primary work station is not in the operating suite(s) or whose  
 138 | primary work tasks do not require them to be in the operating suite(s) of a surgical facility. Examples of  
 139 | personnel who would normally use sterile corridors include physicians, surgeons, operating room nurses,  
 140 | laboratory or radiology personnel, and central supply or housekeeping personnel. Other terms commonly  
 141 | used to represent "sterile" in describing access areas include "restricted," "controlled," "limited access," or  
 142 | "clean."

143 | (~~hhBB~~) "Surgical case" means a single visit to an operating room during which one or more surgical  
 144 | procedures are performed.

145 | (ii) "Surgical facility" means either:

146 | (i) a licensed FSOF;

147 | (ii) a certified ASC; or

148 | (iii) a licensed hospital site authorized to provide inpatient or outpatient surgery.

149 | (jj) "Surgical service" means performing surgery in a surgical facility.

150 | (~~kkCC~~) "Trauma care," for purposes of these standards, means surgical services provided to a trauma  
 151 | patient in a licensed hospital site that has been verified as meeting the standards of the American College of  
 152 | Surgeons for a Level I or II trauma center, or equivalent standards.

153 | (~~llDD~~) "Verifiable data" means surgical data (cases and/or hours) from the most recent Annual Survey or  
 154 | more recent data that can be validated by the Department.

155 |

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

157 |

158 **Section 3. Inventory of operating rooms used to perform surgical services; surgical cases, or hours**  
 159 **of use; and evaluating compliance with minimum volume requirements**  
 160

161 Sec. 3. (1) The Department shall use the number of operating rooms and verifiable data pursuant to  
 162 subsection (2) to determine the number of surgical cases, hours of use, or both, as applicable, pursuant to  
 163 subsection (3) for purposes of evaluating compliance with the actual and proposed volume requirements set  
 164 forth in the applicable sections of these standards. Compliance with CON minimum volume requirements  
 165 established by these standards shall be determined based on the average number of surgical cases, hours  
 166 of use, or both, per operating room of the surgical service as permitted by these standards.  
 167

168 (2) The number of operating rooms for each type of surgical facility shall be determined as follows:

169 (a) In a licensed hospital site, all operating rooms in which surgery is or will be performed excluding:

170 (i) A delivery room(s) if that room is located in an area of a licensed hospital site designated primarily  
 171 for obstetrical services.

172 (ii) An operating room that is or will be used exclusively for endoscopy or cystoscopy cases.

173 (iii) An operating room in which a fixed lithotripter is or will be located and utilized. A mobile lithotripter  
 174 shall not be considered as an operating room.

175 (iv) An operating room that is or will be used, though not exclusively, to provide surgical services to  
 176 patients requiring burn care or trauma care, as those terms are defined in these standards. No more than  
 177 0.5 burn care and 0.5 trauma care operating rooms shall be excluded pursuant to this subdivision, AND  
 178 PRECLUDES THE USE OF THE ROOM IN SUBSECTION (2)(A)(V).

179 (V) AN OPERATING ROOM THAT IS OR WILL BE USED EXCLUSIVELY TO PROVIDE SURGICAL  
 180 SERVICES TO PATIENTS REQUIRING BURN CARE OR TRAUMA CARE, AS THOSE TERMS ARE  
 181 DEFINED IN THESE STANDARDS. NO MORE THAN 1 BURN CARE AND 1 TRAUMA CARE  
 182 OPERATING ROOM SHALL BE EXCLUDED PURSUANT TO THIS SUBDIVISION, AND PRECLUDES  
 183 THE USE OF THE ROOM IN SUBSECTION (2)(A)(IV).

184 (VI) A HYBRID ORCCL SHALL HAVE 0.5 EXCLUDED FOR EACH ROOM MEETING THE  
 185 REQUIREMENTS OF SECTION 8 OF THESE STANDARDS. A SURGICAL FACILITY WILL NOT BE  
 186 LIMITED TO THE NUMBER OF HYBRID ORCCLS WITHIN A SINGLE LICENSED FACILITY.

187 (b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all rooms  
 188 in which endoscopy or cystoscopy cases are or will be performed.

189 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all  
 190 operating rooms in which surgery is or will be performed, excluding any operating rooms used exclusively  
 191 for endoscopy or cystoscopy cases.  
 192

193 (3) The number of surgical cases, or hours of use, shall be determined as follows:

194 (a) In a licensed hospital site, all surgical cases, or hours of use, performed in operating rooms,  
 195 including surgical cases, or hours of use, performed in an operating room identified in subsection (2)(a)(iv),  
 196 but excluding the surgical cases, or hours of use, performed in operating rooms identified in subsection  
 197 (2)(a)(i), (ii), and (iii).

198 (b) In an FSOF or ASC that is or will be used exclusively for endoscopy or cystoscopy cases, all  
 199 endoscopy or cystoscopy cases, or hours of use, performed in the operating rooms identified in subsection  
 200 (2)(b).

201 (c) In an FSOF or ASC that is not or will not be used exclusively for endoscopy or cystoscopy cases, all  
 202 surgical cases, or hours of use, performed in the operating rooms identified in subsection (2)(c). Cases, or  
 203 hours of use, performed in any operating room used exclusively for endoscopy or cystoscopy cases, shall  
 204 be excluded.  
 205

206 **Section 4. Requirements ~~for approval for applicants proposing~~ to initiate a surgical service**  
 207

208 Sec. 4. ~~(1) An applicant proposing to~~ To initiate a surgical service means to begin operation of a surgical  
 209 facility at a site that has not offered surgical services within the 12-month period immediately preceding the  
 210 date an application is submitted to the Department. The term does not include the relocation of a surgical

~~service of one or more operating rooms.~~ AN APPLICANT PROPOSING TO INITIATE A SURGICAL SERVICE shall demonstrate THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

~~(1) that e~~Each proposed operating room shall perform an average of at least 1,128 surgical cases per year per operating room in the second 12 months of operation, ~~and annually thereafter.~~

(2) Subsection (1) shall not apply if the proposed project involves the initiation of a surgical service with 1 or 2 operating rooms at a licensed hospital site located in a rural or micropolitan statistical area county that does not offer surgical services as of the date an application is submitted to the Department.

(3) An applicant shall demonstrate that it meets the requirements of Section 140(2) for the number of surgical cases projected under subsection (1).

### Section 5. Requirements to replace a surgical service

Sec. 5. TO replace a surgical service or one or more operating rooms, means the development of new space (whether through new construction, purchase, lease or similar arrangement) to house one or more operating rooms operated by an applicant at the same site as the operating room(s) to be replaced. This also includes designating an OR as a dedicated endoscopy or cystoscopy OR. The term also includes relocating an existing surgical facility or one or more operating rooms to a different NEW GEOGRAPHIC location of an existing surgical facility or one or more operating rooms to a different location currently offering surgical services within the relocation zone. The term does not include the renovation of an existing surgical service or one or more operating rooms. AN APPLICANT REQUESTING TO REPLACE AN EXISTING SURGICAL SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

(1) AN APPLICANT PROPOSING TO REPLACE SHALL DEMONSTRATE:

(a) All existing operating rooms in the existing surgical facility have performed an average of at least:

(i) 1,042 surgical cases per year per operating room for which verifiable data is available to the Department, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for which verifiable data is available to the Department, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or

(iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the facility per year per operating room for which verifiable data is available to the Department and calculated as follows:

(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)

(b) All operating rooms, existing and replaced, are projected to perform an average of at least:

(i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and annually thereafter, or

(ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in the second twelve months of operation, and annually thereafter, or

(iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in the second twelve months of operation, and annually thereafter and calculated as follows:

264 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 265 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours  
 266 would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or  
 267 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 268 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
 269 facility per year per operating room in the second twelve months of operation, and annually thereafter and  
 270 calculated as follows:  
 271 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 272 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases  
 273 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)  
 274 \_\_\_\_\_  
 275 (2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located  
 276 in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of  
 277 not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most  
 278 recent federal decennial census shall demonstrate each of the following:  
 279 (a) The applicant has three, four, or five ORs at the licensed hospital.  
 280 (b) All existing operating rooms have performed an average of at least:  
 281 (i) 839 surgical cases per year per operating room for which verifiable data is available to the  
 282 Department, or  
 283 (ii) 1,200 hours of use per year per operating room for which verifiable data is available to the  
 284 Department.  
 285 (c) All operating rooms, existing and replaced, are projected to perform an average of at least:  
 286 (i) 839 surgical cases per year per operating room in the second twelve months of operation, and  
 287 annually thereafter, or  
 288 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and  
 289 annually thereafter.  
 290 \_\_\_\_\_  
 291 (3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more  
 292 operating rooms at the same licensed hospital site, if the surgical facility is located in a rural or micropolitan  
 293 statistical area county and has one or two operating rooms.  
 294 \_\_\_\_\_  
 295 (4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of  
 296 1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs  
 297 at the surgical service has not increased as of March 31, 2003, and the location does not change.  
 298 \_\_\_\_\_  
 299 (5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall  
 300 submit notification to the Department on a form provided by the Department. An applicant under this  
 301 subsection shall not be required to comply with subsections (1) and (2).  
 302 \_\_\_\_\_  
 303 (6) An applicant proposing to relocate an existing surgical service or one or more operating rooms shall  
 304 demonstrate each of the following, as applicable:  
 305 (a) The proposed new site is within a 10-mile radius of the site at which an existing surgical service is  
 306 located if an existing surgical service is located in a metropolitan statistical area county, or a 20-mile radius if  
 307 an existing surgical service is located in a rural or micropolitan statistical area county.  
 308 (b) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be  
 309 relocated have performed an average of at least:  
 310 (i) 1,042 surgical cases per year per operating room for which verifiable data is available to the  
 311 Department, or  
 312 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for  
 313 which verifiable data is available to the Department, or,  
 314 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 315 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for  
 316 which verifiable data is available to the Department and calculated as follows:

317 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 318 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours  
 319 would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or

320 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 321 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
 322 facility per year per operating room for which verifiable data is available to the Department and calculated as  
 323 follows:

324 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 325 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases  
 326 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)

327 (c) All operating rooms, existing and relocated, are projected to perform an average of at least:

328 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation or

329 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in  
 330 the second twelve months of operation, and annually thereafter, or

331 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 332 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in  
 333 the second twelve months of operation, and annually thereafter and calculated as follows:

334 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 335 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours  
 336 would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.) or

337 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 338 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
 339 facility per year per operating room in the second twelve months of operation, and annually thereafter and  
 340 calculated as follows:

341 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 342 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases  
 343 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)

344  
 345 (7) Subsection (6) shall not apply if the proposed project involves relocating one or two operating  
 346 rooms within a 20-mile radiusthe relocation zone, if the surgical facility is located in a rural or micropolitan  
 347 statistical area county.

348  
 349 (8) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to  
 350 another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a  
 351 city, village, or township with a population of not more than 12,000 and in a county with a population of not  
 352 more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the  
 353 following:

354 (a) The applicant has three, four, or five ORs at the licensed hospital.

355 (b) All existing operating rooms have performed an average of at least:

356 (i) 839 surgical cases per year per operating room for which verifiable data is available to the  
 357 Department, or

358 (ii) 1,200 hours of use per year per operating room for which verifiable data is available to the  
 359 Department.

360 (c) All operating rooms, existing and relocated, are projected to perform an average of at least:

361 (i) 839 surgical cases per year per operating room in the second twelve months of operation or

362 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation.,

363  
 364 (9) An applicant shall demonstrate that it meets the requirements of Section 10(2) for the number of  
 365 surgical cases, or hours of use, projected under subsection (1), (2), (6), and (8).

366  
 367 **Section 56. Requirements for approval for surgical services proposing to expand an existing**  
 368 **surgical service**

370 Sec. 56. (1) TO expand a surgical service means the addition of one or more operating rooms at an  
 371 existing surgical service. This term also includes the change from a dedicated endoscopy or cystoscopy OR  
 372 to a non-dedicated OR. An applicant proposing to add one or more operating rooms at an existing surgical  
 373 service shall demonstrate each of the following AS APPLICABLE, TO THE PROPOSED PROJECT.  
 374

375 (a1) AN APPLICANT SHALL DEMONSTRATE THE FOLLOWING:

376 (a) all All existing operating rooms in the existing surgical facility have performed an average of at least:

377 (i) 1,216 surgical cases per year per operating room for which verifiable data is available to the  
 378 Department, or

379 (ii) 1,313 hours of use in a facility that performs only outpatient surgery per year per operating room for  
 380 which verifiable data is available to the Department, or

381 (iii) a licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 382 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for  
 383 which verifiable data is available to the Department and calculated as follows:

384 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750 plus  
 385 the outpatient hours divided by 1,313. (For example: Using 438 inpatient hours and 985 outpatient hours  
 386 would equate to  $438/1,750 + 985/1,313 = 0.25 + 0.75 = 1.00$  OR), or

387 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 388 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
 389 facility per year per operating room for which verifiable data is available to the Department and calculated as  
 390 follows:

391 (A) ~~the~~The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,750  
 392 plus the outpatient cases divided by 1,216. (For example: Using 438 inpatient hours and 912 outpatient  
 393 cases would equate to  $438/1,750 + 912/1,216 = 0.25 + 0.75 = 1.00$  OR.)

394 (b) All proposed operating rooms are projected to perform an average of at least:

395 (i) 1,042 surgical cases per year per operating room in the second twelve months of operation, ~~and~~  
 396 ~~annually thereafter,~~ or

397 (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in  
 398 the second twelve months of operation, ~~and annually thereafter,~~ or

399 (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 400 of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in  
 401 the second twelve months of operation, ~~and annually thereafter~~ and calculated as follows:

402 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 403 the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours  
 404 would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or

405 (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average  
 406 of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the  
 407 facility per year per operating room in the second twelve months of operation, ~~and annually thereafter~~ and  
 408 calculated as follows:

409 (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus  
 410 the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases  
 411 would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)  
 412

413 (2) An applicant proposing to add one or more operating rooms at a licensed hospital and is located in  
 414 a rural or micropolitan county or the applicant is located in a city, village, or township with a population of not  
 415 more than 12,000 and in a county with a population of not more than 110,000 as defined by the most recent  
 416 federal decennial census shall demonstrate each of the following:

417 (a) The applicant has two, three, or four ORs at the licensed hospital.

418 (b) All existing operating rooms have performed an average of at least:

419 (i) 979 surgical cases per year per operating room for which verifiable data is available to the  
 420 Department, or

421 (ii) 1,400 hours of use per year per operating room for which verifiable data is available to the  
 422 Department.

- 423 (c) All proposed operating rooms are projected to perform an average of at least:  
 424 (i) 839 surgical cases per year per operating room in the second twelve months of operation, ~~and~~  
 425 ~~annually thereafter~~, or  
 426 (ii) 1,200 hours of use per year per operating room in the second twelve months of operation, ~~and~~  
 427 ~~annually thereafter~~.

428  
 429  
 430 (3) Subsections (1) and (2) shall not apply if the proposed project involves adding a second operating  
 431 room in a licensed hospital site located in a rural or micropolitan statistical area county that currently has  
 432 only one operating room.

433  
 434 (4) An applicant shall demonstrate that it meets the requirements of Section 140(2) for the number of  
 435 surgical cases, or hours of use, projected under subsections (1) ~~and (2)~~.

436  
 437 **Section 6. Requirements for approval for facilities proposing to replace a surgical service or one or**  
 438 **more operating rooms**

439  
 440 ~~— Sec. 6. (1) An applicant proposing to replace an existing surgical service or one or more operating~~  
 441 ~~rooms at the same site shall demonstrate each of the following:~~

442 ~~— (a) All existing operating rooms in the existing surgical facility have performed an average of at least:~~

443 ~~— (i) 1,042 surgical cases per year per operating room for which verifiable data is available to the~~  
 444 ~~Department, or~~

445 ~~— (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for~~  
 446 ~~which verifiable data is available to the Department, or~~

447 ~~— (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
 448 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for~~  
 449 ~~which verifiable data is available to the Department and calculated as follows:~~

450 ~~— (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
 451 ~~the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours~~  
 452 ~~would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or~~

453 ~~— (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
 454 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~  
 455 ~~facility per year per operating room for which verifiable data is available to the Department and calculated as~~  
 456 ~~follows:~~

457 ~~— (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
 458 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~  
 459 ~~would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)~~

460 ~~— (b) All operating rooms, existing and replaced, are projected to perform an average of at least:~~

461 ~~— (i) 1,042 surgical cases per year per operating room in the second twelve months of operation, and~~  
 462 ~~annually thereafter, or~~

463 ~~— (ii) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in~~  
 464 ~~the second twelve months of operation, and annually thereafter, or~~

465 ~~— (iii) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
 466 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in~~  
 467 ~~the second twelve months of operation, and annually thereafter and calculated as follows:~~

468 ~~— (A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
 469 ~~the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours~~  
 470 ~~would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or~~

471 ~~— (iv) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
 472 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~  
 473 ~~facility per year per operating room in the second twelve months of operation, and annually thereafter and~~  
 474 ~~calculated as follows:~~

475 ~~—(A) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
 476 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~  
 477 ~~would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)~~

478 ~~—(2) An applicant proposing to replace one or more operating rooms at a licensed hospital and is located~~  
 479 ~~in a rural or micropolitan county or the applicant is located in a city, village, or township with a population of~~  
 480 ~~not more than 12,000 and in a county with a population of not more than 110,000 as defined by the most~~  
 481 ~~recent federal decennial census shall demonstrate each of the following:~~

482 ~~—(a) The applicant has three, four, or five ORs at the licensed hospital.~~

483 ~~—(b) All existing operating rooms have performed an average of at least:~~

484 ~~—(i) 839 surgical cases per year per operating room for which verifiable data is available to the~~  
 485 ~~Department, or~~

486 ~~—(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the~~  
 487 ~~Department.~~

488 ~~—(c) All operating rooms, existing and replaced, are projected to perform an average of at least:~~

489 ~~—(i) 839 surgical cases per year per operating room in the second twelve months of operation, and~~  
 490 ~~annually thereafter, or~~

491 ~~—(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and~~  
 492 ~~annually thereafter.~~

493  
 494 ~~—(3) Subsections (1) and (2) shall not apply if the proposed project involves replacing one or more~~  
 495 ~~operating rooms at the same licensed hospital site, if the surgical facility is located in a rural or micropolitan~~  
 496 ~~statistical area county and has one or two operating rooms.~~

497  
 498 ~~—(4) Subsections (1) and (2) shall not apply to those hospitals licensed under Part 215 of PA 368 of~~  
 499 ~~1978, as amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs~~  
 500 ~~at the surgical service has not increased as of March 31, 2003, and the location does not change.~~

501  
 502 ~~—(5) An applicant proposing to designate an OR as a dedicated endoscopy or cystoscopy OR shall~~  
 503 ~~submit notification to the Department on a form provided by the Department. An applicant under this~~  
 504 ~~subsection shall not be required to comply with subsections (1) and (2).~~

505  
 506 **Section 7. Requirements for approval for applicants proposing to relocate an existing surgical**  
 507 **service or one or more operating rooms**

508  
 509 ~~—Sec. 7. An applicant proposing to relocate an existing surgical service or one or more operating rooms~~  
 510 ~~shall demonstrate each of the following, as applicable:~~

511  
 512 ~~—(1) The proposed relocation will not result in an increase in the total number of operating rooms~~  
 513 ~~operated by an applicant at the existing and proposed sites unless an applicant can demonstrate~~  
 514 ~~compliance with the applicable requirements of Section 5.~~

515  
 516 ~~—(2) The proposed new site is located within the relocation zone.~~

517  
 518 ~~—(3) All existing operating rooms in the surgical facility from which one or more ORs are proposed to be~~  
 519 ~~relocated have performed an average of at least:~~

520 ~~—(a) 1,042 surgical cases per year per operating room for which verifiable data is available to the~~  
 521 ~~Department, or~~

522 ~~—(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room for~~  
 523 ~~which verifiable data is available to the Department, or,~~

524 ~~—(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
 525 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room for~~  
 526 ~~which verifiable data is available to the Department and calculated as follows:~~

- 527 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
528 ~~the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours~~  
529 ~~would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.), or~~  
530 ~~—(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
531 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~  
532 ~~facility per year per operating room for which verifiable data is available to the Department and calculated as~~  
533 ~~follows:~~  
534 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
535 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~  
536 ~~would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)~~  
537  
538 ~~—(4) All operating rooms, existing and relocated, are projected to perform an average of at least:~~  
539 ~~—(a) 1,042 surgical cases per year per operating room in the second twelve months of operation, and~~  
540 ~~annually thereafter, or~~  
541 ~~—(b) 1,125 hours of use in a facility that performs only outpatient surgery per year per operating room in~~  
542 ~~the second twelve months of operation, and annually thereafter, or~~  
543 ~~—(c) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
544 ~~of inpatient hours of use and outpatient hours of use as billed by the facility per year per operating room in~~  
545 ~~the second twelve months of operation, and annually thereafter and calculated as follows:~~  
546 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
547 ~~the outpatient hours divided by 1,125. (For example: Using 375 inpatient hours and 844 outpatient hours~~  
548 ~~would equate to  $375/1,500 + 844/1,125 = 0.25 + 0.75 = 1.00$  OR.) or~~  
549 ~~—(d) A licensed hospital that provides both inpatient and outpatient surgery may use a weighted average~~  
550 ~~of hours of use (inpatient surgical volume) and surgical cases (outpatient surgical volume) as billed by the~~  
551 ~~facility per year per operating room in the second twelve months of operation, and annually thereafter and~~  
552 ~~calculated as follows:~~  
553 ~~—(i) The number of operating rooms shall be the sum of the inpatient hours of use divided by 1,500 plus~~  
554 ~~the outpatient cases divided by 1,042. (For example: Using 375 inpatient hours and 785 outpatient cases~~  
555 ~~would equate to  $375/1,500 + 785/1,042 = 0.25 + 0.75 = 1.00$  OR.)~~  
556  
557 ~~—(5) Subsections (3) and (4) shall not apply if the proposed project involves relocating one or two~~  
558 ~~operating rooms within the relocation zone, if the surgical facility is located in a rural or micropolitan~~  
559 ~~statistical area county.~~  
560  
561 ~~—(6) An applicant proposing to relocate one or more operating rooms from one licensed hospital site to~~  
562 ~~another licensed hospital site and is located in a rural or micropolitan county or the applicant is located in a~~  
563 ~~city, village, or township with a population of not more than 12,000 and in a county with a population of not~~  
564 ~~more than 110,000 as defined by the most recent federal decennial census shall demonstrate each of the~~  
565 ~~following:~~  
566 ~~—(a) The applicant has three, four, or five ORs at the licensed hospital.~~  
567 ~~—(b) All existing operating rooms have performed an average of at least:~~  
568 ~~—(i) 839 surgical cases per year per operating room for which verifiable data is available to the~~  
569 ~~Department, or~~  
570 ~~—(ii) 1,200 hours of use per year per operating room for which verifiable data is available to the~~  
571 ~~Department.~~  
572 ~~—(c) All operating rooms, existing and relocated, are projected to perform an average of at least:~~  
573 ~~—(i) 839 surgical cases per year per operating room in the second twelve months of operation, and~~  
574 ~~annually thereafter, or~~  
575 ~~—(ii) 1,200 hours of use per year per operating room in the second twelve months of operation, and~~  
576 ~~annually thereafter.~~  
577  
578 ~~—(7) An applicant shall demonstrate that it meets the requirements of Section 11(2) for the number of~~  
579 ~~surgical cases, or hours of use, projected under subsection (4) and (6).~~

580  
581 **Section 87. Requirements ~~for approval for applicants proposing~~ to acquire an existing surgical**  
582 **service**  
583

584 Sec. 87. Acquisition of a surgical service means a project involving the issuance of a new license for a  
585 hospital or a freestanding surgical outpatient facility or a new certification as an ambulatory surgical center  
586 as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an  
587 existing surgical service. An applicant proposing to acquire an existing surgical service shall demonstrate  
588 each of the following, as applicable TO THE PROPOSED PROJECT.  
589

590 ~~(1) The acquisition will not result in an increase in the number of operating rooms at the surgical service to~~  
591 ~~be acquired unless an applicant can demonstrate compliance with the applicable requirements of Section 5.~~  
592

593 ~~— (2) The location of the surgical service does not change as a result of the acquisition unless an~~  
594 ~~applicant can demonstrate compliance with the applicable requirements of Section 7.~~  
595

596 (31) An applicant agrees and assures to comply with all applicable project delivery requirements.  
597

598 (42) For the first application ~~for proposed proposing TO acquisition of~~ ACQUIRE an existing surgical  
599 service, for which a final decision has not been issued, on or after January 27, 1996, ~~an THE~~ existing  
600 surgical service ~~to be acquired~~ shall not be required to be in compliance with the APPLICABLE volume  
601 requirements ~~applicable to the seller/lessor on the date the acquisition occurs~~ SET FORTH IN THESE  
602 STANDARDS. The surgical service shall be operating at the applicable volume requirements in the second  
603 12 months after the effective date of the acquisition, ~~and annually thereafter.~~  
604

605 (53) For any application ~~for proposed acquisition of~~ PROPOSING TO ACQUIRE an existing surgical  
606 service except the first application, for which a final decision has not been issued, on or after January 27,  
607 1996, THE EXISTING SURGICAL SERVICE ~~an applicant~~ shall be required to ~~document~~ BE IN compliance  
608 with the APPLICABLE volume requirements ~~applicable to the existing surgical service~~ on the date ~~an THE~~  
609 application is submitted to the Department.  
610

611 (64) Subsection (53) shall not apply to those hospitals licensed under Part 215 of PA 368 of 1978, as  
612 amended that had fewer than 70 licensed beds on December 1, 2002 provided the number of ORs at the  
613 surgical service has not increased as of March 31, 2003, and the location does not change.  
614

615 **SECTION 8. REQUIREMENTS FOR A HYBRID OPERATING ROOM/CARDIAC CATHETERIZATION**  
616 **LABORATORY (OR/CCL)**  
617

618 SEC. 8. A HYBRID OR/CCL MEANS AN OPERATING ROOM LOCATED ON A STERILE CORRIDOR  
619 AND EQUIPPED WITH AN ANGIOGRAPHY SYSTEM PERMITTING MINIMALLY INVASIVE  
620 PROCEDURES OF THE HEART AND BLOOD VESSELS WITH FULL ANESTHESIA CAPABILITIES. AN  
621 APPLICANT PROPOSING TO ADD ONE OR MORE HYBRID OR/CCLS AT AN EXISTING SURGICAL  
622 SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING:  
623

624 (1) THE APPLICANT OPERATES AN OPEN HEART SURGERY SERVICE WHICH IS IN FULL  
625 COMPLIANCE WITH THE CURRENT CON REVIEW STANDARDS FOR OPEN HEART SURGERY  
626 SERVICES.  
627

628 (2) IF THE HYBRID OR/CCL(S) REPRESENTS AN INCREASE IN THE NUMBER OF LICENSED  
629 OPERATING ROOMS AT THE FACILITY, THE APPLICANT IS IN COMPLIANCE WITH SECTION 6 OF  
630 THESE STANDARDS.  
631

632 (3) IF THE HYBRID OR/CCL(S) REPRESENTS CONVERSION OF AN EXISTING OPERATING  
 633 ROOM(S), THE APPLICANT IS IN COMPLIANCE WITH THE PROVISIONS OF SECTION 5, IF  
 634 APPLICABLE.

635  
 636 (4) THE APPLICANT MEETS THE APPLICABLE REQUIREMENTS OF THE CON REVIEW  
 637 STANDARDS FOR CARDIAC CATHETERIZATION SERVICES.

638  
 639 (5) EACH CASE PERFORMED IN A HYBRID OR/CCL SHALL BE INCLUDED EITHER IN THE  
 640 SURGICAL VOLUME OR THE THERAPEUTIC CARDIAC CATHETERIZATION VOLUME OF THE  
 641 FACILITY. NO CASE SHALL BE COUNTED MORE THAN ONCE.

642  
 643 **Section 989. Requirements for approval -- all applicants** MEDICAID PARTICIPATION

644  
 645 Sec. 989. An applicant shall provide VERIFICATION evidence-OF MEDICAID PARTICIPATION.of  
 646 participation in Medicaid or in Medicaid managed care products or attestation that the applicant has been  
 647 unable to contract at current Medicaid rates at the time the application is submitted to the Department.  
 648 By providing a signed affidavit, an applicant that is an ASC or FSOE shall demonstrate a willingness to  
 649 participate when accepted by Medicaid. An applicant that is initiating a new service or is a new provider  
 650 not currently enrolled in Medicaid shall provide CERTIFY a signed affidavit stating that proof of Medicaid  
 651 participation will be provided to the Department within six (6) months from the offering of services if a  
 652 CON is approved. If the required documentation is not submitted with the application on the designated  
 653 application date, the application will be deemed filed on the first applicable designated application date  
 654 after all required documentation is received by the Department.

655  
 656 **Section 10910. Project delivery requirements -- terms of approval for all applicants**

657  
 658 Sec. 10910. ~~(1)~~ An applicant shall agree that, if approved, the project SURGICAL SERVICES shall be  
 659 delivered in compliance with the following terms of CON approval:

660  
 661 (a1) Compliance with these standards.

662 ~~(b) Compliance with applicable operating standards.~~

663 (2) COMPLIANCE WITH THE FOLLOWING QUALITY ASSURANCE STANDARDS:

664 ~~(c) Compliance with the following terms of approval, as applicable:~~

665 ~~(i) The approved services and/or operating rooms shall be operating at the applicable required~~  
 666 ~~volumes within the time periods specified in these standards, and annually thereafter.~~

667 ~~(iii) The designation of ORs as defined by the standards shall not be changed without prior notification~~  
 668 ~~to the Department.~~

669 (ii) Surgical facilities shall have established policies for the selection of patients and delineate  
 670 procedures which may be performed in that particular facility.

671 (iii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including  
 672 cardiopulmonary resuscitation.

673 (iv) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of  
 674 patients when necessary. All surgeons who perform surgery within the facility shall have evidence of  
 675 admitting privileges or of written arrangements with other physicians for patient admissions at a local  
 676 hospital. The surgical facility shall have an established procedure, including a transfer agreement, that  
 677 provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the  
 678 surgical facility to a hospital that is capable of providing the necessary inpatient services and is located  
 679 within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an  
 680 applicant shall have a transfer agreement with the nearest hospital having such capability.

681 (v) An applicant shall have written policies and procedures regarding the administration of a surgical  
 682 facility.

683 (vi) An applicant shall have written position descriptions which include minimum education, licensing, or  
 684 certification requirements for all personnel employed at the surgical facility.

685 (vii) An applicant shall have a process for credentialing individuals authorized to perform surgery or  
 686 provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the  
 687 selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of  
 688 licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,  
 689 podiatric medicine and surgery, or dentistry.

690 (viii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including  
 691 biologicals) services, either on-site or through contractual arrangements.

692 (ix) An applicant shall have written policies and procedures for advising patients of their rights.

693 (x) An applicant shall develop and maintain a system for the collection, storage, and use of patient  
 694 records.

695 (xi) Surgical facilities shall have separate patient recovery and non-patient waiting areas.

696 (xii) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,  
 697 and the public. Each facility shall incorporate a safety management program to maintain a physical  
 698 environment free of hazards and to reduce the risk of human injury.

699 (B) For purposes of evaluating subsection (A), the Department shall consider it prima facie evidence as  
 700 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint  
 701 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital  
 702 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an  
 703 ambulatory surgical center.

704 (C) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA  
 705 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

706

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

708 (iii)a) ~~An~~THE applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

709 (Ab) not deny surgical services to any individual based on ability to pay or source of payment;

710 (Bc) provide surgical services to any individual based on the clinical indications of need for the service.

711 (Cd) maintain information by payer and non-paying sources to indicate the volume of care from each  
 712 source provided annually.

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

714 (e) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12  
 715 consecutive months within the first two years of operation and continue to participate annually thereafter  
 716 or attest that the applicant has been unable to contract with Medicaid managed care products at current  
 717 Medicaid rates.

718

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

720 (iva) EXISTING OPERATING ROOMS SHALL PERFORM AN AVERAGE OF AT LEAST:

721 (i) 1,042 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE  
 722 DEPARTMENT, OR

723 (ii) 1,125 HOURS OF USE IN A FACILITY THAT PERFORMS ONLY OUTPATIENT SURGERY PER  
 724 YEAR PER OPERATING ROOM VERIFIABLE BY THE DEPARTMENT, OR

725 (iii) BE IN COMPLIANCE USING THE APPLICABLE WEIGHTED AVERAGES UNDER SECTION 5.

726 (b) EXISTING OPERATING ROOMS, LOCATED IN A RURAL OR MICROPOLITAN COUNTY, OR  
 727 WITHIN A CITY, VILLAGE, OR TOWNSHIP WITH A POPULATION OF NOT MORE THAN 12,000 AND IN  
 728 A COUNTY WITH A POPULATION OF NOT MORE THAN 110,000 AS DEFINED BY THE MOST  
 729 RECENT FEDERAL DECENNIAL CENSUS IN A SURGICAL SERVICE THAT HAS THREE, FOUR, OR  
 730 FIVE OR'S SHALL PERFORM AN AVERAGE OF AT LEAST:

731 (i) 839 SURGICAL CASES PER YEAR PER OPERATING ROOM VERIFIABLE BY THE  
 732 DEPARTMENT OR

733 (ii) 1,200 HOURS OF USE PER YEAR PER OPERATING ROOM VERIFIABLE BY THE  
 734 DEPARTMENT.

735 (C) ~~An~~THE applicant shall participate in a data collection ~~network~~SYSTEM established and  
 736 administered by the Department. The data may include, but is not limited to, hours of use of operating  
 737 rooms, annual budget and cost information, operating schedules, and demographic, diagnostic, morbidity

738 and mortality information, as well as the volume of care provided to patients from all payer sources. An  
 739 applicant shall provide the required data on a separate basis for each licensed or certified site, in a format  
 740 established by the department, and in a mutually agreed upon media. The Department may elect to verify  
 741 the data through on-site review of appropriate records.

742 ~~(vD) The applicant SURGICAL SERVICE shall provide the Department with a TIMELY notice stating OF  
 743 the first date on which the service became operational, and such notice shall be submitted to the  
 744 Department PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated  
 745 rules.~~

746 ~~— (d) Compliance with the following quality assurance standards, as applicable:~~

747 ~~— (i) Surgical facilities shall have established policies for the selection of patients and delineate  
 748 procedures which may be performed in that particular facility.~~

749 ~~— (ii) Surgical facilities shall have provisions for handling all types of in-house emergencies, including  
 750 cardiopulmonary resuscitation.~~

751 ~~— (iii) Surgical facilities performing outpatient surgery shall have policies which allow for hospitalization of  
 752 patients when necessary. All surgeons who perform surgery within the facility shall have evidence of  
 753 admitting privileges or of written arrangements with other physicians for patient admissions at a local  
 754 hospital. The surgical facility shall have an established procedure, including a transfer agreement, that  
 755 provides for the immediate transfer of a patient requiring emergency care beyond the capabilities of the  
 756 surgical facility to a hospital that is capable of providing the necessary inpatient services and is located  
 757 within 30 minutes of the surgical facility. If no hospital is located within 30 minutes of the surgical facility, an  
 758 applicant shall have a transfer agreement with the nearest hospital having such capability.~~

759 ~~— (iv) An applicant shall have written policies and procedures regarding the administration of a surgical  
 760 facility.~~

761 ~~— (v) An applicant shall have written position descriptions which include minimum education, licensing, or  
 762 certification requirements for all personnel employed at the surgical facility.~~

763 ~~— (vi) An applicant shall have a process for credentialing individuals authorized to perform surgery or  
 764 provide anesthesia services at a surgical facility. An applicant's credentialing process shall insure that the  
 765 selection and appointment of individuals to the staff of a surgical facility does not discriminate on the basis of  
 766 licensure, registration, or professional education as doctors of medicine, osteopathic medicine and surgery,  
 767 podiatric medicine and surgery, or dentistry.~~

768 ~~— (vii) An applicant shall provide laboratory, diagnostic imaging, pathology and pharmacy (including  
 769 biologicals) services, either on-site or through contractual arrangements.~~

770 ~~— (viii) An applicant shall have written policies and procedures for advising patients of their rights.~~

771 ~~— (ix) An applicant shall develop and maintain a system for the collection, storage, and use of patient  
 772 records.~~

773 ~~— (x) Surgical facilities shall have separate patient recovery and non-patient waiting areas.~~

774 ~~— (xi) Surgical facilities shall provide a functionally safe and sanitary environment for patients, personnel,  
 775 and the public. Each facility shall incorporate a safety management program to maintain a physical  
 776 environment free of hazards and to reduce the risk of human injury.~~

777 ~~— (e) For purposes of evaluating subsection (d), the Department shall consider it prima facie evidence as  
 778 to compliance with the applicable requirements if an applicant surgical facility is accredited by the Joint  
 779 Commission on the Accreditation of Healthcare Organizations, the American Osteopathic Hospital  
 780 Association, or the Accreditation Association for Ambulatory Health Care, or certified by Medicare as an  
 781 ambulatory surgical center.~~

782 ~~— (f) An applicant shall participate in Medicaid or in Medicaid managed care products at least 12  
 783 consecutive months within the first two years of operation and continue to participate annually thereafter  
 784 or attest that the applicant has been unable to contract with Medicaid managed care products at current  
 785 Medicaid rates.~~

786 ~~— (2) The operation of and referral of patients to the surgical facility shall be in conformance with 1978 PA  
 787 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

790

791 | (35) The agreements and assurances required by this section shall be in the form of a ~~certification~~  
 792 | ~~agreed~~certification agreed to by the applicant or its authorized agent.

793 |  
 794 | **Section 44101. Documentation of projections**

795 |  
 796 | Sec. 44101. (1) An applicant required to project volumes of service shall specify how the volume  
 797 | projections were developed and shall include only those surgical cases performed in an OR.

798 |  
 799 |     (a) The applicant shall include a description of the data source(s) used as well as an assessment of the  
 800 | accuracy of these data used to make the projections. Based on this documentation, the Department shall  
 801 | determine if the projections are reasonable.

802 |       (b) The Department shall subtract any previous commitment, pursuant to subsection 2(d).

803 |  
 804 |       (2) If a projected number of surgical cases, or hours of use, under subsection (1) includes surgical  
 805 | cases, or hours of use, performed at another existing surgical facility(s), an applicant shall demonstrate, with  
 806 | documentation satisfactory to the Department, that the utilization of the existing surgical facility(s) is in  
 807 | compliance with the volume requirements applicable to that facility, and will continue to be in compliance  
 808 | with the volume requirements (cases and/or hours) applicable to that facility subsequent to the initiation,  
 809 | expansion, or ~~relocation~~REPLACEMENT of the surgical services proposed by an applicant. In  
 810 | demonstrating compliance with this subsection, an applicant shall provide each of the following:

811 |       (a) The name of each physician that performed surgical cases to be transferred to the applicant  
 812 | surgical facility.

813 |       (b) The number of surgical cases each physician, identified in subdivision (a), performed during the  
 814 | most recent 12-month period for which verifiable data is available.

815 |       (c) The location(s) at which the surgical cases to be transferred were performed, including evidence  
 816 | that the existing location and the proposed location are within 20 miles of each other.

817 |       (d) A written commitment from each physician, identified in subdivision (a), that he or she will perform  
 818 | at least the volume of surgical cases to be transferred to the applicant surgical facility for no less than 3  
 819 | years subsequent to the initiation, expansion, or ~~relocation~~REPLACEMENT of the surgical service  
 820 | proposed by an applicant.

821 |       (e) The number of surgical cases performed, at the existing surgical facility from which surgical cases  
 822 | will be transferred, during the most recent 12-month period prior to the date an application is submitted to  
 823 | the Department for which verifiable annual survey data is available.

824 |  
 825 |       (3) An applicant, other than an applicant proposing to initiate a surgical service, may utilize hours of  
 826 | use in documenting compliance with the applicable sections of these standards, if an applicant provides  
 827 | documentation, satisfactory to the Department, from the surgical facility from which the hours of use are  
 828 | being transferred.

829 |  
 830 | **Section 12. Effect on prior CON review standards; comparative reviews**

831 |  
 832 | Sec. 12. ~~(1) PROPOSED projects reviewed under these standards shall not be subject to comparative~~  
 833 | ~~review.~~ These CON review standards supercede and replace the CON Review Standards for Surgical  
 834 | Facilities approved by the CON Commission on ~~March 21, 2006~~APRIL 30, 2008 and effective on June ~~520,~~  
 835 | ~~2006~~2008.

836 |  
 837 | ~~—(2) Projects reviewed under these standards shall not be subject to comparative review.~~

**APPENDIX A**

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**CON REVIEW STANDARDS  
FOR SURGICAL SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

**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 ~~for all projects approved and Certificates of Need issued~~ under Part 222 of the Code ~~which involve cardiac catheterization services.~~

~~—(2)—~~ PURSUANT TO PART 222 OF THE CODE, ~~Cardiac cardiac~~ catheterization services are A covered clinical services ~~for purposes of Part 222 of the Code.~~

~~—(3)—~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, 9, 10, 11 and 14 as applicable,~~ THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

~~—(4)—~~ ~~The Department shall use Section 12 and 13 in applying~~ AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~—(5)—~~ ~~The Department shall use Section 3(2), in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

**Section 2. Definitions**

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

(a) ~~"Balloon atrial septostomy" means a procedure in which a balloon-tipped catheter is placed across the atrial septum and withdrawn to create an enlarged atrial opening.~~

~~—(b)—~~ "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.

~~(c)~~ "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, ~~as applicable,~~ performed on a patient during a single session in a ~~cardiac catheterization~~ 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. ~~Cardiac catheterization shall~~ THIS TERM DOES not include "float catheters" ~~which~~ THAT are performed at the bedside or in settings outside the ~~cardiac catheterization~~ 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.

~~(d)~~ "Cardiac catheterization service" means the provision of one or more of the following types of procedures ~~in compliance with Part 222 of the Code:~~ adult diagnostic cardiac catheterizations; pediatric

53 diagnostic cardiac catheterizations; adult therapeutic cardiac catheterizations; and pediatric therapeutic  
54 cardiac catheterizations.

55 ~~—(e) "Central service coordinator" means the organizational entity that has operational responsibility  
56 for a mobile cardiac catheterization network. It shall be a legal entity authorized to do business in  
57 Michigan.~~

58 (fD) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to  
59 Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

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

63 (iG) "Diagnostic cardiac catheterization service" means providing diagnostic ~~only~~ cardiac  
64 catheterization PROCEDURES on an organized, regular basis, in a laboratory TO DIAGNOSE  
65 ANATOMICAL AND/OR PHYSIOLOGICAL PROBLEMS IN THE HEART. ~~The term PROCEDURES~~  
66 ~~includes, but is not limited to:~~ the intra coronary administration of drugs; left heart catheterization; right  
67 heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies  
68 (echo-guided or fluoroscopic). ~~For purposes of these standards, the term also includes balloon atrial~~  
69 ~~septostomy procedure in a~~ hospital that provides pediatric diagnostic cardiac catheterization services  
70 MAY ALSO PERFORM BALLOON ATRIAL SEPTOSTOMY PROCEDURES. ~~This term also includes~~  
71 ~~cardiac permanent pacemaker/ICD device implantations in a~~ hospital that ~~does not provide~~  
72 ~~therapeutic~~ PROVIDES DIAGNOSTIC cardiac catheterization services MAY ALSO PERFORM  
73 IMPLANTATIONS OF CARDIAC PERMANENT PACEMAKERS AND ICD DEVICES.

74 (jH) "Electrophysiology study" means a study of the electrical conduction activity of the heart and  
75 characterization of atrial and ventricular arrhythmias, obtained by means of a cardiac catheterization  
76 procedure. The term also includes the implantation of permanent pacemakers and ICD  
77 DEVICES ~~defibrillators~~.

78 ~~—(k) "Expand a cardiac catheterization service" means either:~~

79 ~~—(i) an increase in the number of cardiac catheterization laboratories at a hospital; or~~  
80 ~~—(ii) expanding the types of cardiac catheterization procedures authorized to be performed including~~  
81 ~~adult or pediatric, diagnostic or therapeutic, at a hospital that currently performs cardiac catheterization~~  
82 ~~procedures.~~

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

84 ~~—(m) "Host facility" means a hospital at which a mobile cardiac catheterization network is authorized to~~  
85 ~~provide cardiac catheterization services.~~

86 (nJ) "ICD-9-CM code" means the disease codes and nomenclature found in the International  
87 Classification of Diseases - 9th Revision - Clinical Modification, prepared by the Commission on  
88 Professional and Hospital Activities for the U.S. National Center for Health Statistics.

89 ~~—(o) "Initiate a cardiac catheterization service" means to begin performing cardiac catheterization~~  
90 ~~procedures at a hospital that does not perform cardiac catheterization procedures as of the date an~~  
91 ~~application is submitted to the Department.~~

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

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

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

102 ~~—(s) "Mobile cardiac catheterization network" means the provision of adult diagnostic-only cardiac~~  
103 ~~catheterization services by a central service coordinator and two or more host hospitals.~~

104 ~~—(t) "On-site open heart surgery services" means a facility that does have a CON to perform open~~  
105 ~~heart surgery services and does perform open heart surgery services in the existing hospital.~~

(uL) "Pediatric cardiac catheterization service" means ~~the offering and provision of~~PROVIDING cardiac catheterization services on an organized, regular basis to infants and children ages 18 and below, except for electrophysiology studies ~~which-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 of 426.7 (ANOMALOUS ATRIOVENTRICULAR EXCITATION), 427.0 (CARDIAC DYSRHYTHMIAS), 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).

(vM) "Primary ~~percutaneous coronary intervention (PCI)~~" means a PCI performed ~~within 120 minutes for emergency~~ON AN acute myocardial infarction (AMI) patients ~~seen in the emergency room (ER)~~ with confirmed ST elevation or new left bundle branch block.

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

~~(x) "Replace/upgrade" means any equipment change that involves a capital expenditure of \$500,000 or more in any consecutive 24-month period which results in the applicant operating the same number of cardiac catheterization laboratories before and after project completion.~~

~~(y) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.~~

(zO) "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. ~~The term~~PROCEDURES includes, ~~but is not limited to:~~ ~~percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, or catheter ablation,~~ and cardiac permanent pacemaker, ICD device implantations, TRANSCATHETER VALVE, OTHER STRUCTURAL HEART DISEASE PROCEDURES, PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) AND 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 for approval -- all applicants**

~~Sec. 3. (1) 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.~~

~~(2) 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 4. Requirements for approval -- applicants proposing to initiate an adult diagnostic cardiac catheterization service**

Sec. 43. AN APPLICANT PROPOSING TO INITIATE CARDIAC CATHETERIZATION SERVICES SHALL DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

158 ~~\_\_\_ (1) An applicant proposing to initiate an adult diagnostic cardiac catheterization service shall project a~~  
 159 ~~minimum of 300 procedure equivalents in the category of adult diagnostic cardiac catheterization will be~~  
 160 ~~performed in the second 12 months of operation after initiation of the adult diagnostic cardiac~~  
 161 ~~catheterization service, and annually thereafter.~~

162  
 163 ~~\_\_\_ (2) An applicant proposing to initiate an adult diagnostic cardiac catheterization service in a new~~  
 164 ~~single laboratory shall project DEMONSTRATE the following volume of procedure equivalents, as~~  
 165 ~~applicable, will be performed in the second 12 months of operation after initiation of the service, and~~  
 166 ~~annually thereafter. TO THE PROPOSED PROJECT:~~

167 (a) ~~For a hospital located in~~ FOR AN APPLICANT PROPOSING TO INITIATE A DIAGNOSTIC  
 168 CARDIAC CATHETERIZATION SERVICE WITH A SINGLE LABORATORY IN A -rural or micropolitan  
 169 statistical area county, SHALL PROJECT a minimum of 500 procedure equivalents ~~which shall~~  
 170 ~~include~~ including the 300 procedure equivalents in the category of ~~adult~~ diagnostic cardiac catheterization  
 171 ~~required under subsection (1)~~ PROCEDURES BASED ON DATA FROM THE MOST RECENT 12-  
 172 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE  
 173 DEPARTMENT.

174 (b) ~~For a hospital located~~ AN APPLICANT PROPOSING TO INITIATE A DIAGNOSTIC CARDIAC  
 175 CATHETERIZATION SERVICE -WITH A SINGLE LABORATORY in a metropolitan statistical area  
 176 county, SHALL PROJECT a minimum of 750 procedure equivalents ~~which shall~~ THAT include includes the  
 177 300 procedure equivalents in the category of ~~adult~~ diagnostic cardiac catheterization ~~required under~~  
 178 ~~subsection (1)~~ PROCEDURES BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD  
 179 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

180  
 181 ~~(3C) An applicant proposing to initiate~~ A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE an  
 182 ~~adult diagnostic cardiac catheterization service in 2~~ WITH TWO or more laboratories shall project ~~that~~ a  
 183 minimum of 1,000 procedure equivalents per laboratory THAT INCLUDES 300 PROCEDURE  
 184 EQUIVALENTS IN THE CATEGORY OF DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES  
 185 ~~will be performed in~~ DURING BASED ON DATA FROM the ~~second~~ MOST RECENT 12-  
 186 ~~months of~~ operation after initiation of the service, and annually thereafter. The projected volume shall include the  
 187 ~~procedure equivalents required by subsection (1)~~ PERIOD PRECEDING THE DATE THE APPLICATION  
 188 WAS SUBMITTED TO THE DEPARTMENT.

189  
 190 ~~\_\_\_ (2) An applicant proposing to perform~~ INITIATE AN ADULT therapeutic cardiac catheterization  
 191 SERVICE shall demonstrate both of the following:

192 ~~\_\_\_ (a) An~~ THE applicant provides, IS APPROVED TO PROVIDE, or has APPLIED to provide adult  
 193 diagnostic cardiac catheterization services AT THE HOSPITAL. THE APPLICANT MUST BE  
 194 APPROVED FOR ADULT DIAGNOSTIC CARDIAC CATHETERIZATION SERVICES IN ORDER TO BE  
 195 APPROVED FOR ADULT THERAPEUTIC CARDIAC CATHETERIZATION SERVICES.

196 ~~\_\_\_ (b) AN~~ APPLICANT OPERATING AN ADULT DIAGNOSTIC CARDIAC CATHETERIZATION  
 197 SERVICE HAS PERFORMED A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY  
 198 OF ADULT DIAGNOSTIC CARDIAC CATHETERIZATIONS DURING THE MOST RECENT 12-MONTH  
 199 PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT IF  
 200 THE SERVICE HAS BEEN IN OPERATION MORE THAN 24 MONTHS.

201 ~~\_\_\_ (C) THE~~ applicant HAS APPLIED TO provides adult open heart surgery services AT the hospital.  
 202 The APPLICANT MUST BE APPROVED FOR AN ADULT OPEN HEART SURGERY SERVICE IN  
 203 ORDER TO BE APPROVED FOR AN ADULT therapeutic cardiac catheterization SERVICE.

204  
 205 ~~\_\_\_ (D) THE~~ applicant shall project a minimum of 300 procedure equivalents in the category of adult  
 206 therapeutic cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD  
 207 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

208  
 209 ~~\_\_\_ (3) An applicant proposing to initiate a pediatric cardiac catheterization service SHALL~~  
 210 DEMONSTRATE THE FOLLOWING:

211 (A) THE APPLICANT HAS A board certified pediatric cardiologist with training in pediatric  
 212 catheterization procedures to direct the pediatric catheterization laboratory.

213 (B) THE APPLICANT HAS standardized equipment as DEFINED IN THE MOST CURRENT  
 214 AMERICAN ACADEMY OF PEDIATRICS (AAP) Guidelines FOR PEDIATRIC CARDIOVASCULAR  
 215 CENTERS.

216 (C) THE APPLICANT HAS on-site ICU as outlined in THE MOST CURRENT AAP guidelines  
 217 ABOVE.

218 (D) THE APPLICANT HAS APPLIED TO PROVIDE pediatric open heart surgery SERVICES AT THE  
 219 HOSPITAL. THE APPLICANT MUST BE APPROVED FOR A PEDIATRIC OPEN HEART SURGERY  
 220 SERVICE IN ORDER TO BE APPROVED FOR PEDIATRIC CARDIAC CATHETERIZATION SERVICES.

221 (E) THE applicant shall project a minimum of 600 procedure equivalents in the category of pediatric  
 222 cardiac catheterizations BASED ON DATA FROM THE MOST RECENT 12-MONTH PERIOD  
 223 PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

224  
 225 **~~Section 5. Requirements for approval -- applicants proposing to initiate an adult diagnostic~~**  
 226 **~~cardiac catheterization service with provision to perform primary PCI for patients experiencing~~**  
 227 **~~AMI (ST elevation or new left bundle branch block) without on-site open heart surgery services~~**  
 228

229 ~~Sec. 5.-(4)~~ An applicant proposing to initiate primary PCI service without on-site open heart surgery  
 230 services shall ~~submit documentation demonstrating demonstrate~~ all of the following:

231 (a) The applicant's OPERATES AN adult diagnostic cardiac catheterization service THAT HAS  
 232 performed a minimum of 400-500 diagnostic procedures EQUIVALENTS THAT INCLUDES 400  
 233 PROCEDURE EQUIVALENTS IN THE CATEGORY OF CARDIAC CATHETERIZATION PROCEDURES  
 234 (excluding diagnostic electrophysiology studies and right heart catheterizations) during the most recent 12  
 235 months preceding the date the application was submitted to the Department. ~~Mobile cardiac~~  
 236 catheterization laboratories are not eligible to apply under Section 5.

237 (b) The APPLICANT HAS AT LEAST TWO interventional cardiologists (at least two) to perform the  
 238 primary PCI PROCEDURES AND are experienced interventionalists who THAT have EACH  
 239 CARDIOLOGIST HAS each performed at least 75 interventions PCI SESSIONS annually, as the primary  
 240 operator at an open heart surgery facility during the most recent 24-month PERIODs preceding the date  
 241 the application was submitted to the Department, and annually thereafter.

242 (c) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill  
 243 patients and comfortable with interventional equipment; have acquired experience in dedicated  
 244 interventional laboratories at an open heart surgery facility HOSPITAL; and participate in an un-interrupted  
 245 24-hour, 365-day call schedule. Competency should SHALL be documented annually.

246 (d) The catheterization laboratory OR LABORATORIES is ARE well equipped, with optimal imaging  
 247 systems, resuscitative equipment, AND intra-aortic balloon pump (IABP) support, and must be well-  
 248 stocked with a broad array of interventional equipment.

249 (e) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
 250 Competency should SHALL be documented annually.

251 (f) A written agreement with an open heart surgery facility HOSPITAL that includes ALL OF THE  
 252 FOLLOWING:

253 (i) Involvement in credentialing criteria and recommendations for physicians approved to perform  
 254 primary PCI PROCEDURES;

255 (ii) Provision for ongoing cross-training for professional and technical staff involved in the provision of  
 256 primary PCI to ensure familiarity with interventional equipment; and, competency Competency  
 257 should SHALL be documented annually;

258 (iii) Provision for ongoing cross training for emergency department, catheterization laboratory, and  
 259 critical care unit staff to ensure experience in handling the high acuity status of primary PCI patient  
 260 candidates; and competency Competency should SHALL be documented annually;

261 (iv) Regularly held joint cardiology/cardiac surgery conferences to include review of all primary PCI  
 262 cases;

263 (v) Development and ongoing review of patient selection criteria for primary PCI patients and  
 264 implementation of those criteria;

- 265 (vi) A mechanism to provide for appropriate patient transfers between facilities and an agreed plan for  
 266 prompt care;
- 267 (vii) Written protocols, signed by the applicant and the open heart surgery ~~facility~~HOSPITAL, ~~must be~~  
 268 ~~in place, with provisions~~ for the ~~implementation for~~ immediate ~~and efficient~~ transfer, (within 1 hour from  
 269 THE cardiac catheterization laboratory to evaluation on site in the open heart ~~surgical-surgERY~~  
 270 ~~facility~~HOSPITAL), of patients requiring surgical evaluation and/or intervention 365 days a year, ~~the~~  
 271 ~~The~~ protocols shall be reviewed ~~AND~~ tested on a ~~regular~~ (quarterly) basis; ~~and~~.
- 272 (viii) Consultation on facilities, equipment, staffing, ancillary services, and policies and procedures for  
 273 the provision of interventional procedures.
- 274 (g) A written protocol must be established and maintained for case selection for the performance of  
 275 primary PCI ~~that is consistent with current practice guidelines set forth by the American College of~~  
 276 ~~Cardiology and the American Heart Association.~~
- 277 (h) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
 278 transfer from the emergency department to the CARDIAC catheterization laboratory must be developed  
 279 and maintained so that door-to-balloon targets are met.
- 280 (i) ~~Because primary PCI must be available to emergency patients 24 hours per day, 365 days a~~  
 281 ~~year, a~~ least two physicians credentialed to perform primary PCI must commit to functioning as a  
 282 coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day  
 283 per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
 284 the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate  
 285 with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
 286 quality assurance procedures pertaining to primary PCI designed to meet the requirements for this  
 287 certification and in keeping with the current guidelines for the provision of primary PCI promulgated by the  
 288 American College of Cardiology and American Heart Association.

290 (2J) ~~An THE~~ applicant shall project a minimum of ~~48-36~~ primary PCI ~~procedures~~ CASES BASED ON  
 291 DATA ~~will be performed in the second~~ FROM THE MOST 12-RECENT 12-months of operation after  
 292 initiation of service, and annually thereafter PERIOD PRECEDING THE DATE THE APPLICATION WAS  
 293 SUBMITTED TO THE DEPARTMENT. ~~Primary PCI volume shall be projected by documenting, as~~  
 294 ~~outlined in Section 13, and certifying that the applicant treated or transferred enough ST segment~~  
 295 ~~elevation AMI cases during the most recent 12 months preceding the date the application was submitted~~  
 296 ~~to the Department to maintain 48 primary PCI cases annually. Factors that may be considered in~~  
 297 ~~projecting primary PCI volume are the number of thrombolytic eligible patients per year seen in the~~  
 298 ~~Emergency Department (as documented through hospital pharmacy records showing the number of~~  
 299 ~~doses of thrombolytic therapy ordered for AMI in the Emergency Department) and/or documentation of~~  
 300 ~~emergency transfers to an open heart surgery facility for primary PCI.~~

302 **~~Section 7. Requirements for approval – applicants proposing to initiate an adult therapeutic~~**  
 303 **~~cardiac catheterization service~~**

- 305 ~~—Sec. 7. (1) An applicant proposing to perform therapeutic cardiac catheterization procedures shall~~  
 306 ~~demonstrate both of the following:~~
- 307 ~~—(a) An applicant provides or has CON approval to provide an adult diagnostic cardiac catheterization~~  
 308 ~~service.~~
- 309 ~~—(b) An applicant provides or has CON approval to provide an adult open heart surgery service within~~  
 310 ~~the hospital in which the therapeutic cardiac catheterizations are to be performed.~~
- 311 ~~—(c) Subsections (a) and (b) do not preclude an applicant from simultaneously applying for a~~  
 312 ~~diagnostic and therapeutic cardiac catheterization service and an open heart surgery service.~~
- 313
- 314 ~~—(2) An applicant proposing to perform therapeutic cardiac catheterization procedures shall project the~~  
 315 ~~following volume of procedure equivalents, as applicable, will be performed in the second 12 months of~~  
 316 ~~operation after initiation of the service, and annually thereafter:~~
- 317 ~~—(a) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac~~  
 318 ~~catheterizations.~~

319 | **Section 84. Requirements for approval -- applicants proposing to replace/upgrade AN EXISTING**  
 320 | **cardiac catheterization ~~laboratories~~SERVICE OR laboratory**  
 321 |

322 |  
 323 | **Sec. 84. (1) ~~An applicant, other than a hospital that provides only pediatric cardiac catheterization~~**  
 324 | **~~services, proposing to replace/upgrade its only laboratory, shall demonstrate that it meets each of the~~**  
 325 | **~~following, as applicable~~ REPLACING A CARDIAC CATHETERIZATION LABORATORY MEANS A**  
 326 | **CHANGE IN THE ANGIOGRAPHY X-RAY EQUIPMENT OR A RELOCATION OF THE SERVICE TO A**  
 327 | **NEW SITE. THE TERM DOES NOT INCLUDE A CHANGE IN ANY OF THE OTHER EQUIPMENT OR**  
 328 | **SOFTWARE USED IN THE LABORATORY. AN APPLICANT PROPOSING TO REPLACE A CARDIAC**  
 329 | **CATHETERIZATION LABORATORY OR SERVICE SHALL DEMONSTRATE THE FOLLOWING, AS**  
 330 | **APPLICABLE TO THE PROPOSED PROJECT:**  
 331 |

332 | **(a1) ~~For a hospital located in a rural county:~~ AN APPLICANT PROPOSING TO REPLACE CARDIAC**  
 333 | **CATHETERIZATION LABORATORY EQUIPMENT SHALL DEMONSTRATE THE FOLLOWING:**

334 | **(iA) ~~A minimum of 500 procedure equivalents were performed in the applicant's cardiac~~**  
 335 | **~~catheterization laboratory during the most recent 12 months of normal operation preceding the date the~~**  
 336 | **~~application was submitted to the Department; and~~ THE EXISTING LABORATORY OR LABORATORIES**  
 337 | **TO BE REPLACED ARE FULLY DEPRECIATED ACCORDING TO GENERALLY ACCEPTED**  
 338 | **ACCOUNTING PRINCIPLES OR DEMONSTRATES EITHER OF THE FOLLOWING:**

339 | **(ii) ~~A minimum of 500 procedure equivalents will be performed in the applicant's cardiac~~**  
 340 | **~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~**  
 341 | **~~annually thereafter.~~ THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE REPLACED POSES A**  
 342 | **THREAT TO THE SAFETY OF THE PATIENTS.**

343 | **(b1) ~~For a hospital located in a non-rural county:~~ THE REPLACEMENT ANGIOGRAPHY X-RAY**  
 344 | **EQUIPMENT OFFERS TECHNOLOGICAL IMPROVEMENTS THAT ENHANCE QUALITY OF CARE,**  
 345 | **INCREASES EFFICIENCY, AND REDUCES OPERATING COSTS.**

346 | **(iB) ~~A minimum of 750 procedure equivalents was performed in the applicant's cardiac catheterization~~**  
 347 | **~~laboratory during the most recent 12 months of normal operation preceding the date the application was~~**  
 348 | **~~submitted to the Department; and~~ THE EXISTING ANGIOGRAPHY X-RAY EQUIPMENT TO BE**  
 349 | **REPLACED WILL BE REMOVED FROM SERVICE ON OR BEFORE BEGINNING OPERATION OF THE**  
 350 | **REPLACEMENT EQUIPMENT.**

351 | **~~(ii) A minimum of 750 procedure equivalents will be performed in the applicant's cardiac~~**  
 352 | **~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~**  
 353 | **~~annually thereafter.~~**  
 354 |

355 | **(2) ~~If a~~ An applicant is a hospital that provides only pediatric PROPOSING TO REPLACE A cardiac**  
 356 | **~~catheterization services~~ proposes to replace/upgrade an existing cardiac catheterization laboratory, an**  
 357 | **~~applicant shall demonstrate that it meets each of~~ TO A NEW SITE SHALL DEMONSTRATE the following:**

358 | **(a) ~~A minimum of 500 procedure equivalents was performed in the applicant's cardiac catheterization~~**  
 359 | **~~laboratory in the most recent 12 months of normal operation preceding the date the application was~~**  
 360 | **~~submitted to the Department; and~~ THE PROPOSED PROJECT IS PART OF AN APPLICATION TO**  
 361 | **REPLACE THE ENTIRE HOSPITAL.**

362 | **(b) ~~A minimum of 500 procedure equivalents will be performed in the applicant's cardiac~~**  
 363 | **~~catheterization laboratory in the first 12 months of operation after installation of the new equipment, and~~**  
 364 | **~~annually thereafter.~~ THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST**  
 365 | **RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE**  
 366 | **DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT:**

367 | **(I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT**  
 368 | **DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.**

369 | **(II) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT**  
 370 | **THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.**

371 (III) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC  
 372 CARDIAC CATHETERIZATION PROCEDURES.

373 (IV) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR  
 374 MICROPOLITAN COUNTY WITH ONE LABORATORY.

375 (V) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN  
 376 COUNTY WITH ONE LABORATORY.

377 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION  
 378 LABORATORY FOR- A HOSPITAL WITH TWO OR MORE LABORATORIES.

379 (C) THE EXISTING CARDIAC CATHETERIZATION SERVICE HAS BEEN IN OPERATION FOR AT  
 380 LEAST 36 MONTHS AS OF THE DATE THE APPLICATION HAS BEEN SUBMITTED TO THE  
 381 DEPARTMENT.

382 ~~—(3) An applicant with 2 or more laboratories proposing to replace/upgrade any of its laboratories shall~~  
 383 ~~demonstrate that it meets each of the following, as applicable:~~

384 ~~—(a) An average of 1,000 procedure equivalents per room was performed in each existing cardiac~~  
 385 ~~catheterization laboratory in the hospital during the most recent 12 months of operation preceding the~~  
 386 ~~date the application was submitted to the Department, and~~

387 ~~—(b) A minimum of 1,000 procedure equivalents will be performed in each cardiac catheterization~~  
 388 ~~laboratory in the first 12 months of operation after installation of the new equipment, and annually~~  
 389 ~~thereafter.~~

391 ~~—(4) An applicant proposing to replace equipment shall demonstrate that the existing equipment to be~~  
 392 ~~replaced is fully depreciated according to generally accepted accounting principles, or can clearly~~  
 393 ~~demonstrate that the existing equipment poses a threat to the safety of the public, or offers significant~~  
 394 ~~technological improvements which enhance quality of care, increases efficiency, and/or reduces~~  
 395 ~~operating costs.~~

397 ~~—(5) If an application involves the replacement/upgrade of equipment used by a mobile cardiac~~  
 398 ~~catheterization network, an applicant shall demonstrate both of the following:~~

399 ~~—(a) At least 500 procedure equivalents were performed in the most recent 12 months of normal~~  
 400 ~~operation preceding the date the application was submitted to the Department; and~~

401 ~~—(b) A minimum of 500 procedure equivalents will be performed in the first 12 months of operation~~  
 402 ~~after installation of the new equipment, and annually thereafter.~~

403 ~~—(c) In evaluating compliance with subsections (a) and (b), the Department shall consider the~~  
 404 ~~combined utilization for all approved host facilities.~~

406 ~~—(6) In demonstrating compliance with the minimum volume requirements set forth in each applicable~~  
 407 ~~subsection of this section, an applicant shall demonstrate that the minimum volume requirement~~  
 408 ~~applicable to the specific type of cardiac catheterization procedures offered by an applicant (adult,~~  
 409 ~~pediatric, diagnostic or therapeutic) as set forth in Section 4(1), 6(2) or 7(2)(a), as applicable, have also~~  
 410 ~~been met.~~

411  
 412 **Section 95. Requirements for approval ~~— applicants proposing to expand a cardiac~~**  
 413 **catheterization service ~~by adding a laboratory~~**

414  
 415 Sec. 95. An applicant proposing to add a laboratory to an existing cardiac catheterization service shall  
 416 demonstrate ~~both of~~ the following:

417  
 418 (1) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-  
 419 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE  
 420 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT~~An average of 1,500 procedure~~  
 421 ~~equivalents per room per year was performed in each existing cardiac catheterization laboratory in the~~  
 422 ~~hospital during the most recent 12-month period preceding the date the application was submitted to the~~  
 423 ~~Department;~~

424 (A) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
 425 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

426 (B) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
 427 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

428 (C) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC  
 429 CARDIAC CATHETERIZATION PROCEDURES.

430  
 431 (2) THE APPLICANT HAS PERFORMED An An average A MINIMUM OF of 1,0001,400 procedure  
 432 equivalents will be performed in each cardiac catheterization laboratory (both PER existing and  
 433 proposedAPPROVED) LABORATORIES DURING THE MOST RECENT in the second 12-months of  
 434 operation after initiating operation of the additional room, and annually thereafter PERIOD PRECEDING  
 435 THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

436  
 437 **Section 106. Requirements for approval -- applicants for TO ACQUIRE a mobile cardiac**  
 438 **catheterization networkSERVICE**

439  
 440 Sec. 106. An application involving a mobile cardiac catheterization network shall demonstrate that it  
 441 meets each of the following, as applicable: ACQUIRING A CARDIAC CATHETERIZATION SERVICE  
 442 AND ITS LABORATORIES MEANS OBTAINING POSSESSION AND CONTROL BY CONTRACT,  
 443 OWNERSHIP, LEASE OR OTHER COMPARABLE ARRANGEMENT OR RENEWAL OF A LEASE FOR  
 444 EXISTING ANGIOGRAPHY X-RAY EQUIPMENT. AN APPLICANT PROPOSING TO ACQUIRE A  
 445 CARDIAC CATHETERIZATION SERVICE OR RENEW A LEASE FOR EQUIPMENT SHALL  
 446 DEMONSTRATE THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT:

447  
 448 (1) An application will not result in an increase in the number of mobile cardiac catheterization  
 449 networks with valid CON approval as of the effective date of these standards. AN APPLICANT  
 450 PROPOSING TO ACQUIRE A CARDIAC CATHETERIZATION SERVICE SHALL DEMONSTRATE THE  
 451 FOLLOWING:

452  
 453 (2A) An application will not result in an increase in the number of host facilities being served by a  
 454 mobile cardiac catheterization network from the number of host facilities authorized to be served by that  
 455 same network as of the effective date of these standards THE PROPOSED PROJECT IS PART OF AN  
 456 APPLICATION TO ACQUIRE THE ENTIRE HOSPITAL.

457  
 458 (4)(3B) An application does not involve the initiation of a mobile cardiac catheterization network not  
 459 authorized by a valid CON as of the effective date of these standards AN APPLICATION FOR THE FIRST  
 460 ACQUISITION OF AN EXISTING CARDIAC CATHETERIZATION SERVICE AFTER <INSERT  
 461 EFFECTIVE DATE OF THESE STANDARDS> SHALL NOT BE REQUIRED TO BE IN COMPLIANCE  
 462 WITH THE APPLICABLE VOLUME REQUIREMENTS IN SUBDIVISION (C). THE CARDIAC  
 463 CATHETERIZATION SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES SET FORTH  
 464 IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF OPERATION OF  
 465 THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.

466  
 467 (4C) THE APPLICANT HAS PERFORMED THE FOLLOWING DURING THE MOST RECENT 12-  
 468 MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE  
 469 DEPARTMENT, AS APPLICABLE TO THE PROPOSED PROJECT An application involving the provision  
 470 of mobile cardiac catheterization services shall demonstrate that cardiac catheterization procedures will  
 471 be performed within a hospital. The Department shall consider procedures performed in a mobile cardiac  
 472 catheterization unit as within a hospital if the mobile unit is or will be physically adjoined to the hospital by  
 473 means of a connector such that patients will not be transported outside the hospital in order to receive  
 474 cardiac catheterization services.:

475 (I) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
 476 DIAGNOSTIC CARDIAC CATHETERIZATION PROCEDURES.

477 (II) A MINIMUM OF 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT  
 478 THERAPEUTIC CARDIAC CATHETERIZATION PROCEDURES.

479 (III) A MINIMUM OF 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC  
 480 CARDIAC CATHETERIZATION PROCEDURES.

481 (IV) A MINIMUM OF 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR  
 482 MICROPOLITAN COUNTY WITH ONE LABORATORY.

483 (V) A MINIMUM OF 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN  
 484 COUNTY WITH ONE LABORATORY.

485 (VI) A MINIMUM OF 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION  
 486 LABORATORY FOR TWO OR MORE LABORATORIES.

487 \_\_\_\_\_  
 488 (2) AN APPLICANT PROPOSING TO RENEW A LEASE FOR EXISTING ANGIOGRAPHY X-RAY  
 489 EQUIPMENT SHALL DEMONSTRATE THE RENEWAL OF THE LEASE IS MORE COST EFFECTIVE  
 490 THAN REPLACING THE EQUIPMENT.

### 491 **Section 7. REQUIREMENT FOR MEDICAID PARTICIPATION**

492 \_\_\_\_\_  
 493 \_\_\_\_\_  
 494 Sec. 7. An applicant shall provide verification of Medicaid participation at the time the application is  
 495 submitted to the Department. An applicant that is initiating a new service or is a new provider not  
 496 currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the  
 497 Department within six (6) months from the offering of services if a CON is approved.

### 498 **Section 11. Methodology for computing cardiac catheterization equivalents — procedures and** 499 **weights**

500 \_\_\_\_\_  
 501 \_\_\_\_\_  
 502 Sec..11. (1) The following procedure equivalents shall be used in calculating and evaluating  
 503 utilization of a cardiac catheterization laboratory:

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
Diagnostic cardiac catheterization	1.0	3.0
Therapeutic cardiac catheterization	1.5	3.0
Therapeutic, other (PFO/ASD/Valvuloplasty, LVAD)	2.5	3.5
Diagnostic, peripheral <sup>1</sup>	1.0	2.0
Therapeutic, peripheral — Carotid, Subclavian, Renal, Iliac, Mesenteric	1.5	2.5
Therapeutic, peripheral — Superficial Femoral Artery	2.5	2.5
Therapeutic, peripheral — Infrapopliteal	3.0	3.0
Therapeutic, peripheral — Aorta	4.0	4.0
Diagnostic, electro-physiology (EP)	2.0	3.5
Therapeutic, EP — Permanent Pacemaker, ICD	2.5	5.0
Therapeutic, EP — Ablation Non-AF	3.0	5.0
Therapeutic, EP — Ablation AF or VT	4.0	6.0
Therapeutic, EP — Cardioversion	1.0	1.0
Other procedures (IVC Filter, Temporary Venous Pacemaker, IABP, other radiological procedures)	1.0	2.0
Multiple procedures within the same session (diagnostic and/or therapeutic)	The sum of procedure weights minus 0.5 for each procedure after the first	The sum of procedure weights minus 0.5 for each procedure after the first

<b>PROCEDURE TYPE</b>	<b>PROCEDURE EQUIVALENT</b>	
	<b>Adult</b>	<b>Pediatric</b>
	procedure	procedure
<sup>4</sup> <del>Excludes selective common femoral angiography when performed as part of a diagnostic or therapeutic cardiac catheterization for a possible closure device.</del>		

506  
507 ~~—(2) For purposes of evaluating whether an applicant meets applicable volume requirements set forth~~  
508 ~~in these standards, cardiac catheterization procedures per laboratory must be met exclusive of the intra-~~  
509 ~~vascular catheterization procedures when considering expansion or replace/upgrade. The peripheral~~  
510 ~~non-cardiac procedures shall count toward the total volume requirements for procedures, but the~~  
511 ~~minimum volumes remain the same for initiation of cardiac catheterization services.~~

512 ~~—(a) Intra-vascular catheterization is a medical diagnostic or therapeutic procedure during which a~~  
513 ~~catheter is inserted into an artery in a patient. Subsequently, the free end of the catheter is manipulated~~  
514 ~~by a physician to travel along the course of a non-coronary artery. X-rays and an electronic image~~  
515 ~~intensifier are used as aids in placing the catheter tip into the desired position. When the catheter is in~~  
516 ~~place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the~~  
517 ~~artery. Intra-vascular catheterization shall not include "float catheters" or "hemodynamic monitoring~~  
518 ~~catheters" which are performed, and/or are used at the bedside for the purposes of monitoring or~~  
519 ~~administering hemodynamic medication.~~

520  
521 **Section 128. Project delivery requirements —AND terms of approval for all applicants**  
522

523 Sec. 128. ~~(1)~~ An applicant shall agree that, if approved, the project-CARDIAC CATHETERIZATION  
524 SERVICE AND ALL EXISTING AND APPROVED LABORATORIES shall be delivered in compliance with  
525 the following terms of CON-approval:  
526

527 (a1) Compliance with these standards.  
528

529 ~~—(b) Compliance with applicable operating standards.~~

530 (e2) Compliance with the following quality assurance standards:

531 (iA) The approved services shall be operating at the applicable required volumes within the time  
532 periods specified in these standards, and annually thereafter Cardiac catheterization procedures shall be  
533 performed in a cardiac catheterization laboratory located within a hospital, and have within, or  
534 immediately available to the room, dedicated emergency equipment to manage cardiovascular  
535 emergencies.

536 (iiB) The approved services shall be staffed with sufficient medical, nursing, technical and other  
537 personnel to permit regular scheduled hours of operation and continuous 24-hour on-call availability.

538 (iiiC) The medical staff and governing body shall receive and review at least annual reports describing  
539 the activities of the cardiac catheterization service including: complication rates ~~(including emergency~~  
540 ~~surgical procedures);~~<sub>1</sub> morbidity and mortality ~~data;~~<sub>1</sub> success rates and the number of procedures  
541 performed.

542 (ivD) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization  
543 procedures shall perform, as the primary operator, a minimum of 75 adult therapeutic cardiac  
544 catheterization procedures per year in the second 12 months after being credentialed to perform  
545 procedures at the applicant hospital, and annually thereafter. The annual case load for a physician  
546 means adult therapeutic cardiac catheterization procedures performed by that physician in any hospital or  
547 in any combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~  
548 ~~annual basis, the name and the number of adult therapeutic cardiac catheterization procedures~~  
549 ~~performed by each physician credentialed to perform adult therapeutic cardiac catheterization~~  
550 ~~procedures.~~

551 (vE) Each physician credentialed by a hospital to perform pediatric diagnostic cardiac catheterizations  
552 shall perform, as the primary operator, a minimum of 50 pediatric diagnostic cardiac catheterization  
553 procedures per year in the second 12 months after being credentialed to perform procedures at the  
554 applicant hospital, and annually thereafter. The annual case load for a physician means pediatric  
555 diagnostic cardiac catheterization procedures performed by that physician in any hospital or in any  
556 combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~  
557 ~~annual basis, the name and the number of pediatric diagnostic cardiac catheterization procedures~~

558 performed by each physician credentialed to perform pediatric diagnostic cardiac catheterization  
559 procedures.

560 (viF) Each physician credentialed by a hospital to perform pediatric therapeutic cardiac  
561 catheterizations shall perform, as a primary operator, a minimum of 25 pediatric therapeutic cardiac  
562 catheterizations per year in the second 12 months after being credentialed to perform procedures at the  
563 applicant hospital, and annually thereafter. The annual case load for a physician means pediatric  
564 therapeutic cardiac catheterization procedures performed by that physician in any hospital or in any  
565 combination of hospitals. ~~The applicant shall be responsible for reporting to the Department, on an~~  
566 ~~annual basis, the name and the number of pediatric therapeutic cardiac catheterization procedures~~  
567 ~~performed by each physician credentialed to perform pediatric therapeutic cardiac catheterization~~  
568 ~~procedures.~~

569 ~~—(vii) For purposes of evaluating subdivisions (v) or (vi), a diagnostic cardiac catheterization followed~~  
570 ~~by a therapeutic cardiac catheterization (including electrophysiology studies) in the same session shall be~~  
571 ~~considered both 1 diagnostic procedure and 1 therapeutic procedure. Two physicians, one credentialed~~  
572 ~~to perform diagnostic cardiac catheterizations and one credentialed to perform therapeutic cardiac~~  
573 ~~catheterizations, each may be considered to have performed either 1 diagnostic or 1 therapeutic~~  
574 ~~catheterization if both were involved in performing a diagnostic cardiac catheterization procedure followed~~  
575 ~~by a therapeutic procedure in the same session.~~

576 (viiiG) An applicant proposing to offer an adult diagnostic cardiac catheterization service shall have a  
577 minimum of two (2) appropriately trained physicians on its active hospital staff. ~~For purposes of~~  
578 ~~evaluating this subsection, The Department shall consider it prima facie~~ MAY ACCEPT OTHER evidence  
579 OR SHALL CONSIDER IT of appropriate training if the staff physicians:

580 (A) are trained consistent with the recommendations of the American College of Cardiology;  
581 (B) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and  
582 (C) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding  
583 12 months.

584 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~  
585 ~~physicians performing adult diagnostic cardiac catheterizations are appropriately trained.~~

586 (ixH) An applicant proposing to offer an adult therapeutic cardiac catheterization service shall have a  
587 minimum of two (2) appropriately trained physicians on its active hospital staff. ~~For purposes of~~  
588 ~~evaluating this subsection, The Department shall consider it prima facie~~ MAY ACCEPT OTHER evidence  
589 OR SHALL CONSIDER IT of appropriate training if the staff physicians:

590 (A) are trained consistent with the recommendations of the American College of Cardiology;  
591 (B) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and  
592 (C) have each performed a minimum of 75 adult therapeutic cardiac catheterization procedures in the  
593 preceding 12 months.

594 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~  
595 ~~physicians performing adult therapeutic cardiac catheterizations are appropriately trained.~~

596 (xI) An applicant proposing to offer a pediatric cardiac catheterization service shall demonstrate  
597 an HAVE AN appropriately trained physician(s) shall be on the ITS active hospital staff to perform  
598 diagnostic or therapeutic, as applicable, pediatric cardiac catheterizations. ~~For purposes of evaluating~~  
599 ~~this subsection, The Department shall consider it prima facie~~ MAY ACCEPT OTHER evidence of OR  
600 SHALL CONSIDER IT appropriate training if the staff physician(s) is:

601 (A) IS board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;  
602 (B) IS credentialed by the hospital to perform diagnostic or therapeutic, as applicable, pediatric  
603 cardiac catheterizations; and

604 (C) HAS trained consistently with the recommendations of the American College of Cardiology.

605 ~~—However, the applicant may submit and the Department may accept other evidence that the staff~~  
606 ~~physician(s) performing pediatric cardiac catheterizations is appropriately trained.~~

607 (xiJ) A cardiac catheterization service shall be directed by an appropriately trained physician. ~~For~~  
608 ~~purposes of evaluating this subsection, The Department shall consider it prima facie evidence of~~  
609 appropriate training and experience of the cardiac catheterization service OF THE director if the physician  
610 is board certified in cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable.

611 The director of an adult cardiac catheterization service shall have performed at least 200 catheterizations  
 612 per year during each of the ~~5-FIVE~~ preceding years. ~~However, the applicant may submit and~~ The  
 613 Department may accept other evidence that the ~~cardiac catheterization service~~ director is appropriately  
 614 trained.

615 ~~(xiiiK)~~ An ~~approved~~ cardiac catheterization service shall be operated consistently with the  
 616 recommendations of the American College of Cardiology.

617  
 618 (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

619 ~~(xiiiA)~~ The SERVICE shall accept referrals for cardiac catheterization services from all appropriately  
 620 licensed health care practitioners.

621 ~~(B)~~ An applicantTHE SERVICE shall participate in Medicaid at least 12 consecutive months within  
 622 the first two years of operation and ~~continue to participate~~ annually thereafter.

623 ~~(d)~~ Compliance with the following terms of approval:

624 ~~(i)~~ Equipment that is replaced shall be removed from the cardiac catheterization service.

625 ~~(ii)~~ The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

626 ~~(AC)~~ THE SERVICE SHALL not deny cardiac catheterization services to any individual based on ability  
 627 to pay or source of payment;\_

628 ~~(B)~~ Provide cardiac catheterization services to all individuals based on the clinical indications of need  
 629 for the service; and

630 ~~(CD)~~ Maintain information by payor and non-paying sources to indicate the volume of care from each  
 631 source provided annuallyTHE OPERATION OF AND REFERRAL OF PATIENTS TO THE CARDIAC  
 632 CATHETERIZATION SERVICE SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS  
 633 AMENDED BY 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

634  
 635 (4) Compliance with selective contracting requirements shall not be construed as a violation of this  
 636 termTHE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:;

637 (A) THE SERVICE SHALL BE OPERATING AT OR ABOVE THE APPLICABLE VOLUMES IN THE  
 638 SECOND 12 MONTHS OF OPERATION OF THE SERVICE, OR AN ADDITIONAL LABORATORY, AND  
 639 ANNUALLY THEREAFTER:

640 (I) 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT DIAGNOSTIC CARDIAC  
 641 CATHETERIZATION PROCEDURES.

642 (II) 300 PROCEDURE EQUIVALENTS IN THE CATEGORY OF ADULT THERAPEUTIC CARDIAC  
 643 CATHETERIZATION PROCEDURES.

644 (III) 600 PROCEDURE EQUIVALENTS IN THE CATEGORY OF PEDIATRIC CARDIAC  
 645 CATHETERIZATION PROCEDURES.

646 (IV) 500 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A RURAL OR MICROPOLITAN  
 647 COUNTY WITH ONE LABORATORY.

648 (V) 750 PROCEDURE EQUIVALENTS FOR A HOSPITAL IN A METROPOLITAN COUNTY WITH  
 649 ONE LABORATORY.

650 (VI) 1,000 PROCEDURE EQUIVALENTS PER CARDIAC CATHETERIZATION LABORATORY FOR  
 651 TWO OR MORE LABORATORIES.

652 (VII) 36 ADULT PRIMARY PCI CASES FOR A PRIMARY PCI SERVICE.

653 ~~(iiiB)~~ The ~~applicant~~HOSPITAL shall participate in a data collection network established and  
 654 administered by the Department or its designee. ~~The Data~~ may include, but is not limited to, annual  
 655 budget and cost information, operating schedules, ~~and PATIENT demographics~~demographics, diagnostic,  
 656 morbidity and mortality information, ~~as well as the volume of care provided to patients from all~~AND payor  
 657 ~~sources and other data requested by the Department or its designee and approved by the Commission.~~  
 658 ~~The applicant shall provide the required data on a separate basis for each separate and distinct site or~~  
 659 ~~unit as required by the Department, in a format established by the Department and in a mutually agreed~~  
 660 ~~upon media.~~ The Department may ~~elect to~~verify the data through on-site review of appropriate records.

661 ~~(ivC)~~ The ~~applicant~~HOSPITAL shall participate in a quality improvement data registry administered by  
 662 the Department or its designee. The ~~Department or its designee shall require that the~~  
 663 ~~applicant~~HOSPITAL SHALL submit a summary ~~report~~reports as required by the Department. The

664 ~~applicant HOSPITAL~~ shall provide the required data in a format established by the Department or its  
 665 designee. The ~~applicant HOSPITAL shall be~~ liable for the cost of data submission and on-site reviews  
 666 in order for the Department to verify and monitor volumes and assure quality. ~~An applicant shall~~ **THE**  
 667 **HOSPITAL MUST** become a member of the data registry upon initiation of the service and continue to  
 668 participate annually thereafter **FOR THE LIFE OF THAT SERVICE**.

669 ~~—(v) The applicant shall provide the Department with a notice stating the date on which the first~~  
 670 ~~approved service is performed and such notice shall be submitted to the Department consistent with~~  
 671 ~~applicable statute and promulgated rules.~~

672 ~~—(vi) The applicant shall accept referrals for cardiac catheterization services from all appropriately~~  
 673 ~~licensed health care practitioners.~~

674  
 675 ~~—(2) The agreements and assurances required by this section shall be in the form of a certification~~  
 676 ~~agreed to by the applicant or its authorized agent.~~

677  
 678 **Section 13. Project delivery requirements—additional terms of approval for applicants approved**  
 679 **under Section 5**

680 ~~—Sec. 13. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with~~  
 681 ~~the following terms of CON approval:~~

682  
 683 ~~\_\_ (a5) COMPLIANCE WITH THE FOLLOWING PRIMARY PCI REQUIREMENTS, IF APPLICABLE:~~

684 ~~\_\_ (A) THE requirements set forth in Section 3(4).~~

685 ~~\_\_ (B) THE HOSPITAL shall immediately report to the Department any changes in the interventional~~  
 686 ~~cardiologists who perform the primary PCI procedures.~~

687 ~~Compliance with requirements of the standards set forth in Section 53(14).~~

688  
 689 ~~(2BC) The applicant HOSPITAL shall have performed a minimum of 48-36 primary PCI procedures at~~  
 690 ~~the facility HOSPITAL in the preceding 12--months PERIOD OF OPERATION OF THE SERVICE and~~  
 691 ~~annually thereafter.~~

692  
 693 ~~\_\_ (D) THE HOSPITAL SHALL MAINTAIN A 90-MINUTE DOOR-TO-BALLON TIME OR LESS IN AT~~  
 694 ~~LEAST 75% OF THE PRIMARY PCI SESSIONS.~~

695 ~~(3E) The applicant HOSPITAL shall participate in a data registry, administered by the Department or~~  
 696 ~~its designee. The Department or its designee shall require that the applicant submit data on all~~  
 697 ~~consecutive cases of primary PCI as is necessary to comprehensively assess and provide comparative~~  
 698 ~~analyses of case selection, processes and outcome of care, and trend in efficiency. The applicant shall~~  
 699 ~~provide the required data in a format established by the Department or its designee. The applicant shall~~  
 700 ~~be liable for the cost of data submission and on-site reviews in order for the Department to verify and~~  
 701 ~~monitor volumes and assure quality.~~

702  
 703 **Section 9. Methodology for computing cardiac catheterization equivalents—procedures and**  
 704 **weights**

705  
 706 ~~Sec. 9. The following procedure equivalents shall be used in calculating PROCEDURE~~  
 707 ~~EQUIVALENTS and evaluating utilization of a cardiac catheterization SERVICE AND ITS laboratories:~~

<b>PROCEDURE TYPE</b>	<b>PROCEDURE EQUIVALENT</b>	
	<b>Adult</b>	<b>Pediatric</b>
<b>Diagnostic cardiac catheterization/PERIPHERAL SESSIONS</b>	<b>1.5</b>	<b>2.7</b>
<b>Therapeutic cardiac catheterization/PERIPHERAL SESSIONS</b>	<b>2.7</b>	<b>4.0</b>
<b>COMPLEX PERCUTANEOUS VALVULAR SESSIONS*</b>	<b>4.0</b>	<b>7.0</b>
<b>* COMPLEX PERCUTANEOUS VALVULAR SESSIONS INCLUDES, BUT IS NOT LIMITED TO, PROCEDURES PERFORMED PERCUTANEOUSLY OR WITH SURGICAL ASSISTANCE TO REPAIR OR</b>		

PROCEDURE TYPE	PROCEDURE EQUIVALENT	
	Adult	Pediatric
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 SERVICES.		

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**Section 4410. Documentation of projections**

Sec. 4410. An applicant required to project volumes of service under sections 4, 5, 6, and 7 shall specify how the volume projections were developed. This specification of the projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable. 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.

**Section 4511. Comparative reviews; Effect on prior CON Review Standards; ~~comparative reviews~~**

Sec. 4511. ~~(4)-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 ~~March 9, 2004~~ DECEMBER 11, 2007 and effective on ~~June 4, 2004~~ FEBRUARY 25, 2008.

~~(2) Projects reviewed under these standards shall not be subject to comparative review.~~

**APPENDIX A**

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<b>HEALTH SERVICE AREAS</b>	<b>COUNTIES</b>		
<b>1 – SOUTHEAST</b>	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
<b>2 – MID-SOUTHERN</b>	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE
<b>3 – SOUTHWEST</b>	BARRY	CALHOUN	ST. JOSEPH
	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
<b>4 – WEST</b>	ALLEGAN	MASON	NEWAYGO
	IONIA	MECOSTA	OCEANA
	KENT	MONTCALM	OSCEOLA
	LAKE	MUSKEGON	OTTAWA
<b>5 - GLS</b>	GENESEE	LAPEER	SHIAWASSEE
<b>6 – EAST</b>	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	
<b>7 – NORTHERN LOWER</b>	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GRAND TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
<b>8 – UPPER PENINSULA</b>	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

**APPENDIX AB**

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**CON REVIEW STANDARDS**  
**FOR CARDIAC CATHETERIZATION SERVICES**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

The Hospital Bed Standard Advisory Committee (HBSAC) has met three times on June 23, 2011, July 20, 2011 and August 25, 2011. Four additional meetings are scheduled, and final recommendations will be completed, on or before the final meeting of the HBSAC on December 20, 2011.

The HBSAC assigned each of the seven (7) elements of the charge approved by the CON Commission on January 26, 2011 to a member of the committee and subgroups have been actively working between committee meetings. The committee has already finalized recommendations for items 3, 4 and 5 of the charge dealing with size requirements for replacement hospitals, the elimination of the existing Addendum for HIV infected individuals, and the requirement for payment of all outstanding debt obligations for QAAP and CMP before receiving or replacing hospital beds respectively. Work has not commenced on item 2 (review of project delivery requirements) but is anticipated to begin this month. MDCH staff is working with the committee on item 7 (any technical changes or updates to be consistent with other CON standards and the Public Health Code).

The intensity of discussion and review has centered on items 1 (the review and update of the subarea methodology) and item 6 (considering the proper number of beds for Michigan's population with consideration of concepts of reduce "excess beds").

With regards to item 1 on subarea methodology, the subgroup has presented at the last two meetings various approaches and updates to the methodology. At the present time, there is the certainty that a new methodology will be recommended to the CON Commission. There is consensus on the committee that the newly formed methodology needs to be adaptable and sustainable for several years to come and consider some of the unique characteristics of urban and rural communities within the state. It is anticipated that this methodology will be finalized within the next two meetings of the HBSAC.

Item 6 on the proper number of beds and possible reduction of "excess" beds has engendered many ideas and robust discussion. The subgroup for this item has met three times with other meetings planned between now and November. Formal proposals were submitted by the Economic Alliance of Michigan and these proposals have served as a platform for the discussions that have included members of the HBSAC, non-members of the HBSAC from providers, business and labor as well as representatives from the MDCH licensing division. The group is reviewing proposals to determine their impact on cost, quality and access to acute care services. Although predicting the final outcome of these discussions is not clear at the time of this update, I have high confidence that substantive recommendation(s) will be forthcoming in this area.

In conclusion, the HBSAC is working well together and making progress towards addressing the full charge from the CON Commission. I would also like to compliment the staff of MDCH for their support, expertise and guidance in this process.

Respectively submitted,

Robert F. Casalou

CERTIFICATE OF NEED  
**2<sup>nd</sup> Quarter Compliance Report to the CON Commission**  
 October 1, 2010 through September 30, 2011 (FY 2011)

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.

Activity	3 <sup>rd</sup> Quarter	Year-to-Date
Approved projects requiring 1-year follow up	105	251
Approved projects contacted on or before anniversary date	77	168
Approved projects completed on or before 1-year follow up	73%	62%
CON approvals expired due to noncompliance with Part 222	21	66
Total follow up correspondence sent	280	586
Total approved projects still ongoing	357	

*Compliance:* The Evaluation Section continues to conduct statewide compliance checks based on 2010 annual survey data.

CERTIFICATE OF NEED  
**3<sup>rd</sup> Quarter Program Activity Report to the CON Commission**  
 October 1, 2010 through September 30, 2011 (FY 2011)

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.

Activity	3 <sup>rd</sup> Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	94	N/A	347	N/A
Letters of Intent Processed within 15 days	94	100%	346	99%
Letters of Intent Processed Online	94	100%	345	99%

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.

Activity	3 <sup>rd</sup> Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	110	N/A	264	N/A
Applications Processed within 15 Days	110	100%	263	99%
Applications Incomplete/More Information Needed	52	47%	122	46%
Applications Filed Online*	96	98%	215	98%
Application Fees Received Online*	19	20%	54	25%

\* 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.

Activity	3 <sup>rd</sup> Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	41	100%	143	100%
Substantive Applications	20	100%	79	100%
Comparative Applications	2	100%	11	100%

*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.

Activity	3 <sup>rd</sup> Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	1	N/A
Decisions Issued within 10 workings Days	0	N/A	1	100%

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

Activity	3 <sup>rd</sup> Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	18	100%	57	98%

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.

Activity	3 <sup>rd</sup> Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

### **Other Measures**

Activity	3 <sup>rd</sup> Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	33	N/A	77	N/A
FOIA Requests Processed on Time	33	100%	77	100%
Number of Applications Viewed Onsite	3	N/A	6	N/A

FOIA – Freedom of Information Act.

STATE OF MICHIGAN  
IN THE CIRCUIT COURT FOR THE COUNTY OF LIVINGSTON

MEDILODGE OF HOWELL, INC.,  
Appellant,

Case No. 11-26078-AV

Hon. Michael P. Hatty

v.

MICHIGAN DEPARTMENT OF COMMUNITY  
HEALTH, and TRILOGY – HOWELL HEALTH  
CAMPUS  
Appellees.

**TRUE COPY**  
MICHAEL P. HATTY  
44th Circuit Court

**OPINION & ORDER**  
**ON APPELLEE'S MOTION TO DISMISS**

At a session of the 44<sup>th</sup> Circuit Court,  
held in the City of Howell, Livingston County,  
on the 1 day of September 2011

THIS MATTER HAVING COME before the Court on Appellee Michigan Department of Community Health's ["the Department"] motion to dismiss under MCR 7.105(J), and the Court having received briefs from all three parties and being otherwise familiar with the record and controlling law, the Court GRANTS appellee's motion to dismiss for the reasons that follow.

**I. Procedural History**

Medilodge of Howell ["Medilodge"] and the Trilogy – Howell Health Campus ["Trilogy"] both applied for the issuance of a Certificate of Need for new beds to be added to their nursing home facilities during the 2010 application cycle. Medilodge had an existing facility in Howell and Trilogy intended to open a new facility in Howell. Because both applications were at the time of submission competing for a limited number of beds in the Livingston County area and at that time the Department could not grant both, the two applications were submitted together for a comparative review per MCL 333.22229. In its initial

proposed decision on November 23, 2010, the Department recommended granting Medilodge's application and denying Trilogy's. Trilogy sought an administrative hearing on its denial, and prior to the hearing, Medilodge moved to dismiss the request for hearing. However, before Medilodge's motion to dismiss was decided, the state substantially increased the number of beds available in the Livingston County area. As a result, Trilogy's application was remanded to the Department for reconsideration, and the Department ultimately issued a single decision granting both Medilodge's and Trilogy's applications for beds. The Department's final decision approving the two applications was rendered on May 13, 2011.

Medilodge filed an appeal of that decision to this Court on June 9, 2011 arguing that the decision violated the statute and administrative rules governing Certificate of Need applications, exceeded the jurisdiction of the Department, has materially prejudiced Medilodge, and it is otherwise arbitrary and capricious. The Department filed this motion to dismiss Medilodge's appeal under MCR 7.105(J) on July 22, 2011. Trilogy has filed a concurrence in the Department's motion. The motion was initially scheduled for hearing on August 11, 2011, but the request for hearing was withdrawn and the motion was submitted to the court per MCR 7.105(J)(6).

## **II. Analysis**

The Department does not identify the subsection of MCR 7.105(J) under which it moves. The Department advances two arguments for dismissal, both of which contend that Medilodge may not invoke the jurisdiction of this Court because it lacks standing to bring this appeal. The Department argues that Medilodge lacks standing because (a) Medilodge's application was approved and its CON was granted so it has not suffered any particular injury, and (b) the statute precludes an appeal by a competitor and provides that the final decision "may be appealed only

by the applicant . . .” Under MCR 7.105(J)(2),

“A motion to dismiss an appeal may be made by a respondent on the ground that:

- (a) the appeal is not within the jurisdiction of the court;
- (b) the appeal was not taken or pursued in conformity with the rules, or a special statutory review procedure;
- (c) the petitioner has failed to exhaust administrative remedies; [or]
- (d) the appeal is moot.”

The Department apparently contends that this Court lacks jurisdiction, and Trilogy has further argued in its concurrence that the appeal should be dismissed because it is moot.

The core issue of this motion, framed as a question of “standing,” is whether or not the statute provides Medilodge with an avenue for appeal of the decision granting Trinity’s application for a CON. MCL 333.22231(9) states:

“Within 30 days after the final decision of the director, the final decision of the director may be appealed *only by the applicant* and only on the record directly to the circuit court for the county where the applicant has its principal place of business in this state or the circuit court for Ingham County.” (emphasis supplied).

The Department and Trilogy both argue that the statutory language referencing “*the applicant*” and relevant case law<sup>1</sup> dictate that a competitor cannot appeal the grant of a CON to another applicant. Medilodge counters that standing exists under case law providing standing to businesses for injuries inflicted by illegal competition. Further, Medilodge contends that the case *Michigan Affiliated Healthcare System* case cited by Trilogy and the Department is not on point because it did not involve comparative review, and Medilodge indicates that the comparative review process has placed it in a position to appeal the grant of a CON to Trilogy.

The Court agrees that the statute does not provide Medilodge with an avenue for appeal of the Department’s grant of a CON to Trilogy. The statutory language is clear that a final decision may be appealed “only by the applicant . . .” The legislature could have chosen language more accommodating to the comparative review process such as referring to “*an*

<sup>1</sup> See *Michigan Affiliated Healthcare System, Inc v Dep’t of Public Health*, 173 Mich App 68 (1988).

applicant,” and thus allow any applicant in the comparative review process to appeal any aspect of the decision. Instead, it chose restrictive language that is clearly intended to limit appeals only to the entity most directly affected by a grant or denial of a CON. Similarly, the *Michigan Affiliated Healthcare System* case confirmed the restrictive purpose of that statutory language when the Court of Appeals ruled that “[t]he legislation providing for the CON procedure does not explicitly or implicitly confer standing to a health care facility seeking to invalidate the grant of a CON application to a competing facility.”<sup>2</sup>

Although the procedural stance of the parties in *Michigan Affiliated Healthcare System* was different than that of the parties in this case, the comparative review between Medilodge and Trilogy does not alter Medilodge’s posture as a competing “health care facility seeking to invalidate the grant of a CON application to a competing facility.”<sup>3</sup> While Medilodge and Trilogy’s applications were decided under comparative review, the continued existence of comparative review after the state’s decision to revise the CON Review Standards and increase the bed need in the Livingston County area on March 11, 2011 was a relative fiction. Medilodge and Trilogy were no longer competing for the same beds due to the revised standards that added an additional 118 beds in addition to those that Medilodge and Trilogy had initially been competing for—an approximately 20% increase in the overall availability of beds in the Livingston County area. Therefore, under both the language of the statute and the case law interpreting it, Medilodge lacks the right to invoke this Court’s review.

Whether the Court calls this a lack of standing, a general lack of jurisdiction, or a failure to take the appeal pursuant to the review statute, dismissal of this appeal is mandatory. A party

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<sup>2</sup> *Id.* at 70.

<sup>3</sup> *Id.*

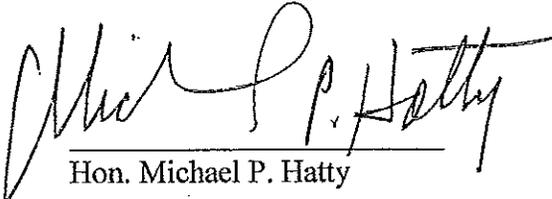
who lacks standing may not properly invoke the jurisdiction of the Court to review a case.<sup>4</sup> In addition, the Circuit Court's appellate jurisdiction is subject to the restrictions imposed by law.<sup>5</sup> Further, under MCR 7.105(J)(2)(b), it is a basis for dismissal that "the appeal was not taken or pursue in conformity with the rules, or a special statutory review procedure . . ." which undoubtedly includes the restrictions of the review statute involved in this case. Because Medilodge does not have a right of appeal under MCL 333.22231(9), all of these grounds serve as a basis for dismissal, and require the Court to dismiss this case.

Finally, Trilogy has argued that the Medilodge appeal is moot since Medilodge does not have a vested property or liberty right at stake<sup>6</sup> other than a speculative future interest. However, the Court need not rule on whether this appeal is moot as the Court has already determined that there are several grounds mandating dismissal.

### III. Conclusion

For the reasons stated above, Medilodge is not entitled to appeal the Department's grant of Trilogy's CON Application, and the Court DISMISSES Medilodge's appeal under MCR 7.105(J)(2).

IT IS SO ORDERED.

  
Hon. Michael P. Hatty

<sup>4</sup> See, e.g., *Covert Twp v Consumers Power Co*, 217 Mich App 352, 356 (1996).

<sup>5</sup> Const 1963, art 6 § 13.

<sup>6</sup> *W A Foote Memorial Hospital v Dep't of Public Health*, 210 Mich App 516, 524 (1994).

**DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN**

	2010												2011											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Bone Marrow Transplantation Services																						PH		
Cardiac Catheterization Services			•	•	•	•	•	•	•	PH	■	■	■	■	■	■	■	•R—	•	•	—	•P	•	•▲F
Computed Tomography (CT) Scanner Services**	•R	•	•	•			■	■	■	■	■	■	■	•	—	•	•P	•▲	•P	•	•▲F			
Heart/Lung and Liver Transplantation Services																						PH		
Hospital Beds and Addendum for HIV Infected Individuals										PH•	•	•	•R	•S	•S	•S		■	■	■	■	■	■	
Magnetic Resonance Imaging (MRI) Services								•R—	P•	•	•▲F	•	•	•R	•	•	•R—	•P	•	•▲F	PH			
Megavoltage Radiation Therapy (MRT) Services/Units										PH	•	•	•R	•	•R	•	•	•R—	•P	•	•▲F			
Open Heart Surgery Services										PH	•	•	•R	Pending CCSAC							D			
Pancreas Transplantation Services																						PH		
Positron Emission Tomography (PET) Scanner Services										PH	•	•	•R	•	•R	•	•	•R—	•P	•	•▲F			
Psychiatric Beds and Services																						PH		
Surgical Services										PH	•	•	•R	•	•	•	•	•	•	•R—	•P	•	•▲F	
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																								
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	
Commission & Department Responsibilities			M			M			M			M			M			M			M		M	

- 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
  - A - Commission Action
  - C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
  - D - Discussion
  - F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
  - M - Monitor service or new technology for changes
  - P - Commission public hearing/Legislative comment period
  - PH - Public Hearing for initial comments on review standards
  - R - Receipt of report
  - S - Solicit nominations for standard advisory committee or standing committee membership

**SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS\***

<b>Standards</b>	<b>Effective Date</b>	<b>Next Scheduled Update**</b>
Air Ambulance Services	August 12, 2010	2013
Bone Marrow Transplantation Services	December 3, 2010	2012
Cardiac Catheterization Services	February 25, 2008	2014
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2014
Magnetic Resonance Imaging (MRI) Services	March 11, 2011	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	2014
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2013
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2013
Open Heart Surgery Services	February 25, 2008	2014
Pancreas Transplantation Services	November 5, 2009	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2014
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	2014
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2013

\*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 Hearing 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.