

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

Wednesday, March 18, 2015

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

**APPROVED MINUTES**

**I. Call to Order & Introductions**

Chairperson Keshishian called the meeting to order at 9:32 a.m.

A. Members Present:

Denise Brooks-Williams  
Gail J. Clarkson, RN  
Kathleen Cowling, DO  
James B. Falahee, Jr., JD  
Robert Hughes  
Marc Keshishian, MD, Chairperson  
Charles Gayney  
Robert Hughes  
Jessica Kochin  
Gay L. Landstrom, RN arrived at 9:41 a.m.  
Luis Tomatis, MD

B. Members Absent

Suresh Mukherji, MD, Vice-Chairperson

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Tulika Bhattacharya  
Scott Blakeney  
Elizabeth Hertel  
Natalie Kellogg  
Beth Nagel  
Tania Rodriguez  
Brenda Rogers

## **II. Review of Agenda**

Motion by Commissioner Falahee, seconded by Commissioner Clarkston, to approve the agenda as presented. Motion Carried with a vote of 9 – Yes, 0 – No, and 0 - Abstained.

## **III. Declaration of Conflicts of Interests**

No conflicts were declared.

## **IV. Review of Minutes of January 28, 2015**

Motion by Commissioner Tomatis, seconded by Commissioner Brooks-Williams, to approve the minutes of January 28, 2015 as presented. Motion Carried with a vote of 9- Yes, 0- No, and 0- Abstained.

## **V. Cardiac Catheterization (CC) Services – Standard Advisory Committee (SAC) Final Report**

Ms. Turner-Bailey gave the Commission a written report (see Attachment A) and presentation based on SAC outcomes (see Attachment B).

### **A. Public comment**

Douglas Weaver, MD, Henry Ford Health System  
Luay Alkotob, MD, Hurley Medical

### **B. Commission Discussion**

Discussion followed.

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

Motion by Commissioner Brooks-Williams, seconded by Commissioner Landstrom, to accept the language as presented (see Attachment C) and move it forward for public hearing and to the Joint Legislative Committee (JLC) for review. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

## **VI. Megavoltage Radiation Therapy (MRT) Services/ Units – SAC Final Report**

Dr. Paul Chuba gave the Commission a written report (see Attachment D) and presentation based on SAC outcomes (see Attachment E).

### **A. Public Comment**

Dennis MCCafferty, Economic Alliance for Michigan (EAM)

B. Commission Discussion

Discussion followed.

C. Commission Proposed Action

Motion by Commissioner Falahee, seconded by Commissioner Gayney, to accept the proposed language as presented (see Attachment F) and to move it forward for public hearing and to the JLC for review; with the encouragement of anyone with quality data measures to bring it forward to the public hearing for the Commission's consideration before final action. Motion Carried in a vote of 8 - Yes, 2 - No, and 0 - Abstained.

**VII. Positron Emission Tomography (PET) Scanner Services – Review of Draft Language**

Ms. Rogers gave a review of the draft language including mostly technical edits (see Attachment G).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Proposed Action

Motion by Commissioner Gayney, seconded by Commissioner Cowling, to accept the proposed language as presented and move it forward for public hearing and to the JLC for review. Motion Carried in a vote of 10- Yes, 0- No, and 0- Abstained.

Break from 11:41 a.m. - 11:53 a.m.

**VIII. Bone Marrow Transplantation (BMT) Services Discussion**

Chairperson Keshishian gave a review of the January 28<sup>th</sup> CON Special Commission Meeting.

A. Public Comment

Dr. Adil Akhtar, Beaumont Hospital  
Sean Gehle, Ascension Health  
Dr. Edward Peres, Henry Ford Health System  
Dr. Joseph Uberti, Karmanos Cancer Center

Dr. Greg Yanik, University of Michigan

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Kochin, to appoint a SAC and to defer to the chairperson to develop the charge for the SAC working with the Department. Motion Carried in a vote of 8 - Yes, 2 - No, and 0 - Abstained.

**IX. Psychiatric Beds and Services – Effective Date of Updated Bed Need**

Ms. Rogers gave an overview of the updated Psychiatric Beds and Services bed need numbers (see Attachment H).

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Tomatis, seconded by Commissioner Falahee, to set an effective date of April 1, 2015 for the Psychiatric Bed and Services bed need numbers. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

**X. Legislative Report**

Ms. Hertel gave a verbal update on legislative activity.

**XI. Administrative Update**

A. Planning and Access to Care Section Update

Ms. Nagel gave a verbal update of the section.

B. CON Evaluation Section Update

1. Compliance Report (see Attachment I)

Ms. Bhattacharya gave a summary of the compliance report.

2. Quarterly Performance Measures (see Attachment J)

Ms. Bhattacharya gave a summary of the quarterly performance report.

**XII. Legal Activity Report**

Mr. Potchen stated that there is no active CON litigation to report.

**XIII. Future Meeting Dates** – June 11, 2015, September 24, 2015, and December 10, 2015

**XIV. Public Comment**

None.

**XV. Review of Commission Work Plan**

Ms. Rogers gave an overview of the Work Plan (see Attachment K) including today's actions.

A. Commission Discussion

None.

B. Commission Action

Motion by Commissioner Hughes, seconded by Commissioner Cowling, to accept the work plan as presented. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

**XVI. Election of Officers**

Motion by Commissioner Tomatis, seconded by Commissioner Falahee, to nominate and re-elect Chairperson Keshishian as Chairperson of the Commission. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Motion by Commissioner Cowling, seconded by Commissioner Falahee, to nominate and re-elect Vice-Chairperson Mukherji as Vice-Chairperson of the Commission. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

**XVII. Adjournment**

Motion by Commissioner Brooks-Williams, seconded by Commissioner Kochin, to adjourn the meeting at 12:28 p.m. Motion Carried in a vote of 10 - Yes, 0 - No, and 0 - Abstained.

Cardiac Catheterization Standard Advisory Committee  
Report to the Certificate of Need Commission

March 18, 2015

Mr. Chairman,

The Cardiac Catheterization Standard Advisory Committee (CCSAC) was approved by the Commission on January 28, 2014. The charge to the CCSAC was as follows:

At a minimum, the Cardiac Catheterization Services SAC should consider reviewing and recommending any necessary changes to the Cardiac Catheterization Services Standards regarding the following:

1. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations. If it is recommended that these services should be allowed:
  - a. consider the impacts of cost, quality and access under the current standards in determining need for this service; and
  - b. provide specific criteria for this service including initiation and maintenance volumes as well as patient safety and quality criteria.
2. Develop language for a second acquisition, similar to that of other standards.
3. Develop specific measurable quality metrics in the project delivery requirements, similar to that of Open Heart Surgery (OHS) standards.
4. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

During the 7 meetings of the CCSAC, the committee considered research, data and information from experts relative to the issues in the charge. During the course of the first 6 meetings, a decision in principle was made to allow performance of elective percutaneous coronary intervention (PCI) without on-site surgical backup. (Note: The CCSAC received clarification from the Commission Chairperson that they should focus on elective PCI when determining if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site OHS services.) The committee also agreed to recommend quality standards for “new” programs as well as standards for existing programs. Finally, language changes proposed by the Department were agreed upon.

In the final meeting of the CCSAC on December 17, 2014, language was agreed upon reflecting the following recommendations of the committee:

- Allow the performance of elective PCI without on-site surgical backup.
- Require applicants for a primary PCI service without on-site surgical backup to project a minimum of 36 primary PCI procedures per year.

- Require applicants applying for an elective PCI service without on-site surgical backup to project a minimum of 200 PCI procedures per year, to have operated a primary PCI program for at least one year, have data submitted to the state and to a qualified registry, and been found to have acceptable performance as compared to the benchmarks for the most recent 12 months (see proposed quality standards below).
- If the applicant did not have a primary PCI service prior to the effective date of the standards, there must not be a PCI or Open Heart Surgery service within 60 minutes travel time or 60 radius miles of the applicant program.

The CCSAC developed the following proposed quality standards draft language [excerpts from Section 10(5) of the proposed standards below]:

- The applicant hospital shall participate in a data registry administered by the department or its designee as a means to measure quality and risk adjusted outcomes within PCI services by service level. The applicant hospital shall become a member of the data registry specified by the department upon initiation of the service and continue to participate annually thereafter for the life of that service. At a minimum, the applicant hospital shall report the following:
  - The number of patients treated with and without STEMI,
  - The proportion of PCI patients with emergency CABG or required emergent transfer,
  - Risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with STEMI.
  - PCI appropriate use in elective non-acute mi cases, and
  - Rates of ad-hoc multi-vessel PCI procedures in the same session.
- Cath lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC guidelines for PCI including the SCAI/ACC/AHA expert consensus document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria.
- The department shall use these thresholds and metrics in evaluating compliance: performance at a level above the 50th percentile of the statewide performance on each metric listed under subsection (d)(ii) – (v) or another level provided by the data registry designee and accepted by the department.
- The department shall notify those hospitals who fail to meet any of the minimally acceptable objective quality metric thresholds including those under subsection (d)(ii) – (v). The department shall require these hospitals to:
  - Submit a corrective action plan within one month of notification and
  - Demonstrate that performance has improved to meet or exceed all applicable objective quality metric thresholds, including those under subsection (d)(ii) – (v), within 12 months of notification.
- The applicant hospital initiating elective PCI without on-site OHS services shall have Accreditation for Cardiovascular Excellence (ACE) accreditation or an equivalent body perform an on-site review within 3, 6, and 12 months after

implementation. The applicant hospital shall submit the summary reports of the on-site review to the department.

With these and other language changes, the CCSAC is confident that it has met the charge of the Commission.

Respectfully submitted,

Renee Turner-Bailey, M.H.S.A.  
International Union, UAW

# **Report of the Cardiac Catheterization Standard Advisory Committee**

**Certificate of Need Commission  
Meeting  
March 18, 2015**

**Renee Turner-Bailey, M.H.S.A.  
Chairperson**

# Cardiac Catheterization Services

## Standard Advisory Committee (CCSAC) Charge

Attachment B

1. Determine if elective therapeutic cardiac catheterizations should be allowed at facilities that do not provide on-site open heart surgery services by considering the recommendations of national organizations. If it is recommended that these services should be allowed:
  - a. consider the impacts of cost, quality and access under the current standards in determining need for this service; and
  - b. provide specific criteria for this service including initiation and maintenance volumes as well as patient safety and quality criteria.

# Cardiac Catheterization Services

Attachment B

## Standard Advisory Committee (CCSAC) Charge (cont'd)

2. Develop language for a second acquisition, similar to that of other standards.
3. Develop specific measurable quality metrics in the project delivery requirements, similar to that of Open Heart Surgery (OHS) standards.
4. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards an the Public Health Code

# Sub-Committees

- The CCSAC agreed to create sub-committees to research and present findings in the specified area to the CCSAC. The committees were:
  - Science and Prevalence
  - Quality and Access
  - Cost

# Expert Presentations

- **Paul Delamater, PhD**, Michigan State University
- **Hitinder Gurm, MD**, University of Michigan Health System, BMC<sup>2</sup>
- **Gregory Dehmer, MD**, Cardiologist, co-author of: SCAI/ACC/AHA Expert Consensus Document: 2014 Update on Percutaneous Coronary Intervention Without On-Site Surgical Backup

# Recommendations of the CCSAC

Attachment B

- Allow the performance of elective PCI without on-site surgical backup
- Require applicants for a primary PCI service without on-site surgical backup to project a minimum of 36 primary PCI procedures per year
- Require applicants applying for an elective PCI service without on-site surgical backup to project a minimum of 200 PCI procedures per year

# Recommendations of the CCSAC

Attachment B

- Require applicants applying for an elective PCI service without on-site surgical backup to have operated a primary PCI program for at least one year
- Require applicants applying for an elective PCI service without on-site surgical backup to have submitted data to a qualified registry
- Require applicants applying for an elective PCI service without on-site surgical backup to have been found to have acceptable performance as compared to the benchmarks for the most recent 12 months

# Recommendations of the CCSAC

Attachment B

- If the applicant did not have a primary PCI service prior to the effective date of the standards, there must not be a PCI or Open Heart Surgery service within 60 minutes travel time or 60 radius miles of the applicant program

# Quality Standards

## Recommendations of the CCSAC

- The applicant hospital shall participate in a data registry administered by the department or its designee as s means to measure quality and risk adjusted outcomes within PCI services by service level.
- The applicant hospital shall become a member of the data registry specified by the department upon initiation of the service and continue to participate annually thereafter for the life of that service

# Quality Standards

## Recommendations of the CCSAC

- At a minimum, the applicant hospital shall report the following:
  - The number of patients treated with without STEMI
  - The proportion of PCI patients with emergency CABG or required emergent transfer
  - Risk and reliability adjusted patient mortality for all PCI patients and a subset of patients with STEMI
  - PCI appropriate use in elective non-acute mi cases, and
  - Rates of ad-hoc multi-vessel PCI procedures in the same session

# Quality Standards

## Recommendations of the CCSAC

- Cath lab facility requirements and collaborative surgeon cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC/AHA guidelines
- The Department will evaluate compliance based on reaching a level of 50<sup>th</sup> percentile of the statewide performance on each metric or a level provided by the data registry designee

# **Thank You**

# **Questions?**

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**  
**CERTIFICATE OF NEED (CON) REVIEW STANDARDS**  
**FOR CARDIAC CATHETERIZATION SERVICES**

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

**Section 1. Applicability**

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

**Section 2. Definitions**

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

(a) "Cardiac catheterization laboratory" or "laboratory" means an individual radiological room equipped with a variety of x-ray machines and devices such as electronic image intensifiers, high speed film changers and digital subtraction units to assist in performing diagnostic or therapeutic cardiac catheterizations or electrophysiology studies.

(b) "Cardiac catheterization procedure" means any cardiac procedure, including diagnostic, therapeutic, and electrophysiology studies, performed on a patient during a single session in a laboratory. Cardiac catheterization is a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in a patient; subsequently the free end of the catheter is manipulated by a physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aides in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures in the heart. This term does not include "float catheters" that are performed at the bedside or in settings outside the laboratory or the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (ICD) devices that are performed in an interventional radiology laboratory or operating room.

(c) "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; ~~pediatric diagnostic cardiac catheterizations;~~ adult therapeutic cardiac catheterizations; and pediatric ~~therapeutic~~ cardiac catheterizations.

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

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

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

(g) "Diagnostic cardiac catheterization service" means providing diagnostic cardiac catheterization procedures on an organized, regular basis in a laboratory to diagnose anatomical and/or physiological problems in the heart. Procedures include the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic). A hospital that provides diagnostic cardiac catheterization services may also perform implantations of cardiac permanent pacemakers and ICD devices.

(h) "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI)" MEANS A PCI PROCEDURE PERFORMED ON A NON-EMERGENT BASIS.

54 (i) "ELECTIVE PCI SERVICES WITHOUT ON-SITE OPEN HEART SURGERY (OHS)" MEANS  
 55 PERFORMING PCI, PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), AND  
 56 CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A HOSPITAL  
 57 HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE AND A PRIMARY PCI SERVICE  
 58 BUT NOT HAVING OHS ON-SITE AND ADHERING TO PATIENT SELECTION AS OUTLINED IN THE  
 59 SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT: 2014 UPDATED ON PCI WITHOUT ON-SITE  
 60 SURGICAL BACKUP AND PUBLISHED IN CIRCULATION 2014, 129:2610-2626 AND ITS UPDATE OR  
 61 FURTHER GUIDELINE CHANGES.

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

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

66 (lj) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to  
 67 1396g and 1396i to 1396u.

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

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

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

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

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

91  
 92 (2) Terms defined in the Code have the same meanings when used in these standards.  
 93

### 94 **Section 3. Requirements to initiate cardiac catheterization services**

95  
 96 Sec. 3. An applicant proposing to initiate cardiac catheterization services shall demonstrate the  
 97 following, as applicable to the proposed project.  
 98

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

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

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

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

116  
 117 (2) An applicant proposing to initiate an adult therapeutic cardiac catheterization service shall  
 118 demonstrate the following:

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

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

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

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

132  
 133 (3) An applicant proposing to initiate a pediatric cardiac catheterization service shall demonstrate the  
 134 following:

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

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

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

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

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

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

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

154  
 155 **SECTION 4. REQUIREMENTS TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-**  
 156 **SITE OHS SERVICES**

157  
 158 —

159  
160 —(4)SEC. 4. An applicant proposing to initiate primary OR ELECTIVE PCI service~~S~~ without on-site  
161 ~~open heart surgery~~OHS services shall demonstrate the following:

162  
163 (a1) The applicant operates an adult diagnostic cardiac catheterization service that has performed a  
164 minimum of 500 procedure equivalents that includes 400 procedure equivalents in the category of cardiac  
165 catheterization procedures during the most recent 12 months preceding the date the application was  
166 submitted to the Department.

167  
168 (b2) The applicant has at least two interventional cardiologists to perform the ~~primary~~ PCI procedures  
169 and each cardiologist has performed at least ~~75-50~~ PCI sessions annually as the primary operator during  
170 the most recent 24-month period preceding the date the application was submitted to the Department.

171  
172 (e3) The nursing and technical catheterization laboratory staff: are experienced in handling acutely ill  
173 patients and comfortable with interventional equipment; have acquired experience in dedicated  
174 interventional laboratories at an ~~open heart surgery~~OHS hospital; and participate in an un-interrupted 24-  
175 hour, 365-day call schedule. Competency shall be documented annually.

176  
177 (d4) The laboratory or laboratories are equipped with optimal imaging systems, resuscitative  
178 equipment, and intra-aortic balloon pump (IABP) support, and stocked with a broad array of interventional  
179 equipment.

180  
181 (e5) The cardiac care unit nurses are adept in hemodynamic monitoring and IABP management.  
182 Competency shall be documented annually.

183  
184 (f6) A written agreement with an ~~open heart surgery~~OHS hospital that includes all of the following:

185 (ia) Involvement in credentialing criteria and recommendations for physicians approved to perform  
186 ~~primary~~ PCI procedures.

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

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

193 (ivd) Regularly held joint cardiology/cardiac surgery conferences to include review of all ~~primary~~ PCI  
194 cases.

195 (ve) Development and ongoing review of patient selection criteria for ~~primary~~ PCI patients and  
196 implementation of those criteria.

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

199 (viig) Written protocols, signed by the applicant and the ~~open heart surgery~~OHS hospital, for the  
200 immediate transfer, within ~~4 hour~~60 MINUTES TRAVEL TIME from the cardiac catheterization laboratory  
201 to evaluation on site in the ~~open heart surgery~~OHS hospital, of patients requiring surgical evaluation  
202 and/or intervention 365 days a year. IF THE APPLICANT MEETS THE REQUIREMENTS OF SUB-  
203 SECTION (13)(c), THEN THE OHS HOSPITAL CAN BE MORE THAN 60 MINUTES TRAVEL TIME  
204 FROM THE PROPOSED SITE. The protocols shall be reviewed and tested on a quarterly basis.

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

207  
208 (g7) A written protocol must be established and maintained for case selection for the performance of  
209 ~~primary~~ PCI.  
210

211 | (~~h8~~) A system to ensure prompt and efficient identification of potential primary PCI patients and rapid  
 212 | transfer from the emergency department to the cardiac catheterization laboratory must be developed and  
 213 | maintained so that door-to-balloon targets are met.

214 |  
 215 | (~~i9~~) At least two physicians credentialed to perform ~~primary~~ PCI must commit to functioning as a  
 216 | coordinated group willing and able to provide this service at the hospital on a 24-hour per day, 365 day  
 217 | per year call schedule, with ability to be on-site and available to operate within 30 minutes of identifying  
 218 | the need for primary PCI. These physicians must be credentialed at the facility and actively collaborate  
 219 | with administrative and clinical staff in establishing and implementing protocols, call schedules, and  
 220 | quality assurance procedures pertaining to ~~primary~~ PCI designed to meet the requirements for this  
 221 | certification and in keeping with the current guidelines for the provision of ~~primary~~ PCI WITHOUT ON-  
 222 | SITE OHS SERVICES promulgated by the American College of Cardiology and American Heart  
 223 | Association.

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

226 |  
 227 | (10) THE APPLICANT HOSPITAL SHALL PARTICIPATE IN A DATA REGISTRY ADMINISTERED  
 228 | BY THE DEPARTMENT OR ITS DESIGNEE AS A MEANS TO MEASURE QUALITY AND RISK  
 229 | ADJUSTED OUTCOMES WITHIN PCI SERVICES WITHOUT ON-SITE OHS SERVICES, AND THE  
 230 | APPLICANT HOSPITAL SHALL IDENTIFY A PHYSICIAN POINT OF CONTACT FOR THE DATA  
 231 | REGISTRY.

232 |  
 233 | (11) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART  
 234 | SURGEON RELATIONSHIP REQUIREMENTS SHALL CONFORM TO ALL SCAI/ACC GUIDELINES  
 235 | FOR PCI SERVICES WITHOUT ON-SITE OHS INCLUDING THE SCAI/ACC/AHA EXPERT  
 236 | CONSENSUS DOCUMENT. THE APPLICANT HOSPITAL SHALL BE LIABLE FOR THE COST OF  
 237 | DEMONSTRATING COMPLIANCE WITH THESE CRITERIA IN THEIR APPLICATION.

238 |  
 239 | (12) The applicant shall project THE FOLLOWING based on data from the most recent 12-month  
 240 | period preceding the date the application was submitted to the Department, AS APPLICABLE.

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

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

246 |  
 247 | (13) IF THE APPLICANT IS APPLYING FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE  
 248 | OHS, THE APPLICANT ALSO SHALL DEMONSTRATE THE FOLLOWING:

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

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

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

259 |  
 260 | (14) IF THE APPLICANT IS CURRENTLY PROVIDING OHS SERVICES AND THERAPEUTIC  
 261 | CARDIAC CATHETERIZATION SERVICES AND IS PROPOSING TO DISCONTINUE OHS SERVICES  
 262 | AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, THEN THE APPLICANT SHALL  
 263 | APPLY TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS USING THIS

264 | SECTION. THE APPLICANT SHALL DEMONSTRATE ALL OF THE REQUIREMENTS IN THIS  
 265 | SECTION EXCEPT FOR SUB-SECTION (13) AND IS SUBJECT TO ALL REQUIREMENTS IN SECTION  
 266 | 10.

268 | **Section 45. Requirements to replace an existing cardiac catheterization service or laboratory**  
 269 |

270 | Sec. 45. Replacing a cardiac catheterization laboratory means a change in the angiography x-ray  
 271 | equipment or a relocation of the service to a new site. The term does not include a change in any of the  
 272 | other equipment or software used in the laboratory. An applicant proposing to replace a cardiac  
 273 | catheterization laboratory or service shall demonstrate the following as applicable to the proposed project:  
 274 |

275 | (1) An applicant proposing to replace cardiac catheterization laboratory equipment shall demonstrate  
 276 | the following:

277 | (a) The existing laboratory or laboratories to be replaced are fully depreciated according to generally  
 278 | accepted accounting principles or demonstrates either of the following:

279 | (i) The existing angiography x-ray equipment to be replaced poses a threat to the safety of the  
 280 | patients.

281 | (ii) The replacement angiography x-ray equipment offers technological improvements that enhance  
 282 | quality of care, increases efficiency, and reduces operating costs.

283 | (b) The existing angiography x-ray equipment to be replaced will be removed from service on or  
 284 | before beginning operation of the replacement equipment.

285 | (2) An applicant proposing to replace a cardiac catheterization service to a new site shall  
 286 | demonstrate the following:

287 | (a) The proposed project is part of an application to replace the entire hospital.

288 | (b) The applicant has performed the following during the most recent 12-month period preceding the  
 289 | date the application was submitted to the Department as applicable to the proposed project:

290 | (i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
 291 | catheterization procedures.

292 | (ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
 293 | catheterization procedures.

294 | (iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization  
 295 | procedures.

296 | (iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one  
 297 | laboratory.

298 | (v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one  
 299 | laboratory.

300 | (vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for a hospital  
 301 | with two or more laboratories.

302 | (c) The existing cardiac catheterization service has been in operation for at least 36 months as of the  
 303 | date the application has been submitted to the Department.  
 304 |  
 305 |

306 | **Section 56. Requirements to expand a cardiac catheterization service**  
 307 |

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

310 | (1) The applicant has performed the following during the most recent 12-month period preceding the  
 311 | date the application was submitted to the Department as applicable to the proposed project:

312 | (a) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac  
 313 | catheterization procedures.

314 | (b) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac  
 315 | catheterization procedures.  
 316 |

317 (c) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization  
 318 procedures.

319  
 320 (2) The applicant has performed a minimum of 1,400 procedure equivalents per existing and  
 321 approved laboratories during the most recent 12-month period preceding the date the application was  
 322 submitted to the Department.

323  
 324 **Section 67. Requirements to acquire a cardiac catheterization service**

325  
 326 Sec. 67. Acquiring a cardiac catheterization service and its laboratories means obtaining possession  
 327 and control by contract, ownership, lease or other comparable arrangement or renewal of a lease for  
 328 existing angiography x-ray equipment. An applicant proposing to acquire a cardiac catheterization  
 329 service or renew a lease for equipment shall demonstrate the following as applicable to the proposed  
 330 project:

331  
 332 (1) An applicant proposing to acquire a cardiac catheterization service shall demonstrate the  
 333 following:

334 (a) The proposed project is part of an application to acquire the entire hospital.

335 (b) An application for the first acquisition of an existing cardiac catheterization service after February  
 336 27, 2012 shall not be required to be in compliance with the applicable volume requirements in ~~subsection~~  
 337 ~~SECTION (e)10~~. The cardiac catheterization service shall be operating at the applicable volumes set  
 338 forth in the project delivery requirements in the second 12 months of operation of the service by the  
 339 applicant and annually thereafter.

340 (c) ~~FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING CARDIAC~~  
 341 ~~CATHETERIZATION SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO~~  
 342 ~~SUBSECTION (B), AN APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE CARDIAC~~  
 343 ~~CATHETERIZATION SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH THE~~  
 344 ~~VOLUME REQUIREMENTS SET FORTH IN SECTION 10 OF THESE STANDARDS APPLICABLE TO~~  
 345 ~~AN EXISTING CARDIAC CATHETERIZATION SERVICE ON THE DATE THE APPLICATION IS~~  
 346 ~~SUBMITTED TO THE DEPARTMENT. The applicant has performed the following during the most recent~~  
 347 ~~12-month period preceding the date the application was submitted to the Department as applicable to the~~  
 348 ~~proposed project:~~

349 ~~—(i) A minimum of 300 procedure equivalents in the category of adult diagnostic cardiac~~  
 350 ~~catheterization procedures.~~

351 ~~—(ii) A minimum of 300 procedure equivalents in the category of adult therapeutic cardiac~~  
 352 ~~catheterization procedures.~~

353 ~~—(iii) A minimum of 600 procedure equivalents in the category of pediatric cardiac catheterization~~  
 354 ~~procedures.~~

355 ~~—(iv) A minimum of 500 procedure equivalents for a hospital in a rural or micropolitan county with one~~  
 356 ~~laboratory.~~

357 ~~—(v) A minimum of 750 procedure equivalents for a hospital in a metropolitan county with one~~  
 358 ~~laboratory.~~

359 ~~—(vi) A minimum of 1,000 procedure equivalents per cardiac catheterization laboratory for two or more~~  
 360 ~~laboratories.~~

361  
 362 (2) An applicant proposing to renew a lease for existing angiography x-ray equipment shall  
 363 demonstrate the renewal of the lease is more cost effective than replacing the equipment.

364  
 365 **Section 78. Requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL)**

366  
 367 Sec. 78. A hybrid OR/CCL means an operating room located on a sterile corridor and equipped with an  
 368 angiography system permitting minimally invasive procedures of the heart and blood vessels with full

369 anesthesia capabilities. An applicant proposing to add one or more hybrid OR/CCLs at an existing cardiac  
 370 catheterization service shall demonstrate each of the following:

- 371
- 372 | (1) The applicant operates an ~~open heart surgery~~OHS service which is in full compliance with the  
 373 | current CON Review Standards for ~~Open Heart Surgery~~OHS Services.
- 374
- 375 | (2) The applicant operates a therapeutic cardiac catheterization program which is in full compliance  
 376 | with section 45(2) of these standards.
- 377
- 378 | (3) If the hybrid OR/CCL(s) represents an increase in the number of cardiac catheterization laboratories  
 379 | at the facility, the applicant is in compliance with Section ~~5-6~~6 of these standards.
- 380
- 381 | (4) If the hybrid OR/CCL(s) represents conversion of an existing cardiac catheterization laboratory(s),  
 382 | the applicant is in compliance with the provisions of Section 45, if applicable.
- 383
- 384 | (5) The applicant meets the applicable requirements of the CON Review Standards for Surgical  
 385 | Services.
- 386
- 387 | (6) Each case performed in a hybrid OR/CCL shall be included either in the surgical volume or the  
 388 | therapeutic cardiac catheterization volume of the facility. No case shall be counted more than once.
- 389
- 390 | (7) For each hybrid OR/CCL, a facility shall have 0.5 excluded from its inventory of cardiac  
 391 | catheterization laboratories for the purposes of computing the procedure equivalents per room. A facility  
 392 | will not be limited to the number of hybrid ORCCLs within a single licensed facility.
- 393

394 | **Section 89. Requirement for Medicaid participation**

395

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

400

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

402

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

405

- 406 | (1) Compliance with these standards.
- 407
- 408 | (2) Compliance with the following quality assurance standards:
- 409 | (a) Cardiac catheterization procedures shall be performed in a cardiac catheterization laboratory  
 410 | located within a hospital, and have within, or immediately available to the room, dedicated emergency  
 411 | equipment to manage cardiovascular emergencies.
- 412 | (b) The service shall be staffed with sufficient medical, nursing, technical and other personnel to  
 413 | permit regular scheduled hours of operation and continuous 24-hour on-call availability.
- 414 | (c) The medical staff and governing body shall receive and review at least annual reports describing  
 415 | the activities of the cardiac catheterization service including complication rates, morbidity and mortality,  
 416 | success rates and the number of procedures performed.
- 417 | (d) Each physician credentialed by a hospital to perform adult therapeutic cardiac catheterization  
 418 | procedures shall perform, as the primary operator, a minimum of ~~75-50~~ adult therapeutic cardiac  
 419 | catheterization procedures per year in the second 12 months after being credentialed to and annually  
 420 | thereafter. The annual case load for a physician means adult therapeutic cardiac catheterization  
 421 | procedures performed by that physician in any combination of hospitals.

422 (e) Each physician credentialed by a hospital to perform pediatric ~~diagnostic~~ cardiac catheterizations  
 423 shall perform, as the primary operator, a minimum of 50 pediatric ~~diagnostic~~ cardiac catheterization  
 424 procedures per year in the second 12 months after being credentialed and annually thereafter. The  
 425 annual case load for a physician means pediatric ~~diagnostic~~ cardiac catheterization procedures  
 426 performed by that physician in any combination of hospitals.

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

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

- 435 (i) are trained consistent with the recommendations of the American College of Cardiology;
- 436 (ii) are credentialed by the hospital to perform adult diagnostic cardiac catheterizations; and
- 437 (iii) have each performed a minimum of 100 adult diagnostic cardiac catheterizations in the preceding  
 438 12 months.

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

- 442 (i) are trained consistent with the recommendations of the American College of Cardiology;
- 443 (ii) are credentialed by the hospital to perform adult therapeutic cardiac catheterizations; and
- 444 (iii) have each performed a minimum of ~~75-50~~ adult therapeutic cardiac catheterization procedures in  
 445 the preceding 12 months.

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

- 449 (i) is board certified or board eligible in pediatric cardiology by the American Board of Pediatrics;
- 450 (ii) is credentialed by the hospital to perform pediatric cardiac catheterizations; and
- 451 (iii) has trained consistently with the recommendations of the American College of Cardiology.

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

454 (j) A cardiac catheterization service shall be directed by an appropriately trained physician. The  
 455 Department shall consider appropriate training of the director if the physician is board certified in  
 456 cardiology, cardiovascular radiology or cardiology, adult or pediatric, as applicable. The director of an  
 457 adult cardiac catheterization service shall have performed at least ~~200-100~~ catheterizations per year  
 458 during each of the five preceding years. The Department may accept other evidence that the director is  
 459 appropriately trained.

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

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

467  
 468 (3) Compliance with the following access to care requirements:

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

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

473 (c) The service shall not deny cardiac catheterization services to any individual based on ability to  
 474 pay or source of payment.

475 (d) The operation of and referral of patients to the cardiac catheterization service shall be in  
 476 conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.1621; MSA 14.15  
 477 (16221).

478

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

480 (a) The service shall be operating at or above the applicable volumes in the second 12 months of  
 481 operation of the service, or an additional laboratory, and annually thereafter:

482 (i) 300 procedure equivalents in the category of adult diagnostic cardiac catheterization procedures.

483 (ii) 300 procedure equivalents in the category of adult therapeutic cardiac catheterization  
 484 procedures.

485 (iii) 600 procedure equivalents in the category of pediatric cardiac catheterization procedures.

486 (iv) 500 procedure equivalents for a hospital in a rural or micropolitan county with one laboratory.

487 (v) 750 procedure equivalents for a hospital in a metropolitan county with one laboratory.

488 (vi) 1,000 procedure equivalents per cardiac catheterization laboratory for two or more laboratories.

489 (vii) 36 adult primary PCI cases for a primary PCI service WITHOUT ON-SITE OHS SERVICE.

490 (viii) 200 ADULT PCI PROCEDURES FOR AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS  
 491 SERVICE.

492 (b) The APPLICANT hospital shall participate in a data collection network established and  
 493 administered by the Department or its designee. Data may include, but is not limited to, annual budget  
 494 and cost information, operating schedules, patient demographics, morbidity and mortality information, and  
 495 payor. The Department may verify the data through on-site review of appropriate records.

496 (c) The APPLICANT hospital PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION  
 497 SERVICES, PRIMARY PCI SERVICES WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI  
 498 SERVICES WITHOUT ON-SITE OHS SERVICE shall participate in a ~~quality improvement~~ data registry  
 499 administered by the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK  
 500 ADJUSTED OUTCOMES WITHIN CARDIAC CATHETERIZATION SERVICES. The DEPARTMENT OR  
 501 ITS DESIGNEE SHALL REQUIRE THAT THE APPLICANT hospital ~~shall~~ submit summary reports as  
 502 ~~required~~ SPECIFIED by the Department. The APPLICANT hospital shall provide the required data in a  
 503 format established by the Department or its designee. The APPLICANT hospital ~~is~~ SHALL BE liable for  
 504 the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes  
 505 and assure quality. The APPLICANT hospital ~~must~~ SHALL become a member of the data registry  
 506 SPECIFIED BY THE DEPARTMENT upon initiation of the service and continue to participate annually  
 507 thereafter for the life of that service.

508 (d) THE APPLICANT HOSPITAL SHALL PROVIDE THE DEPARTMENT WITH TIMELY NOTICE OF  
 509 THE PROPOSED PROJECT IMPLEMENTATION CONSISTENT WITH APPLICABLE STATUTE AND  
 510 PROMULGATED RULES.

511

512 (5) Compliance with the following primary AND ELECTIVE PCI requirements FOR HOSPITALS  
 513 PROVIDING THERAPEUTIC CARDIAC CATHETERIZATION SERVICES, PRIMARY PCI SERVICES  
 514 WITHOUT ON-SITE OHS SERVICE, OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS  
 515 SERVICE, if applicable:

516 (a) The requirements set forth in Section ~~3(4)~~.

517 (b) The hospital shall immediately report to the Department any changes in the interventional  
 518 cardiologists who perform the primary PCI procedures.

519 ~~—(c) The The hospital shall perform a minimum of 36 primary PCI procedures at the hospital in the~~  
 520 ~~preceding 12-month period of operation of the service and annually thereafter.~~

521 (c) The hospital shall maintain a 90-minute door-to-balloon time or less in at least 75% of the primary  
 522 PCI sessions.

523 (d) The APPLICANT hospital shall participate in a data registry, administered by the Department or  
 524 its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN PCI  
 525 SERVICES BY SERVICE LEVEL. The Department or its designee shall require that the applicant  
 526 HOSPITAL submit ~~data on~~ all consecutive ~~cases of primary~~ PCI CASES PERFORMED WITHIN THE  
 527 HOSPITAL AND MEET DATA SUBMISSION TIMELINESS REQUIRMENTS AND THRESHOLD

528 REQUIREMENTS FOR PCI DATA SUBMISSION, ACCURACY AND COMPLETENESS ESTABLISHED  
 529 BY DATA REGISTRY ADMINISTERED BY THE DEPARTMENT OR ITS DESIGNEE, as is necessary to  
 530 comprehensively assess and provide comparative analyses of case selection, processes and outcome of  
 531 care, and trend in efficiency. The applicant HOSPITAL shall provide the required data in a format  
 532 established by the Department or its designee. The applicant HOSPITAL shall be liable for the cost of  
 533 data submission and on-site reviews in order for the Department to verify and monitor volumes and  
 534 assure quality. THE APPLICANT HOSPITAL SHALL BECOME A MEMBER OF THE DATA REGISTRY  
 535 SPECIFIED BY THE DEPARTMENT UPON INITIATION OF THE SERVICE AND CONTINUE TO  
 536 PARTICIPATE ANNUALLY THEREAFTER FOR THE LIFE OF THAT SERVICE. AT A MINIMUM, THE  
 537 APPLICANT HOSPITAL SHALL REPORT THE FOLLOWING:

538 (i) THE NUMBER OF PATIENTS TREATED WITH AND WITHOUT STEMI,  
 539 (ii) THE PROPORTION OF PCI PATIENTS WITH EMERGENCY CABG OR REQUIRED  
 540 EMERGENT TRANSFER,  
 541 (iii) RISK AND RELIABILITY ADJUSTED PATIENT MORTALITY FOR ALL PCI PATIENTS AND A  
 542 SUBSET OF PATIENTS WITH STEMI,  
 543 (iv) PCI APPROPRIATE USE IN ELECTIVE NON-ACUTE MI CASES, AND  
 544 (v) RATES OF AD-HOC MULTI-VESSEL PCI PROCEDURES IN THE SAME SESSION.  
 545 (e) THE APPLICANT HOSPITAL SHALL MAINTAIN A PHYSICIAN POINT OF CONTACT FOR THE  
 546 DATA REGISTRY.

547 (f) CATH LAB FACILITY REQUIREMENTS AND COLLABORATIVE CARDIOLOGISTS-HEART  
 548 SURGEON RELATIONSHIP REQUIREMENTS SHALL CONFORM TO ALL SCAI/ACC GUIDELINES  
 549 FOR PCI INCLUDING THE SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT. THE APPLICANT  
 550 HOSPITAL SHALL BE LIABLE FOR THE COST OF DEMONSTRATING COMPLIANCE WITH THESE  
 551 CRITERIA.

552 (g) THE DEPARTMENT SHALL USE THESE THRESHOLDS AND METRICS IN EVALUATING  
 553 COMPLIANCE: PERFORMANCE AT A LEVEL ABOVE THE 50TH PERCENTILE OF THE STATEWIDE  
 554 PERFORMANCE ON EACH METRIC LISTED UNDER SUBSECTION (d)(ii) – (v) OR ANOTHER LEVEL  
 555 PROVIDED BY THE DATA REGISTRY DESIGNEE AND ACCEPTED BY THE DEPARTMENT.

556 (h) THE DEPARTMENT SHALL NOTIFY THOSE HOSPITALS WHO FAIL TO MEET ANY OF THE  
 557 MINIMALLY ACCEPTABLE OBJECTIVE QUALITY METRIC THRESHOLDS INCLUDING THOSE  
 558 UNDER SUBSECTION (d)(ii) – (v). THE DEPARTMENT SHALL REQUIRE THESE HOSPITALS TO:

559 (i) SUBMIT A CORRECTIVE ACTION PLAN WITHIN ONE MONTH OF NOTIFICATION AND

560 (ii) DEMONSTRATE THAT PERFORMANCE HAS IMPROVED TO MEET OR EXCEED ALL  
 561 APPLICABLE OBJECTIVE QUALITY METRIC THRESHOLDS, INCLUDING THOSE UNDER  
 562 SUBSECTION (d)(ii) – (v), WITHIN 12 MONTHS OF NOTIFICATION.

563 (i) THE APPLICANT HOSPITAL INITIATING ELECTIVE PCI WITHOUT ON-SITE OHS SERVICES  
 564 SHALL HAVE ACCREDITATION FOR CARDIOVASCULAR EXCELLENCE (ACE) ACCREDITATION OR  
 565 AN EQUIVALENT BODY PERFORM AN ON-SITE REVIEW WITHIN 3, 6, AND 12 MONTHS AFTER  
 566 IMPLEMENTATION. THE APPLICANT HOSPITAL SHALL SUBMIT THE SUMMARY REPORTS OF  
 567 THE ON-SITE REVIEW TO THE DEPARTMENT.

568  
 569 (6) NOTHING IN THIS SECTION PROHIBITS THE DEPARTMENT FROM TAKING COMPLIANCE  
 570 ACTION UNDER MCL 333.22247.

571  
 572 (7) THE AGREEMENTS AND ASSURANCES REQUIRED BY THIS SECTION SHALL BE IN THE  
 573 FORM OF A CERTIFICATION AGREED TO BY THE APPLICANT OR ITS AUTHORIZED AGENT.

574  
 575 **Section 4011. Methodology for computing cardiac catheterization equivalents**

576  
 577 **Sec. 4011.** The following shall be used in calculating procedure equivalents and evaluating utilization  
 578 of a cardiac catheterization service and its laboratories:  
 579

Procedure Type	Procedure equivalent	
	Adult	Pediatric
Diagnostic cardiac catheterization/peripheral sessions	1.5	2.7
Therapeutic cardiac catheterization/peripheral sessions	2.7	4.0
Complex percutaneous valvular sessions*	4.0	7.0
* Complex percutaneous valvular sessions includes, but is not limited to, procedures performed percutaneously or with surgical assistance to repair or replace aortic, mitral and pulmonary valves such as transcatheter aortic valvular implantation (Tavi) procedures. These sessions can only be performed at hospitals approved with <del>open heart surgery</del> OHS services.		

580

581

**Section 4112. Documentation of projections**

582

583

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

584

585

586

(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.

587

588

589

590

(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.

591

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597

(3) AN APPLICANT PROPOSING TO INITIATE AN ELECTIVE PCI SERVICE WITHOUT ON-SITE OHS SERVICES SHALL DEMONSTRATE AND CERTIFY THAT THE HOSPITAL SHALL TREAT 200 OR MORE PATIENTS WITH PCI ANNUALLY USING DATA DURING THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT AS FOLLOWS:

598

599

600

601

602

(a) ALL PRIMARY PCIS PERFORMED AT THE APPLICANT HOSPITAL.

603

604

(b) ALL INPATIENTS TRANSFERRED FROM THE APPLICANT HOSPITAL TO ANOTHER HOSPITAL FOR PCI.

605

606

607

(c) 90% OF PATIENTS WHO RECEIVED DIAGNOSTIC CARDIAC CATHETERIZATIONS AT THE APPLICANT HOSPITAL AND RECEIVED AN ELECTIVE PCI AT ANOTHER HOSPITAL WITHIN 30 DAYS OF THE DIAGNOSTIC CATHETERIZATION (BASED ON PHYSICIAN COMMITMENTS).

608

609

610

611

(d) 50% OF THE ELECTIVE PCI PROCEDURES PERFORMED BY THE COMMITTING PHYSICIAN AT ANOTHER HOSPITAL WITHIN 120 RADIUS MILES OR 120 MINUTES TRAVEL TIME FROM THE APPLICANT HOSPITAL FOR PATIENTS WHO DID NOT RECEIVE DIAGNOSTIC CARDIAC CATHETERIZATION AT THE APPLICANT HOSPITAL (BASED ON PHYSICIAN COMMITMENTS).

612

613

614

615

616

617

(e) AN APPLICANT WITH CURRENT OHS SERVICES AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICES THAT IS PROPOSING TO DISCONTINUE OHS SERVICES AND THERAPEUTIC CARDIAC CATHETERIZATION SERVICES AND IS APPLYING TO INITIATE PRIMARY OR ELECTIVE PCI SERVICES WITHOUT ON-SITE OHS SERVICES MAY COUNT ALL PRIMARY AND ELECTIVE PCI AT THE APPLICANT HOSPITAL WITHIN THE MOST RECENT 12-MONTH PERIOD PRECEDING THE DATE THE APPLICATION WAS SUBMITTED TO THE DEPARTMENT.

618

619

620

**Section 4213. Comparative reviews; Effect on prior CON Review Standards**

621

622 | Sec. ~~12~~13. Proposed projects reviewed under these standards shall not be subject to comparative  
623 | review. These CON Review Standards supercede and replace the CON Review Standards for Cardiac  
624 | Catheterization Services approved by the CON Commission on ~~December 15, 2014~~MARCH 18, 2014  
625 | and effective on ~~February 27, 2012~~JUNE 2, 2014.  
626 |

**APPENDIX A**

627

628

629 Rural Michigan counties are as follows:

630

631	Alcona	<del>Hillsdale</del>	Oceana
632	Alger	Huron	Ogemaw
633	Antrim	Iosco	Ontonagon
634	Arenac	Iron	Osceola
635	Baraga	Lake	Oscoda
636	Charlevoix	Luce	Otsego
637	Cheboygan	Mackinac	Presque Isle
638	Clare	Manistee	Roscommon
639	Crawford	<del>Mason</del>	Sanilac
640	Emmet	<del>Montcalm</del>	Schoolcraft
641	Gladwin	Montmorency	Tuscola
642	Gogebic	<u>NEWAYGO</u>	

643

644 Micropolitan statistical area Michigan counties are as follows:

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646	Allegan	<u>HILLSDALE</u>	<u>MASON</u>
647	Alpena	Houghton	Mecosta
648	Benzie	<u>IONIA</u>	Menominee
649	Branch	Isabella	<del>Midland</del>
650	Chippewa	Kalkaska	Missaukee
651	Delta	Keweenaw	St. Joseph
652	Dickinson	Leelanau	Shiawassee
653	Grand Traverse	Lenawee	Wexford
654	Gratiot	Marquette	

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656 Metropolitan statistical area Michigan counties are as follows:

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658	Barry	<del>onia</del>	<u>MONTCALM</u> <del>Newaygo</del>
659	Bay	Jackson	Muskegon
660	Berrien	Kalamazoo	Oakland
661	Calhoun	Kent	Ottawa
662	Cass	Lapeer	Saginaw
663	Clinton	Livingston	St. Clair
664	Eaton	Macomb	Van Buren
665	Genesee	<u>MIDLAND</u>	Washtenaw
666	Ingham	Monroe	Wayne

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668 Source:

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670 | ~~65-75~~ F.R., p. ~~82238-37245~~ (~~December 27~~JUNE 28, 2000~~2010~~)

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671 Statistical Policy Office

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672 Office of Information and Regulatory Affairs

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673 United States Office of Management and Budget

**APPENDIX B**674  
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677**ICD-9-CM TO ICD-10-CM Code Translation**

<b>ICD-9 Code</b>	<b>Description</b>	<b>ICD-10 Code</b>	<b>Description</b>
426.7	Anomalous Atrioventricular Excitation	I45.6	Pre-Excitation Syndrome
427	Cardiac Dysrhythmias	I47.0-I47.9	Paroxysmal Tachycardia
		I48.0-I48.92	Atrial Fibrillation and Flutter
		I49.01-I49.9	Other Cardiac Arrhythmias
		R00.1	Bradycardia, Unspecified
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	P29.3	Persistent Fetal Circulation
		Q20.0-Q28.9	Congenital Malformations of the Circulatory System

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

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

## State of Michigan MRT-SAC 2014

**Meeting Dates:** July 30 2014, August 28 2014, October 2 2014, November 19 2014

### Members of the SAC:

Paul J. Chuba, MD, Chairperson, St. John Providence Health System  
 Bruce Carl, MD, UAW Retiree Medical Benefits Trust  
 Praveen Dalmia, McLaren Health Care  
 Joseph Delikat, Chrysler Group, LLC  
 James George-Herman, MD, Sparrow Health System  
 James A. Hayman, MD, University of Michigan Health System (UMHS)  
 Christine Kupovits, Oakwood Healthcare, Inc.  
 Gwendolyn Parker, MD, Blue Cross Blue Shield of MI  
 M. Salim U. Siddiqui, MD, Henry Ford Health System  
 Archana Somnay, MS, Huron Valley Sinai Hospital/DMC  
 Jeffery Forman, MD, 21<sup>st</sup> Century Oncology  
 Robert Evans, the International UAW Aerospace and Agriculture Implement  
 Workers of America  
 Tewfik Bichay, MD, Mercy Health-St. Mary's  
 Michael Mahacek, MD, Spectrum Health  
 E. Michael Beck, Oaklawn Hospital

### Background:

This discussion does not include HMRT units, TBI, or research units.

#### Special and and Non-Special MRT Units

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

“Special purpose MRT unit” means... (i) gamma knife, (ii) dedicated stereotactic radiosurgery unit, (iii) dedicated total body irradiator (TBI) or (iv) an OR-based IORT unit, or (v) cyberknife.

#### ETV multipliers for MRT in Michigan

“Equivalent treatment visit” or “ETV” means a unit of measure based on the type of treatment visit that reflects the relative average length of time on patient spends in one treatment visit in an MRT unit.”

ETV multiplier depends on the complexity of the treatment. A ‘simple’ treatment visit essentially means there isn’t any blocking or other devices used, and the multiplier is 1.0, An ‘intermediate visit’ means that a very basic block such as ‘corner block’ is introduced, multiplier 1.10. A ‘complex visit’ essentially means the radiation blocks conform to target usually with CT imaging for planning. An ‘IMRT

visit' means that intensity modulated radiation therapy is used, multiplier is 2.0. Intensity modulation requires computer controlled multileaf collimator and specialized treatment planning software.

### **Rules To Initiate, Replace, Expand, or Purchase an MRT Service in Michigan**

**To initiate** a new service, the applicant must project 8,000 ETVs for each proposed unit. This cannot be a special unit. The projection is based on the commitment of individual treating physicians 'excess ETVs' (see below).

**To replace** an existing MRT unit or service (includes relocation) there has to be either technological improvement, full depreciation, or a threat to patient safety. Simple replacement no longer requires ETVs. If it is replaced to a new site (relocation) then 8,000 ETVs per unit must be demonstrated (5,500 for rural, 1,000 for special purpose) and it must be the same legal entity. For volume purposes the new site remains associated with the existing service for three years.

**To expand** an MRT service by adding a unit, an average of 10,000 ETVs must be demonstrated. To expand with a special purpose unit, an average of 8,000 ETVs are needed.

**To acquire** an MRT service one has to meet volume requirements of minimum average of 8,000 ETVs annually (5,500 for rural and 1,000 for special purpose).

**Excess ETVs** A 2012 Workgroup introduced the concept of 'excess ETV'. "Excess ETVs" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. Excess ETVs are assigned to individual physicians and used to initiate a new service.

### **The Charge:**

1. Update and clarify the definition of a "Special Purpose MRT Unit" to reflect new technologies.
2. Review and revise the current definition and use of a "Cyber Knife".
3. Determine and add language that addresses the expansion of more than one "special purpose MRT unit".
4. Consider methodologies of need that utilize patient residence data.
5. Develop specific measurable quality metrics in the project delivery requirements.
6. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

### **Summary:**

#### **Charges 1-3**

Charges 1-3 are closely related and were essentially considered together by the SAC. It is worthwhile to review a synopsis of the 10/22/13 letter to Chairperson James B. Falahee Jr.

J.D. from Garry C. Faja (President and CEO of Saint Joseph Mercy Health Southeast Michigan Region, and Roger W. Spoelman (Regional President and CEO, Mercy Health West Michigan). The MRT-SAC recommendations outlined here largely follow the suggestions put forth in this letter.

- i. "...radiation therapy vendors have expanded their platform capabilities to create hybridized machines capable of a range of treatment options. This technological shift has essentially blurred the lines between the current CON definitions of "non-special MRT" and "special-purpose MRT".
- ii. "...the existing definition could be revised to be: "A special purpose MRT is any MRT that is not used for standard radiotherapy, but is dedicated to providing radiosurgery (1-5 fractions), total body irradiation, total skin irradiation , or IORT".
- iii. "We continue to support the current requirement that all special-purpose MRT units must be part of an MRT service with non-special MRT units.

The consensus of the group was that: A special purpose MRT unit is one that is dedicated to providing radiosurgery (1-5 fractions), total body irradiation, total skin irradiation, or IORT. The MRT SAC concerned itself only with the units providing radiosurgery and no changes to the total body irradiation, total skin irradiation, or IORT sections were recommended. If a unit is dedicated to providing radiosurgery, the consensus was that "dedicated" means that 90 percent of cases performed on the unit would be for radiosurgery (1-5 fractions)/total body irradiation/or IMRT and only 10 percent for conventional treatments. Otherwise, this would be considered as a non-special unit.

The MRT SAC had consensus that "stand-alone" special purpose MRT services in which the only device(s) are special purpose units should be disallowed. In addition, we recommend that an existing special purpose MRT unit may be replaced by a special MRT unit or a non-special unit as long as the site continues to operate a non-special purpose unit.

There is currently a contractual obligation with a neurosurgeon required in order to have a cyberknife or gamma knife. The MRT SAC recommended eliminating this requirement.

The MRT SAC considered the use of gating and makes the following recommendation. "Gating" also called "Motion management" is considered to be more time consuming and was therefore assigned an ETV of 1. This ETV would be in addition to the usual ETV multiplier assigned based on the use of simple, complex, IMRT methods, etc. Updated definitions for the terms "megavoltage radiation therapy," and "dedicated stereotactic radiosurgery," "gating," as well as "simulator" were constructed.

The MRT SAC requests that the Department no longer track cases treated with IGRT. This is no longer necessary, and in the future, the IGRT billing codes will be bundled with IMRT codes.

Regarding the definition of the 'Cyberknife'. Until recently, Cyber Knife was used exclusively for radiosurgery applications, the addition of multileaf collimator to this device may facilitate treatment with conventional fractionation as well.

There was consensus that the use of a trade name such as "Cyber Knife" or "Gamma Knife" in the standards should be avoided. Such units would be defined as either dedicated radiosurgery devices (i.e. more than 90 percent of cases treated in 1-5 fractions), or alternatively (in the case of a cyberknife) could be designated as non-special unit. In that instance, the somewhat more stringent requirements of non-special unit would apply.

With respect to the expansion with more than one special purpose MRT unit. It is recommended that expansion of an MRT service could include more than one "special purpose MRT unit." A service would include at least one non-special unit but more than one special purpose unit could be allowed.

#### **Charge 4**

With respect to charge 4: Consider methodologies of need that utilize patient residence data, it is worthwhile to review pertinent portions of the 10/24/2013 letter to Chairperson James B. Falahee Jr. J.D. from Ginger Williams MD, FACEP, FACHE (President and CEO, Oaklawn Hospital, Marshall, MI).

- (i) "...in 2012 a workgroup created a new methodology for determining need for a new MRT service...concerns that more work was needed on the planning areas and methodology due to potential unforeseen consequences of the new methodology..."
- (ii) "...it is important to encourage the initiation of new services in geographic areas that are most accessible to patients, which may not be the geographic areas where MRT service currently exist...By only allowing initiations in areas where existing services have excess cases available to be committed, the methodology makes it extremely difficult, if not impossible, to initiate service in geographic areas that did not already have it."
- (iii) "The first suggestion is to look at the residence location of the patients being treated rather than the facility location where they receive their treatment."
- (iv) "The second suggestion is to utilize a mileage radius planning area, instead of the Health Service Area (HSA) (groupings of counties)...If a proposed service is near an HSA boundary, it may be much farther from a patient on the opposite side of the HSA than it is to a patient just on the other side of HSA boundary."

A subcommittee was formed to examine charge '4.' This committee brought back its deliberations to the full committee. In the end, there was no change in the standard recommended by the subcommittee. The full MRT-SAC also recommended no change in the standard.

The purpose of this charge appeared to be to make it easier for new MRT services to emerge in rural or underserved areas. The argument was made that previous workgroups already made it easier for rural areas to start-up radiation services. However, it appears that economic factors rather than CON standard requirements have inhibited rural start-ups. Some alternative ideas that were considered were to change the number of driving miles, or reducing the ETV requirements. Note that for a hospital located more than 90 miles from an MRT service, there is currently no ETV requirement at all.

In order to investigate the question of rural access further, the Department provided an analysis (see below) to examine whether early stage breast cancer patients may choose mastectomy instead of combined lumpectomy and radiation based on geographic location. Because patients with early breast cancer may choose lumpectomy with radiation instead of the alternative of mastectomy, an increase in mastectomy rates in some areas may point up problems with access to radiation therapy services.

It was determined that a very small fraction of patients would be affected by geographic access issues. The Department has provided data showing that less than 2 percent of the population travels significant distance for radiation treatment.

With respect to geographic access please refer to the following attachment:

Mastectomies and Geographic Access, A Michigan Case Study by Mastectomies and MRT Access. September 23, 2014

Paul L. Delamater Department of Geography and GeoInformation Science, George Mason University, Fairfax, Virginia, USA, E-mail: [pdelamat@gmu.edu](mailto:pdelamat@gmu.edu)

### **Charge 5**

With respect to introducing new quality metrics, the MRT-SAC pointed to the changes made by the 2012 workgroup. At that time, project delivery requirements were added to include:

- 1) Evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer
- 2) Evidence of Accreditation by the American College of Surgeons, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HCAP) within the first three years of operation and continued participation thereafter.
- 3) Evidence of accreditation by the American College of Radiology (ACR), the American Society for Radiation Oncology (ASTRO), or the American College of Radiation Oncology (ACRO) within the first three years of operation and continued participation thereafter.

These requirements were reviewed in detail by the group and examples were provided.

Public comment was made regarding expanding the use of quality metrics. The discussion separated measures that would evaluate the technical aspects of the delivery of radiation therapy from measures that would evaluate the appropriateness of a specific radiation treatment. The Radiation Oncologists, Radiation Physicists, and Radiation Technologist on the MRT-SAC generally agreed that the CON section would not be able to monitor technical aspects of delivery. The above-mentioned accreditation processes are stringent and do a better job of this.

- i) Adding a requirement for reporting, in the CON Annual Survey, the percentage of Stage IV patients treated with more than 10 fractions of radiation.
  - (a) It is desirable to treat patients with metastatic disease with between one and ten daily radiation fractions in most cases. If an MRT service were to treat large percentage of patients with Stage IV disease with more fractions, this would be a quality issue.
  - (b) It was felt that the State/CON Department does not have the resources to audit this data.
  - (c) It was not clear what would be done with the results of tracking these treatments.
  
- ii) Requirement for reporting, in the CON Annual Survey, or percentage of Stage I or Stage II breast cancer patients treated with IMRT
  - (a) The use of conventional IMRT for breast cancer is controversial and some feel that similar methods (i.e. forward planned segments) not using IMRT may give equivalent dose distributions. The practice pattern in Michigan appears to vary.
  - (b) It was felt that the State/CON Department does not have resources to audit this data.
  - (c) It was not clear what would be done with the results of tracking these treatments.
  
- iii) Mandating participation in the BCBSM “Michigan Radiation Oncology Quality Consortium” (MROQC) program (or an equivalent program). A number of MRT services in Michigan already participate in the MROQC. This program correlates data regarding patient and disease characteristics, treatment approach, outcome, and acute toxicities. Briefly, the goal is improved standardization and use of defined metrics for selecting patients for treatment with IMRT. This will result in more appropriate utilization of highly complex and costly technology. As of 2014, 23 Michigan hospitals, 2 outpatient clinics, and 40 physicians were participating.

- (a) A major obstacle to this proposal would be funding from BCBS. This proposal would require expanding to all hospitals and outpatient clinics and no source of funding was identified.
  - (b) In principle, it may be preferred that quality assurance mechanism mandated by the State of Michigan, also be administered by the State as opposed to another party.
  - (c) Dr. James Hayman MD, an MRT-SAC member from the University of Michigan, happened to also serve as the co-director of the MROQC project. His opposition to the proposal was based on the above, and did influence the members, in my opinion.
  - (d) The MROQC proposal was discussed at length but not brought to a vote.
- iv) Adding a requirement that individual MRT services make public the results of American College of Surgeons (ACOS) "Cancer Program Practice Profile Reports" annually.
- (a) Currently, the ACOS measures performance rates in many areas including for example:
    - (i) Breast conservation surgery rates
    - (ii) Needle biopsy rates to precede surgical excision
    - (iii) Radiation therapy given after mastectomy for women with 4 or more regional lymph nodes
    - (iv) Radiation given within one year for women under age 70 receiving breast conservation rates for breast cancer.
  - (b) The consensus was that these surveys are beyond the scope of Radiation Oncology, affecting surgical and medical oncology as well as ancillary services.
  - (c) It was stated that requiring publication could lead to unintended consequences.
  - (d) The voluntary publication of this information may already be practiced by some groups for marketing purposes.
  - (e) A motion was made "to require on a yearly basis any facility with MRT services be required to submit their American College of Surgeon scores to the Department. The motion was defeated 5-3 with one abstention.
- v) Requirement to report adverse events. As of May 2012, LARA requires the following: "Except for an event that results from patient intervention, the registrant shall report in

writing within 30 days to the Department any event from the administration of therapeutic radiation that:

1. “Results in the total dose delivered differing from the prescribed dose by 20% or more; or”
2. “Results in any single delivered fraction of a fractionated treatment exceeding the prescribed dose by 50% or more; or”
3. “Involves the wrong patient, wrong treatment modality, or wrong treatment site. “
4. This information is available in easily accessible form for interested citizens of the State. No patient or facility information is provided.

#### **Charge 6**

The department presented the proposed updates and modifications without objection.

The MRT-SAC group did look closely at one of the updates, the so-called “second acquisition” language.

The first acquisition is the first application to acquire an MRT service and is exempted from volume requirements. Although not expressly stated in previous documents, any acquisition other than the first acquisition, must meet volume requirements. Language was added to clarify this and does not represent a change in the administration of the standards.

# State of Michigan MRT-SAC 2014

Paul J. Chuba, MD, PhD, FACR  
Chairperson, St. John Providence Health System

## Meeting Dates:

July 30 2014, August 28 2014, October 2 2014, November 19 2014

## Members of the SAC:

Bruce Carl, MD, UAW Retiree Medical Benefits Trust  
Praveen Dalmia, McLaren Health Care  
Joseph Delikat, Chrysler Group, LLC  
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Archana Somnay, MS, Huron Valley Sinai Hospital/DMC  
Jeffery Forman, MD, 21st Century Oncology  
Robert Evans, the International UAW Aerospace and Agriculture Implement  
Workers of America  
Tewfik Bichay, MD, Mercy Health-St. Mary's  
Michael Mahacek, MD, Spectrum Health

## **Special and Non-Special MRT Unit**

### **“MRT Unit”**

Means...

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

### **“Special purpose MRT unit”**

Means...

(i) gamma knife, (ii) dedicated stereotactic radiosurgery unit, (iii) dedicated total body irradiator (TBI) or (iv) an OR-based IORT unit, or (v) cyberknife.



# CYBERKNIFE: A LINAC ON A ROBOT ARM



**“Equivalent treatment visit” or “ETV”** means a unit of measure based on the type of treatment visit that reflects the relative average length of time on patient spends in one treatment visit in an MRT unit.”

**ETV multiplier** depends on the complexity of the treatment.

A **‘simple’ treatment** visit essentially means one or two ports with two or fewer simple blocks, and the multiplier is 1.0

An **‘intermediate visit’** means two or separate treatment areas, three or more ports, or three or more simple blocks, multiplier 1.10.

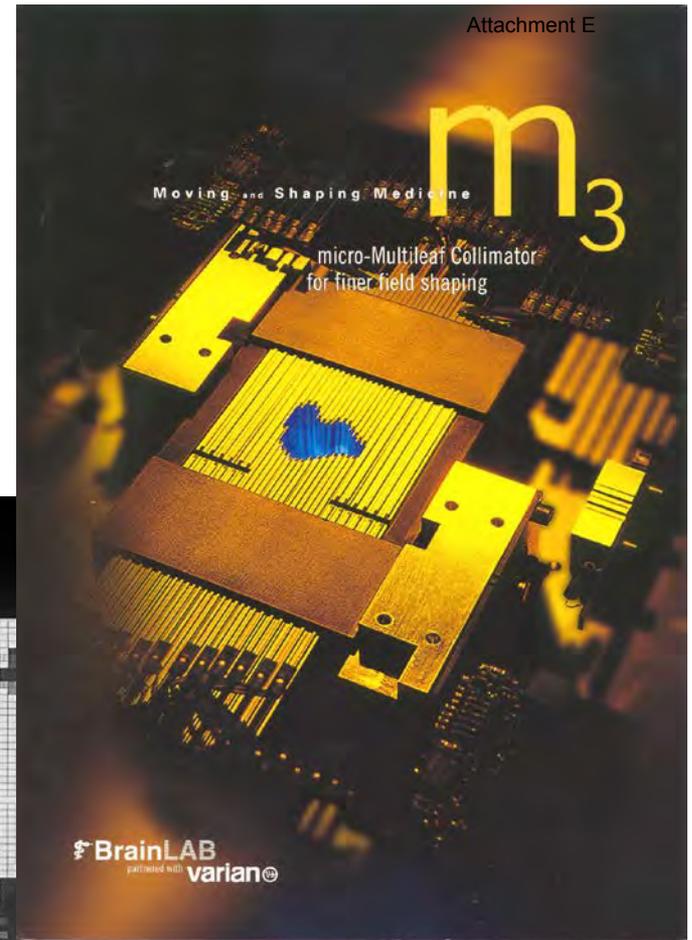
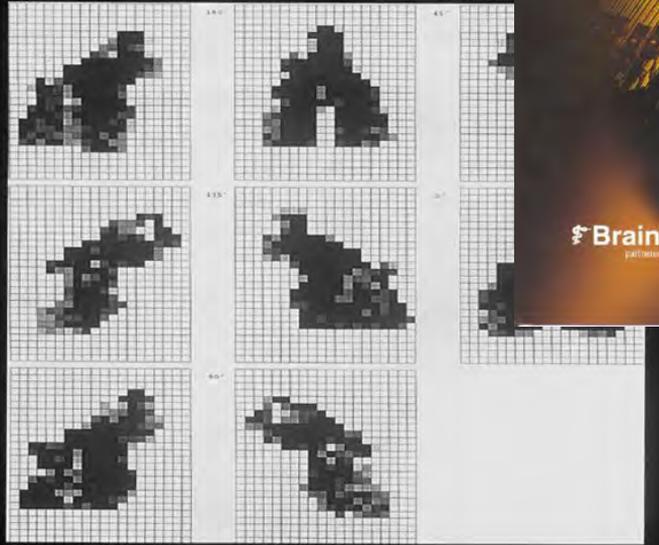
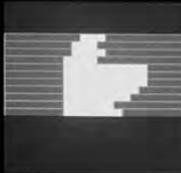
A **‘complex visit’** means three or more separate treatment areas, custom blocking, tangents, wedges, rotational beam, field in field, tissue compensator (conform to target usually with CT imaging for planning)

An **‘IMRT visit’** means that intensity modulated radiation therapy is used, multiplier is 2.0.

Intensity modulation requires computer controlled multileaf collimator and specialized treatment planning software.

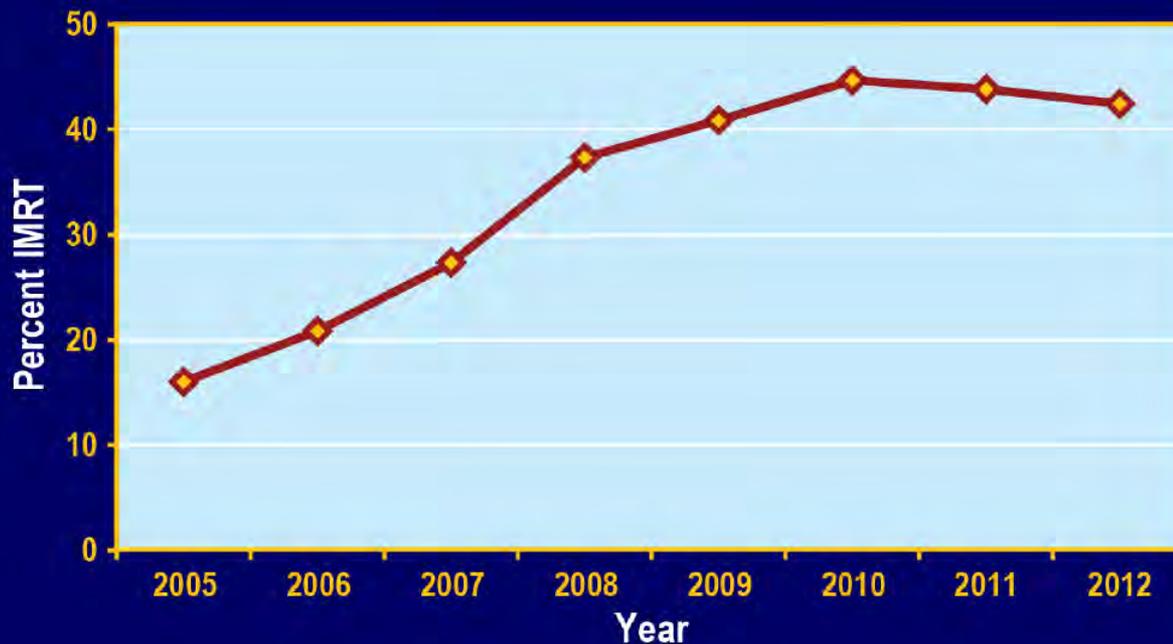
Intensity Modulation =  
IMRT

## MLC Intensity Map





## Median IMRT% in the State of Michigan



- Steady growth in IMRT utilization from a median 16% in 2005 to 42% in 2012
- Percent IMRT increases on average 3.8% per year ( $p < 0.001$ )

# Rules To Initiate, Replace, Expand, or Purchase an MRT Service in Michigan

**To initiate** a new service, the applicant must project 8,000 ETVs for each proposed unit. This cannot be a special unit. The projection is based on the commitment of individual treating physicians 'excess ETVs' (see below).

**To replace** an existing MRT unit or service (includes relocation) there has to be either technological improvement, full depreciation, or a threat to patient safety. Simple replacement no longer requires ETVs. If it is replaced to a new site (relocation) then 8,000 ETVs per unit must be demonstrated (5,500 for rural, 1,000 for special purpose) and it must be the same legal entity. For volume purposes the new site remains associated with the existing service for three years.

**To expand** an MRT service by adding a unit, an average of 10,000 ETVs must be demonstrated. To expand with a special purpose unit, an average of 8,000 ETVs are needed.

**To acquire** an MRT service one has to meet volume requirements of minimum average of 8,000 ETVs annually (5,500 for rural and 1,000 for special purpose).

**Excess ETVs** A 2012 Workgroup introduced the concept of 'excess ETV'. "Excess ETVs" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. Excess ETVs are assigned to individual physicians and used to initiate a new service.

## **The Charge:**

1. Update and clarify the definition of a “Special Purpose MRT Unit” to reflect new technologies.
2. Review and revise the current definition and use of a “Cyber Knife”.
3. Determine and add language that addresses the expansion of more than one “special purpose MRT unit”.
4. Consider methodologies of need that utilize patient residence data.
5. Develop specific measurable quality metrics in the project delivery requirements.
6. Consider any technical or other changes from the Department, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

# Charges 1-3

The consensus of the group was:

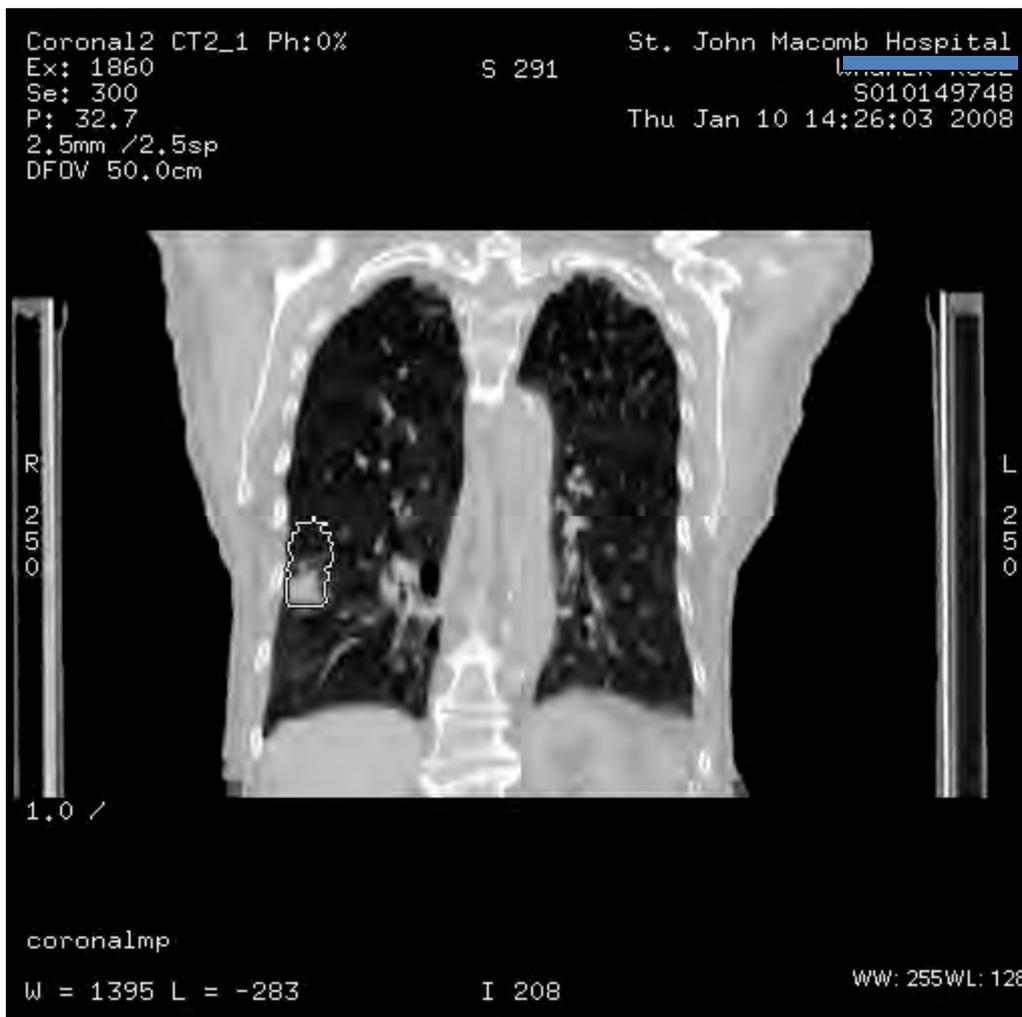
- A special purpose MRT unit is one that is dedicated to providing radiosurgery (1-5 fractions), total body irradiation, total skin irradiation, or IORT.
- If a unit is dedicated to providing radiosurgery, “dedicated” means that 90 percent of cases performed on the unit would be for radiosurgery (1-5 fractions)/total body irradiation/or IMRT and only 10 percent for conventional treatments. Otherwise, this would be considered as a non-special unit.
- The MRT SAC had consensus that “stand-alone” special purpose MRT services in which the only device(s) are special purpose units should be disallowed.
- An existing special purpose MRT unit may be replaced by a special MRT unit or a nonspecial unit as long as the site continues to operate a non-special purpose unit.
- There is currently a contractual obligation with a neurosurgeon required in order to have a cyberknife or gamma knife. The MRT SAC recommended eliminating this requirement

# Charges 1-3 Continued

- Until recently, Cyber Knife was used exclusively for radiosurgery applications, the addition of multileaf collimator to this device may facilitate treatment with conventional fractionation as well.
- There was consensus that the use of a trade name such as “Cyber Knife” or “Gamma Knife” in the standards should be avoided.
- Such units would be defined as either dedicated radiosurgery devices (i.e. more than 90 percent of cases treated in 1-5 fractions), or alternatively (in the case of a cyberknife) could be designated as non-special unit. In that instance, the somewhat more stringent requirements of non-special unit would apply.
- With respect to the expansion with more than one special purpose MRT unit. It is recommended that expansion of an MRT service could include more than one “special purpose MRT unit.” A service would include at least one non-special unit but more than one special purpose unit could be allowed.

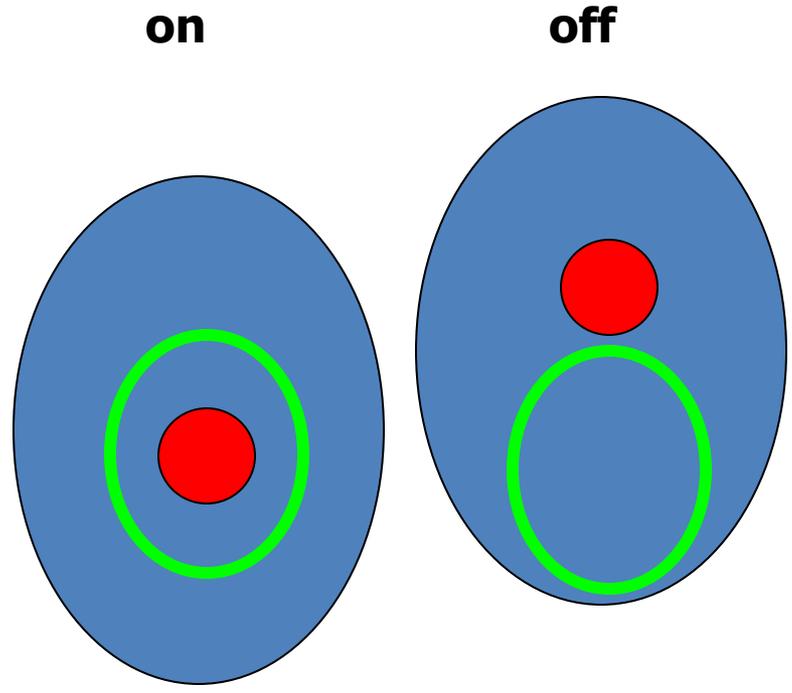
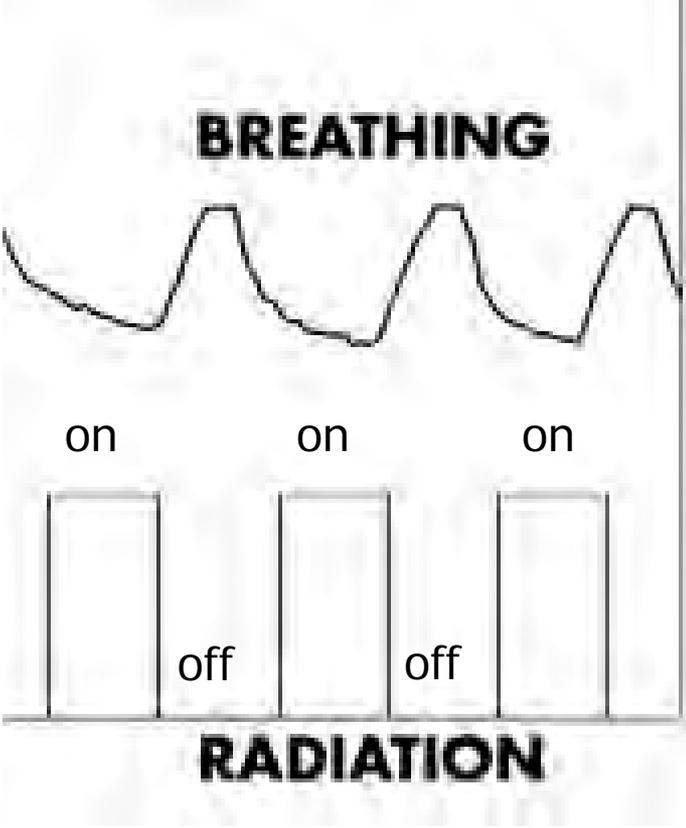
# Gating and Image Guidance

- “Gating” also called “Motion management” is considered to be more time consuming and was therefore assigned an ETV of 1.
- This ETV would be in addition to the usual ETV multiplier assigned based on the use of simple, complex, IMRT methods, etc.
- Updated definitions for the terms “megavoltage radiation therapy,” and “dedicated stereotactic radiosurgery,” “gating,” as well as “simulator” were constructed.
- The MRT SAC requests that the Department no longer track cases treated with IGRT. This is no longer necessary, and in the future, the IGRT billing codes will be bundled with IMRT codes.

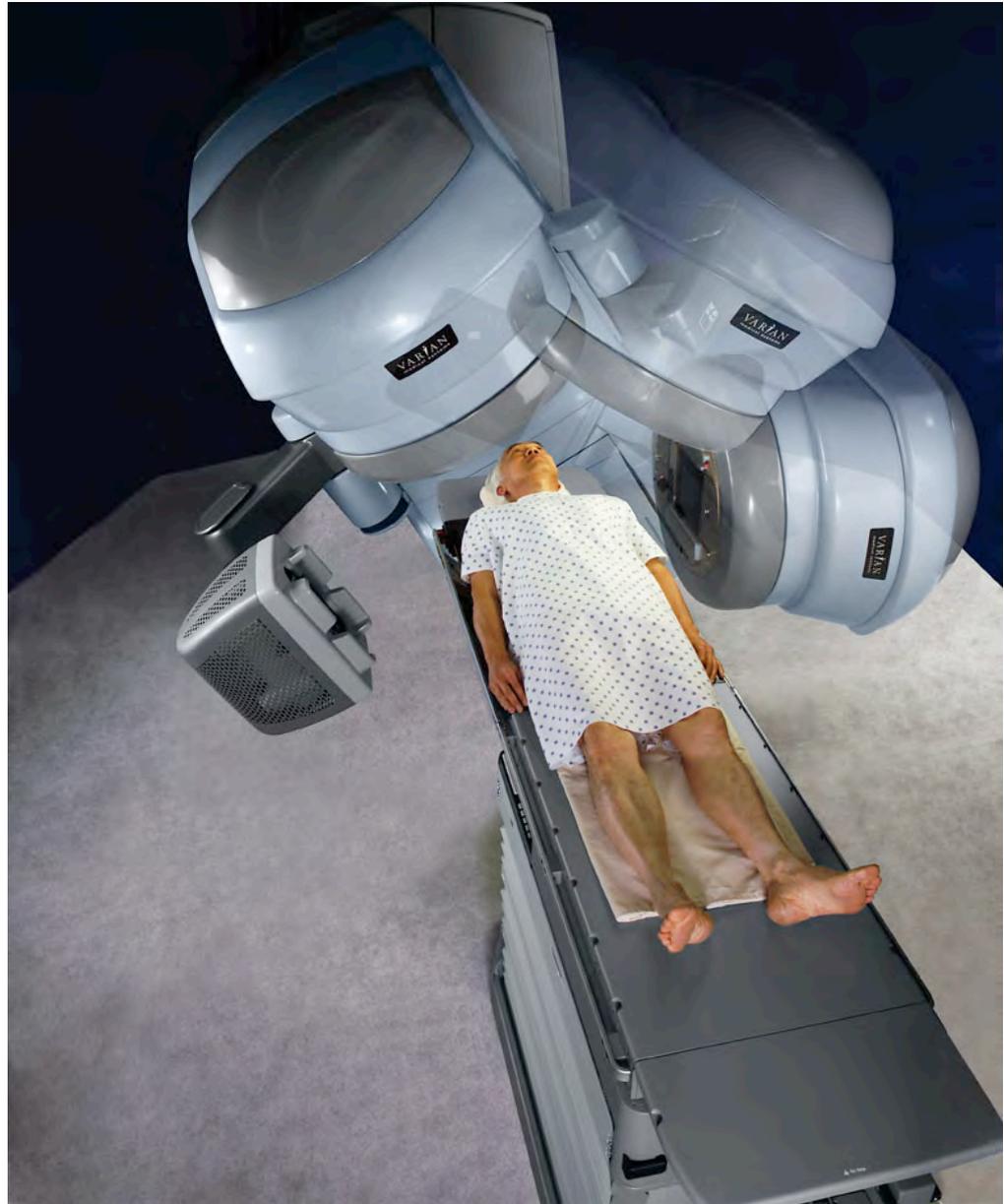


# Gating synchronizes Beam ON time to breathing pattern, allow precise targeting

Attachment E



## Cone-Beam CT



# Charge 4

Background: The purpose of this charge appeared to be to make it easier for new MRT services to emerge in rural or underserved areas. The argument was made that previous workgroups already made it easier for rural areas to start-up radiation services. However, it appears that economic factors rather than CON standard requirements have inhibited rural start-ups.

- The suggestion was instead of using excess ETVs - to use a mileage radius or to “look at the residence location rather than the facility”
- Some alternative ideas that were considered were to change the number of driving miles, or reducing the ETV requirements. Note that for a hospital located more than 90 miles from an MRT service, there is currently no ETV requirement at all.
- In order to investigate the question of rural access further, the Department provided an analysis (see below) to examine whether early stage breast cancer patients may choose mastectomy instead of combined lumpectomy and radiation based on geographic location.
- Because patients with early breast cancer may choose lumpectomy with radiation instead of the alternative of mastectomy, an increase in mastectomy rates in some areas may point up problems with access to radiation therapy services.
- It was determined that a very small fraction of patients would be affected by geographic access issues. The Department has provided data showing that less than 2 percent of the population travels significant distance for radiation treatment.

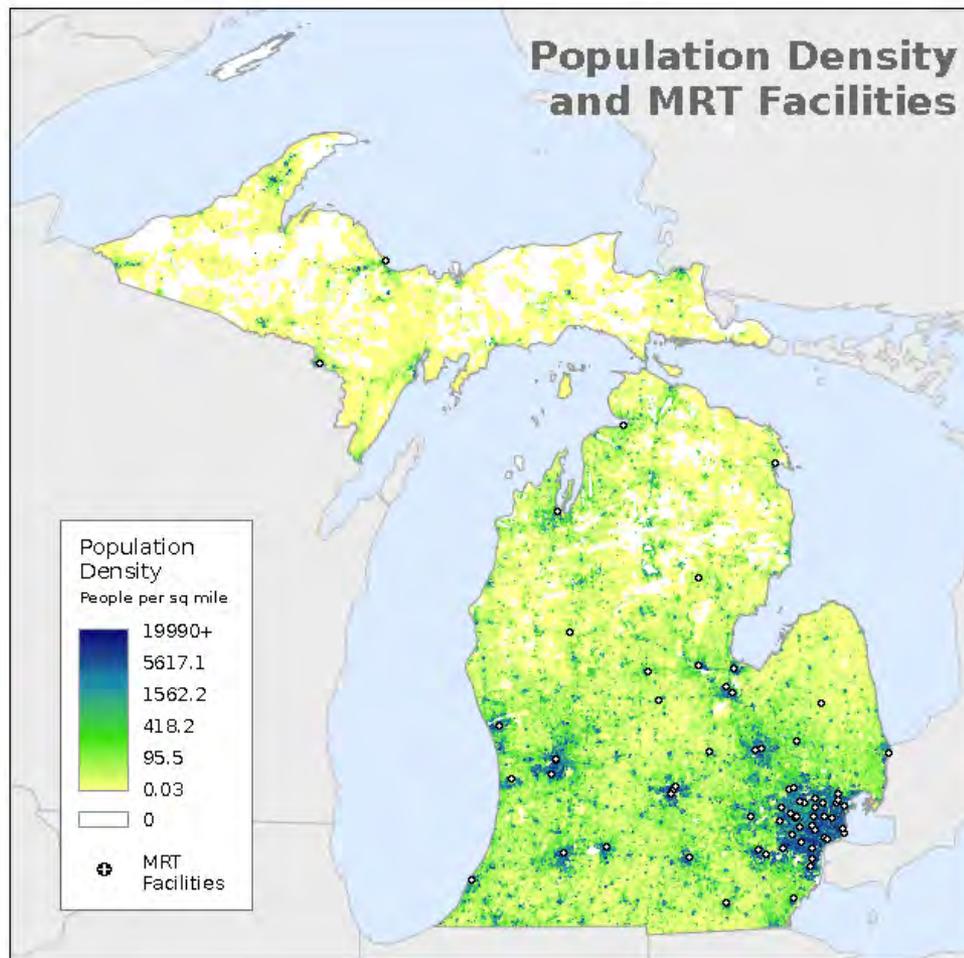


Figure 1. MRT services and population density in Michigan.

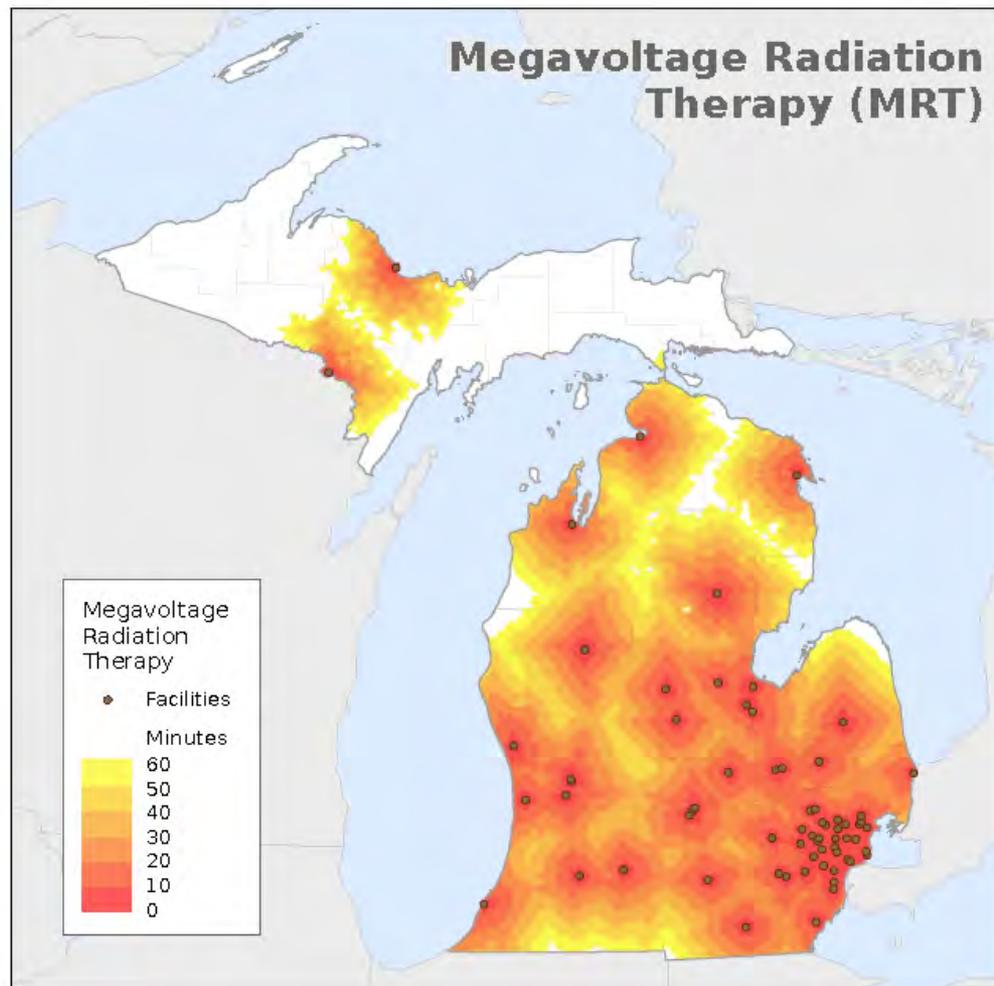


Figure 2. Geographic access to MRT services in Michigan.

**Table 1. Geographic access to MRT services in Michigan.** Travel time for the overall state population (**Pop**). % is percent of the population and C% is the cumulative percent (e.g., 93.04% of the overall population resides within 40 minutes or less of an MRT service location).

Minutes	Pop	%	C%
10	5,429,691	54.94	54.94
20	2,192,680	22.18	77.12
30	1,039,999	10.52	87.64
40	533,407	5.4	93.04
50	291,116	2.95	95.99
60	139,222	1.41	97.39
60+	257,525	2.61	100

## **Rural hospitals closing as financial problems mount.**

The [Washington Post](#) (3/16, Gugliotta) reports on the spate of closures among small rural hospitals as the facilities struggle “to weather the punishment of a changing national health-care environment.” Experts and providers point to declining Federal reimbursements for hospitals under the ACA as a main reason for the closures, as well as additional Medicare cuts “caused by a budget disagreement in Congress.” However, rural hospitals also suffer from “multiple endemic disadvantages that drive down profit margins,” including declining populations; large numbers of elderly and uninsured patients; the inability to provide “lucrative” specialty services and treatments; and an emphasis “on emergency and urgent care, chronic money-losers.”

# Charge 5

With respect to introducing new quality metrics, the MRT-SAC pointed to the changes made by the 2012 workgroup. At that time, project delivery requirements were added to include:

- Evidence of a cancer treatment program approved by the American College of Surgeons Commission on Cancer
- Evidence of Accreditation by the American College of Surgeons, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), or the Healthcare Facilities Accreditation Program (HCAP) within the first three years of operation and continued participation thereafter.
- Evidence of accreditation by the American College of Radiology (ACR), the American Society for Radiation Oncology (ASTRO), or the American College of Radiation Oncology (ACRO) within the first three years of operation and continued participation thereafter.

# Radiation Oncology Practice Accreditation

- New for Many Practices
  - ACR/ASTRO/ACRO
  - Hospital Based? – JCAHO
  - Fee
- ACR
  - Full Day On-Site Survey Per Site
  - Submit Cases
    - Definitively Treated Recently With One Follow-up Visit
    - 5 Breast, 5 Prostate, 5 Head and Neck, 5 Lung, 5 Generic
    - All Treatment Modalities i.e. IMRT, SBRT, Seed Implant
    - All Patient Records Simulation, DRR, Port Film, CT Planning, EMR Access
    - Dosimetrist/Physicist Available

# ACR Survey Components

- Charts
  - Prescriptions
  - Path Reports
  - Consent Form
  - Pathology Reports
  - History and Physical
- Physician Management Rx and F/U
  - Qualifications and Staffing Levels
  - Appropriateness of Treatment
  - Simulation/Treatment Planning
  - Dosimetry Activities
- Exit Interview
- Subsequent Random On-Site Surveys

# Reporting of Adverse Events

## LARA Requirements

- Report any Treatment that: Results in the total dose delivered differing from the prescribed dose by 20% or more.
- Report any Treatment that: Results in any single delivered fraction of a fractionated treatment exceeding the prescribed dose by 50% or more.
- Report any Treatment that: Involves the wrong patient, wrong treatment modality, or wrong treatment site. “
- This information is available in easily accessible form for interested citizens of the State.
- No patient or facility information is provided.



"Judging by your X-rays, I'd say you've been exposed to too much radiation."

# Quality Metrics Proposals: Tracking Specific Treatments

1. Requirement for reporting, in the CON Annual Survey, the percentage of Stage IV patients treated with more than 10 fractions of radiation.
  - It is desirable to treat patients with metastatic disease with between one and ten daily radiation fractions in most cases. If an MRT service were to treat large percentage of patients with Stage IV disease with more fractions, this would be a quality issue.
  
2. Requirement for reporting, in the CON Annual Survey, or percentage of Stage I or Stage II breast cancer patients treated with IMRT.
  - The use of conventional IMRT for breast cancer is controversial and some feel that similar methods (i.e. forward planned segments) not using IMRT may give equivalent dose distributions. The practice pattern in Michigan appears to vary.
  - It was felt that the State/CON Department does not have resources to audit this data.
  - It was not clear what would be done with the results.

# Quality Metrics Proposal: Publishing ACOS Survey

Adding a requirement that individual MRT services make public the results of American College of Surgeons (ACOS) “Cancer Program Practice Profile Reports” annually.

Currently, the ACOS measures performance rates in many areas

- It was felt that these surveys go beyond the scope of just Radiation
- Oncology, affecting surgical and medical oncology as well as ancillary services.
- It was stated that requiring publication could lead to unintended consequences.
- The voluntary publication of this information may already be practiced by some groups for marketing purposes.
- A motion was made “to require on a yearly basis any facility with MRT services be required to submit their American College of Surgeon scores to the Department. The motion was defeated 5-3 with one abstention.



AMERICAN COLLEGE OF SURGEONS

Inspiring Quality:  
Highest Standards, Better Outcomes



Cancer Program Practice Profile Reports (CP<sup>3</sup>R)  
for Rectum Colon Breast 2009 - 2011

St. John Macomb-Oakland Hospital, Warren, MI

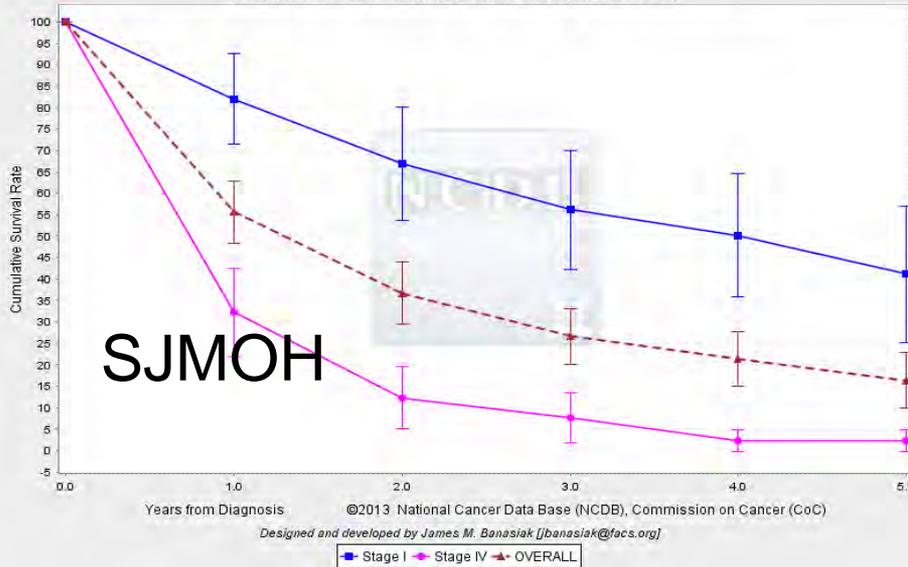
Facility Selection

**Interpreting This Report:** The estimated performance rates shown below provide your cancer program with an estimate of the proportion of patients concordant with measure criteria by diagnosis year. This application provides cancer programs the opportunity to examine data to determine if performance rates are representative of the care provided at the institution and to review and modify case information using the review function for the measure of interest.

Select Measures	Measure	Estimated Performance Rates (%)			Review
		2009	2010	2011	
Breast conservation surgery rate for women with AJCC clinical stage 0, I, or II breast cancer.	BCS				
Needle biopsy to establish diagnosis of cancer precedes surgical excision/resection	nBx				
Radiation therapy is considered or administered following any mastectomy within 1 year (365 days) of diagnosis of breast cancer for women with >= 4 positive regional lymph nodes.	MASTRT				
Radiation is administered within 1 year (365 days) of diagnosis for women under the age of 70 receiving breast conservation surgery for breast cancer.	BCSRT				
Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1c, or stage II or III hormone receptor negative breast cancer.	MAC				
Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1c or stage II or stage III hormone receptor positive breast cancer.	HT				

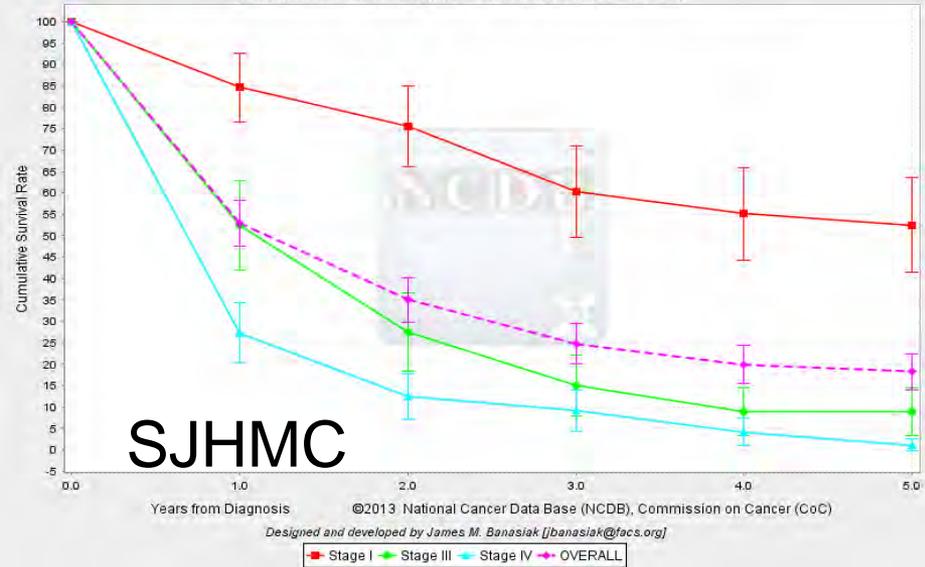
**Observed Survival For Lung, Bronchus - Non-Small Cell Carcinoma**  
 'C340','C341','C342','C343','C348','C349'

Cases Diagnosed in 2003 - 2005 Data from 1 Programs [St. John Maccomb-Oakland Hospital]  
 WARNING: The information within this graphic is not to be used for clinical decision making.



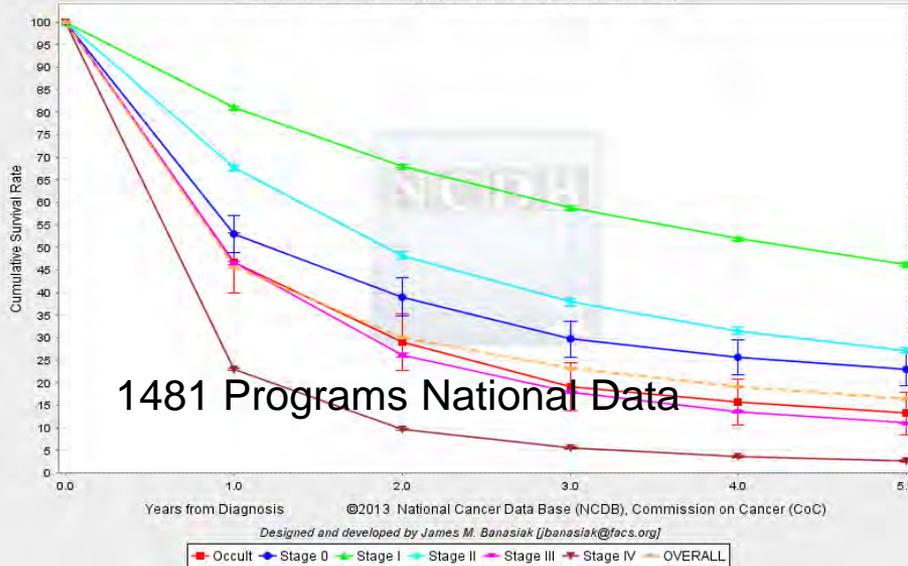
**Observed Survival For Lung, Bronchus - Non-Small Cell Carcinoma**  
 'C340','C341','C342','C343','C348','C349'

Cases Diagnosed in 2003 - 2005 Data from 1 Programs [St. John Hospital and Medical Center]  
 WARNING: The information within this graphic is not to be used for clinical decision making.



**Observed Survival For Lung, Bronchus - Non-Small Cell Carcinoma**  
 'C340','C341','C342','C343','C348','C349'

Cases Diagnosed in 2003 - 2005 Data from 1481 Programs [National]  
 WARNING: The information within this graphic is not to be used for clinical decision making.



# Quality Metrics Proposals: MROQC

Mandating participation in the BCBSM “Michigan Radiation Oncology Quality Consortium” (MROQC) program (or an equivalent program). A number of MRT services in Michigan already participate in the MROQC. This program correlates data regarding patient and disease characteristics, treatment approach, outcome, and acute toxicities.

(a) A major obstacle to this proposal would be funding from BCBS. This proposal would require expanding to all hospitals and outpatient clinics and no source of funding was identified.

(b) In principle, it may be preferred that quality assurance mechanism mandated by the State of Michigan, also be administered by the State as opposed to another party.

## Fact Sheet

### Collaborative Quality Initiative (CQI)

2014



#### About Value Partnerships

Value Partnerships is a collection of clinically oriented initiatives among Michigan physicians, hospitals and Blue Cross Blue Shield of Michigan that are improving clinical quality, reducing complications, controlling cost trends, eliminating errors, and improving health outcomes throughout Michigan.

#### About the Collaborative Quality Initiative (CQI) Program

Sponsored by BCBSM and Blue Care Network, Collaborative Quality Initiatives bring together Michigan physicians and hospital partners to address some of the most common and costly areas of surgical and medical care. CQIs rely on comprehensive clinical registries that include data on patient risk factors, processes of care, and outcomes of care. As a result of the collection and analysis of procedural and outcomes data, the participants are able to implement changes in practice, based on the knowledge acquired from the consortium. These changes in practices lead to increased efficiencies, improved outcomes, and enhanced value. There are 19 CQIs: 14 are hospital-based and 5 are professional-based. CQIs have contributed to BCBSM achieving a lower growth in medical cost trends than the national average, which helps hold down health care costs for Blues customers state-wide.

#### Michigan Radiation Oncology Quality Consortium (MROQC)

##### Overview

Focus on determining which breast and lung cancer patients are most likely to benefit from Intensity Modulated Radiation Therapy (IMRT).

##### Objectives

- Correlate data regarding patient and disease characteristics, treatment approach, outcome, and acute toxicities.
- Standardize IMRT definitions, treatment planning and delivery approaches using this technology.
- Improved standardization and use of defined metrics for selecting patients for treatment with IMRT. This will result in more appropriate utilization of highly complex and costly technology.

##### Inception Date

February 2012

##### Participants

- 23 Michigan hospitals
- 2 outpatient clinics
- 40 physicians

##### Physician Type(s)

- Radiation Oncologists

##### Data Collection

- All cases, all payer registry
- 1,214 cases entered into the registry since inception date
- MROQC-created data registry

##### Results\*

None at this time

## MROQC

Determine Which Breast and Lung Cancer Patients are Most Likely to Benefit from IMRT

Feb 2012 – Present

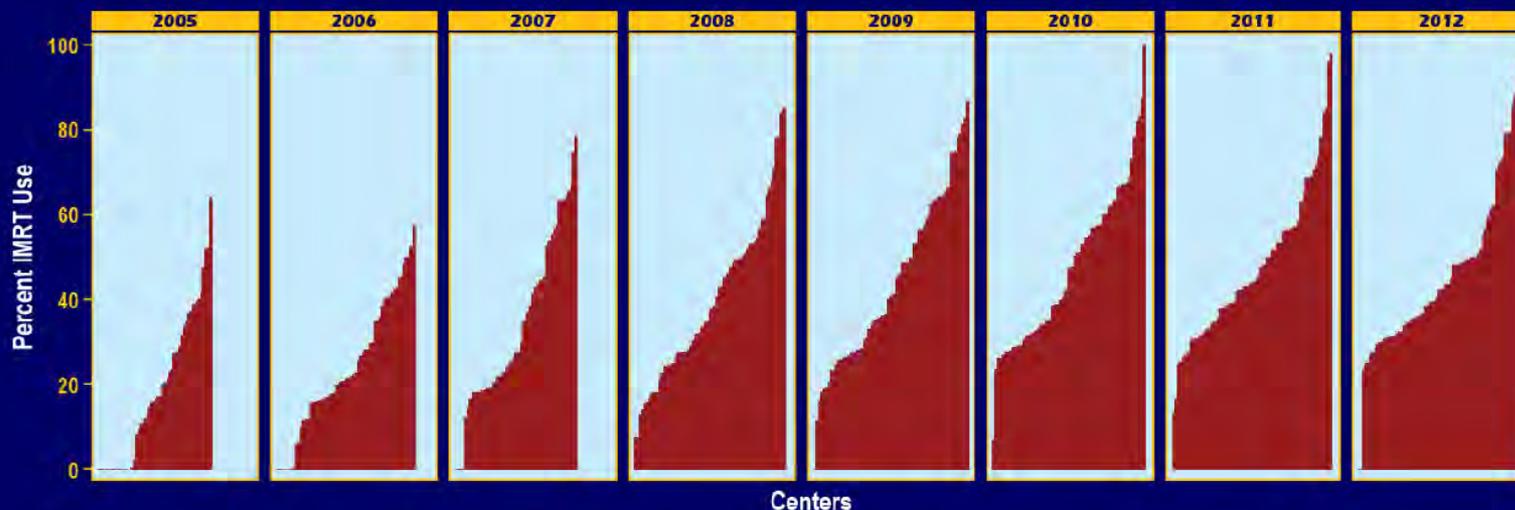
23 Hospitals  
2 Outpatient Clinics  
40 Physicians



**VALUE Partnerships**  
Improving Health Care in Michigan



# Wide variation in IMRT use



- Four-fold variation in IMRT use between centers located within the same geographic region
  - 2012: ranging from 23% to 96%
- Multiple variable model included free-standing facility and year as significant explanatory variables

# CODE GREEN

!@!

Just watch. Environmentalists will use this to push their agenda.



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The End

**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. These standards are requirements for approval to initiate, replace, expand, or acquire an MRT service under Part 222 of the Code. MRT services and units are a covered clinical service pursuant to Part 222 of the Code. The Department shall use these in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

**Section 2. Definitions**

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

(a) "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

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

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

~~—(d) "DEDICATED STEREOTACTIC RADIOSURGERY UNIT" MEANS AN MRT UNIT FOR WHICH MORE THAN 90 PERCENT OF CASES WILL BE TREATED WITH RADIOSURGERY.~~

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

(e) "Equivalent treatment visit" or "ETV" means a unit of measure, based on the type of treatment visit that reflects the relative average length of time one patient spends in one treatment visit in an MRT unit.

(f) "Excess ETVs" means the number of ETVs performed by an existing MRT service in excess of 10,000 per MRT unit. The number of MRT units used to compute excess ETVs shall include both existing and approved but not yet operational MRT units. In the case of an MRT service that operates or has a valid CON to operate that has more than one MRT unit at the same site; the term means number of ETVs in excess of 10,000 multiplied by the number of MRT units at the same site. For example, if an MRT service operates, or has a valid CON to operate, two MRT units at the same site, the excess ETVs is the number that is in excess of 20,000 (10,000 x 2) ETVs.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

95  
 96 (2) The definitions in Part 222 shall apply to these standards.

### 97 98 **Section 3. Requirements to initiate an MRT service**

99  
 100 Sec. 3. Initiate means the establishment of an MRT service where an MRT service is not currently  
 101 provided. The term does not include replacement of an existing MRT service. An applicant proposing to  
 102 initiate an MRT service shall demonstrate the following, as applicable to the proposed project.

103  
 104 (1) An applicant proposing to initiate an MRT service shall demonstrate the following:

- 105 (a) The applicant projects 8,000 equivalent treatment visits for each proposed unit.  
 106 (b) The proposed MRT unit is not a special purpose MRT unit.

107  
 108 (2) An applicant that demonstrates all of the following shall not be required to be in compliance with  
 109 the requirement in subsection (1):

- 110 (a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.  
111 (b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department,  
112 from the nearest MRT service.  
113 (c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.  
114 (d) The proposed MRT unit is not a special purpose MRT unit.  
115  
116 (3) An applicant that demonstrates all of the following shall not be required to be in compliance with  
117 the requirement in subsection (1):  
118 (a) The applicant is a hospital licensed under part 215 of the Code.  
119 (b) The site of the proposed MRT service is a hospital licensed under part 215 of the Code and  
120 located in planning area 8.  
121 (c) The site of the proposed MRT service is 90 driving miles or more, verifiable by the department,  
122 from the nearest MRT service.  
123 (d) The applicant provides comprehensive imaging services including at least the following:  
124 (i) Fixed magnetic resonance imaging (MRI) services,  
125 (ii) Fixed computed tomography (CT) services, and  
126 (iii) Mobile positron emission tomography (PET) services.  
127 (e) The proposed MRT unit is not a special purpose MRT unit.  
128  
129 (4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the  
130 following:  
131 (a) The applicant is a single legal entity authorized to do business in the State of Michigan.  
132 (b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT  
133 services with more than 30,000 equivalent treatment visits based on the most current data available to  
134 the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a  
135 corporation that is itself wholly owned by hospital(s).  
136 (c) The applicant shall include hospital MRT services from more than one planning area from one or  
137 both of the following:  
138 (i) Hospital MRT services qualified under subsection (b).  
139 (ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.  
140 (d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual  
141 Survey.  
142 (e) An application shall not be approved if it includes an MRT service described in subsection (i) or  
143 (ii) except as provided in subsections (iii) or (iv).  
144 (i) An MRT service that was part of another application under this subsection.  
145 (ii) An MRT service owned by, under common control of, or has a common parent, as an MRT  
146 service under subsection (i).  
147 (iii) The prior application, or the approved CON, were subsequently disapproved or withdrawn.  
148 (iv) The application includes a commitment from the MRT service described in subsection (i) to  
149 surrender the CON, or application, described in subsection (i) and that commitment is fulfilled at the time  
150 the application under this section is approved.  
151 (f) An application shall not be approved if it includes any of the following:  
152 (i) An MRT service that is approved but not operational, or that has a pending application, for a  
153 heavy particle accelerator.  
154 (ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT  
155 service described by subsection (i), unless the application under this subsection includes a commitment  
156 from the MRT service described in subsection (i) to surrender the CON, or application, described in  
157 subsection (i) and that commitment is fulfilled at the time the application under this section is approved.  
158 (g) An application shall not be approved if it includes any of the following:  
159 (i) An MRT service that is approved for a heavy particle accelerator that is operational.  
160 (ii) An MRT service that is owned by, under common control of, or has a common parent, as an MRT  
161 service described by subsection (i), unless the application under this section includes a commitment from  
162 the MRT service described in subsection (i) to surrender the CON described in subsection (i), and that  
163 commitment is fulfilled at the time the HMRT unit is approved and operational under this subsection.

164 (h) The applicant shall provide documentation of its process, policies and procedures, acceptable to  
 165 the Department that allows any other interested entities to participate in the collaborative utilization of the  
 166 HMRT unit.

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

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

172 (k) The applicant shall demonstrate simulation capabilities available for use in treatment planning.  
 173

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

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

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

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

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

184 (e) One (1) program director who is a board-certified physician trained in radiation oncology who may  
 185 also be the physician required under subsection (5)(a).  
 186

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

188  
 189 Sec. 4. Replacement of an existing MRT unit means an equipment change that results in a new  
 190 serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan  
 191 Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new  
 192 site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification  
 193 of equipment or software; the replacement components; or change for the purpose of maintaining or  
 194 improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing  
 195 MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.  
 196

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

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

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

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

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

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

208 (d) THE SITE AT WHICH A SPECIAL PURPOSE UNIT IS REPLACED SHALL CONTINUE TO  
 209 OPERATE A NON-SPECIAL PURPOSE UNIT.  
 210

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

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

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

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

218 (ii) HMRT unit(s) AT 8,000 equivalent treatment visits per unit.

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

220

221 (3) An applicant proposing to replace an MRT unit(s) of an existing MRT service to a new site shall  
222 demonstrate the following:

223 (a) The applicant is the same legal entity as the existing MRT service.

224 (b) For volume purposes, the new site shall remain associated with the existing MRT service for a  
225 minimum of three years.

226 (c) The MRT unit(s) to be relocated is a non-special MRT unit(s).

227 (d) The existing non-special MRT unit(s) of the MRT services from where the unit is being relocated  
228 from shall be operating at a minimum average volume of 8,000 equivalent treatment visits per unit.

229 (e) The proposed site meets the requirements of Section 3(45).

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

231 (g) The existing MRT service has been in operation for at least 36 months as of the date the  
232 application was submitted to the Department.

233

### 234 **Section 5. Requirements to expand an existing MRT service**

235

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

238

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

242

243 (2) An applicant proposing to expand an existing MRT service with a special purpose MRT unit shall  
244 demonstrate the following, as applicable to the proposed project:

245 (a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month  
246 period on each of the applicant's existing and approved non-special MRT units AND AN AVERAGE OF  
247 1,000 EQUIVALENT TREATMENT VISITS WAS PERFORMED IN THE MOST RECENT 12-MONTH  
248 PERIOD ON EACH OF THE APPLICANT'S EXISTING AND APPROVED SPECIAL PURPOSE MRT  
249 UNITS.

250 (b) An applicant proposing to add a dedicated total body irradiator shall operate a bone marrow  
251 transplantation program or have a written agreement to provide total body irradiation services to a  
252 hospital that operates a bone marrow transplantation program.

253 (c) ~~An applicant proposing to add a dedicated stereotactic radiosurgery unit such as a gamma knife~~  
254 ~~or cyber knife, shall demonstrate that the applicant has a contractual relationship with a board-eligible or~~  
255 ~~board-certified neurosurgeon(s) trained in stereotactic radiosurgery and on-site 3-dimensional imaging~~  
256 ~~and 3-dimensional treatment planning capabilities.~~

257 ~~—(d)—~~An applicant proposing to add an intraoperative MRT unit in an existing or proposed hospital  
258 operating room shall demonstrate that the unit is a linear accelerator with only electron beam capabilities.

259

### 260 **Section 6. Requirements to acquire an existing MRT service**

261

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

266

267 (1) ~~For the first~~AN application ~~proposing to~~FOR THE FIRST acquire acquisition OF an existing MRT  
268 service, other than the renewal of a lease, on or after November 21, 2011, ~~the existing MRT service~~ shall  
269 not be required to be in compliance with the applicable volume requirements set forth in ~~this~~  
270 ~~section~~Section 11. THE MRT SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES SET  
271 FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF  
272 OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.

273

274 (2) ~~an applicant proposing to acquire an existing MRT service shall demonstrate the following:~~  
 275 ~~—(a) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the~~  
 276 ~~proposed project:—~~  
 277 ~~—(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved~~  
 278 ~~under Section 3(2) or 3(3).~~  
 279 ~~—(ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.~~  
 280 ~~—(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.~~ FOR ANY APPLICATION  
 281 PROPOSING TO ACQUIRE AN EXISTING MRT SERVICE, EXCEPT THE FIRST APPLICATION  
 282 APPROVED PURSUANT TO SUBSECTION (1), AN APPLICANT SHALL BE REQUIRED TO  
 283 DOCUMENT THAT THE MRT SERVICE TO BE ACQUIRED IS OPERATING IN COMPLIANCE WITH  
 284 THE VOLUME REQUIREMENTS SET FORTH IN SECTION 11 OF THESE STANDARDS APPLICABLE  
 285 TO AN EXISTING MRT SERVICE ON THE DATE THE APPLICATION IS SUBMITTED TO THE  
 286 DEPARTMENT.

287  
 288 (3) An applicant proposing to renew a lease for an existing MRT unit shall demonstrate the renewal  
 289 of the lease is more cost effective than replacing the equipment.

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

292  
 293 Sec. 7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the  
 294 following:

295  
 296 (1) The applicant is an existing MRT service.

297  
 298 (2) The applicant agrees that the dedicated research MRT unit(s) will be used primarily (70% or more  
 299 of treatments) for research purposes.

300  
 301 (3) The dedicated research MRT unit(s) shall operate under a protocol approved by the applicant's  
 302 Institutional Review Board (IRB), as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

303  
 304 (4) The applicant operates a therapeutic radiation residency program approved by the American  
 305 Medical Association, the American Osteopathic Association, or an equivalent organization.

306  
 307 (5) The proposed site can have no more than two dedicated research MRT units.

### 309 **Section 8. Requirements for Medicaid participation**

310  
 311 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
 312 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
 313 to the Department within six (6) months from the offering of services, if a CON is approved.

### 315 **Section 9. Methodology for projecting equivalent treatment visits**

316  
 317 Sec. 9. An applicant being reviewed under Section 3 shall apply the methodology set forth in this  
 318 section in computing the projected number of equivalent treatment visits.

319  
 320 (1) An applicant shall demonstrate that the projection is based on the commitments of the  
 321 treatments provided by the treating physician(s) for the most recent 12-month period immediately  
 322 preceding the date of the application. The commitments of the treating physician(s) will be verified with  
 323 the data maintained by the Department through its "CON Annual Survey."

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

326  
 327 (2) An applicant shall demonstrate that the projected number of commitments to be performed at the  
 328 proposed site under subsection (1) are from an existing MRT service that is in compliance with the

329 volume requirements applicable to that service, and will continue to be in compliance with the volume  
 330 requirements applicable to that service subsequent to the initiation of the proposed MRT service by an  
 331 applicant. Only excess ETVs equal to or greater than what is being committed pursuant to this  
 332 subsection may be used to document projections under subsection (1). In demonstrating compliance with  
 333 this subsection, an applicant shall provide each of the following:

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

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

342 (c) The projected commitments are from an existing MRT service within the same planning  
 343 area as the proposed MRT service.

344

### 345 Section 10. Equivalent treatment visits

346

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

348

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

351

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

355

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

359

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

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

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

GATING RECEIVES A 1.00 ADDITIVE FACTOR. GATING IS THE CAPTURING AND MONITORING OF THE TARGET'S OR FIDUCIAL'S MOTION DURING RADIATION TREATMENT AND THE MODULATION OF THE RADIATION BEAM IN ORDER TO MORE PRECISELY DELIVER RADIATION TO THE TARGET AND/OR DECREASE THE RADIATION DOSE TO THE SURROUNDING NORMAL TISSUE.

~~\*\_After the first visit, each additional visit receives 2.5 additional equivalent treatment visits with a maximum of five visits per course of therapy.~~

~~\*\*~~

~~\*\*After the first isocenter, each additional isocenter receives 4\_6 additional equivalent treatment visits.~~  
THERE IS A MAXIMUM OF FIVE VISITS PER COURSE OF THERAPY.

360

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

363

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

366

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

370

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

373

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

376

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

379

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

382

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

385

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

387

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

390

391 (1) Compliance with these standards.

392

393 (2) Compliance with the following quality assurance standards:

394

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

403

403 (b) An applicant shall have the following staff:

404

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

406

406 (ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic  
 407 radiologic physics, immediately available during hours of operation.

- 408 (iii) One (1) dosimetrist for every 300 patients treated with MRT annually.
- 409 (iv) Two (2) radiation therapists registered or eligible by the American Registry of Radiological  
410 Technologists (ARRT), for every MRT unit per shift of operation (not including supervisory time).
- 411 (v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who  
412 may also be the physician required under subsection (i). The Department shall consider it prima facie  
413 evidence as to the training of the physician(s) if the physician is board certified or board qualified in  
414 radiation oncology and/or therapeutic radiology.
- 415 (c) All MRT treatments shall be performed pursuant to a radiation oncologist and at least one  
416 radiation oncologist will be immediately available during the operation of the unit(s).
- 417 (d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur.  
418 Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the  
419 MRT unit at all times when patients are treated. A physician shall be on-site or immediately available to  
420 the MRT unit at all times when patients are treated.
- 421 (e) An applicant shall operate a cancer treatment program. The Department shall consider it prima  
422 facie evidence if the applicant submits evidence of a cancer treatment program approved by the  
423 American College of Surgeons Commission on Cancer. A cancer treatment program is a coordinated,  
424 multi-disciplinary approach to the treatment of patients with cancer or other neoplasms, which must  
425 provide on-site simulation capability, and, either on-site or through written agreements with other  
426 providers, all of the following services: access to consultative services from all major disciplines needed  
427 to develop a comprehensive treatment plan, a computer-based treatment planning system, medical  
428 radiation physicist involvement, MRT capability including electron beam capability, treatment aid  
429 fabrication capability, brachytherapy, a multi-disciplinary cancer committee, a tumor registry, patient care  
430 evaluation studies, and cancer prevention and education programs. The applicant may also submit, and  
431 the Department may accept, other evidence. Patient care evaluation studies means a system of patient  
432 care evaluation, conducted at least twice annually, that documents the methods used to identify problems  
433 and the opportunities to improve patient care. Tumor registry means a manual or computerized data  
434 base containing information about all malignancies and only those that are diagnosed and/or treated at  
435 the applicant's facility. The malignancies must be reportable to the Michigan Cancer Surveillance  
436 Program as required pursuant to Public Act 82 of 1984, as amended.
- 437 (i) An applicant shall submit evidence of accreditation by the American College of Surgeons  
438 Commission on cancer, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO),  
439 or the Healthcare Facilities Accreditation Program (HFAP) within the first three years of operation and  
440 continue to participate annually thereafter.
- 441 (ii) An applicant shall submit evidence of accreditation by the American College of Radiology (ACR),  
442 American Society for Radiation Oncology (ACR/ASTRO) or the American College of Radiation Oncology  
443 (ACRO) within the first three years of operation and continue to participate annually thereafter.
- 444 (f) The MRT service will have simulation capability at the same location.
- 445 (g) An applicant shall participate in the Michigan Cancer Surveillance Program.
- 446 (h) The applicant agrees to operate a special purpose MRT unit(s) only for the specific use for which  
447 it was approved.
- 448 (i) An applicant approved to operate a dedicated total body irradiator that uses cobalt as the source  
449 of radiation shall obtain and maintain Nuclear Regulatory Commission certification. An applicant  
450 approved to operate a dedicated total body irradiator that is a permanently modified linear accelerator, or  
451 an HMRT unit, shall meet any requirements specified by the State of Michigan Radiation Safety Section.
- 452 (j) All patients treated on an HMRT unit shall be evaluated for potential enrollment in research  
453 studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of specific cancer  
454 conditions. The number of patients treated, number enrolled in research studies, and the types of cancer  
455 conditions involved shall be provided to the Department as part of the CON Annual Survey.
- 456 (k) The operation of and referral of patients to the MRT unit shall be in conformance with 1978 PA  
457 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
- 458
- 459 (3) Compliance with the following access to care requirements:
- 460 (a) The applicant shall accept referrals for MRT services from all appropriately licensed health care  
461 practitioners.

- 462 (b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan  
 463 population, the applicant shall:
- 464 (i) not deny MRT services to any individual based on ability to pay or source of payment,  
 465 (ii) provide MRT services to an individual based on the clinical indications of need for the service,  
 466 and
- 467 (iii) maintain information by payor and non-paying sources to indicate the volume of care from each  
 468 source provided annually. Compliance with selective contracting requirements shall not be construed as  
 469 a violation of this term.
- 470 (c) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years  
 471 of operation and continue to participate annually thereafter.
- 472
- 473 (4) Compliance with the following monitoring and reporting requirements:
- 474 (a) Non-special MRT units and HMRT units shall be operating at a minimum average volume of  
 475 8,000 Equivalent Treatment Visits per unit annually by the end of the third full year of operation, and  
 476 annually thereafter. All special purpose MRT units shall be operating at a minimum average volume of  
 477 1,000 equivalent treatment visits per special purpose unit by the end of the third full year of operation, and  
 478 annually thereafter. An applicant shall not include any treatments conducted on a dedicated research  
 479 MRT unit.
- 480 (b) Non-special MRT units and HMRT units approved pursuant to Section 3(2) or 3(3) of these  
 481 standards shall be operating at a minimum average volume of 5,500 equivalent treatment visits per unit  
 482 by the end of the third full year of operation, and annually thereafter. An applicant shall not include any  
 483 treatments conducted on a dedicated research MRT unit.
- 484 (c) An applicant is not required to be in compliance with subsections (4)(a) or (b) if the applicant is  
 485 replacing an MRT unit under section 4(1).
- 486 (d) An applicant shall participate in a data collection network established and administered by the  
 487 Department or its designee. The data may include, but is not limited to, annual budget and cost  
 488 information, operating schedules, through-put schedules, demographic and diagnostic information, and  
 489 the volume of care provided to patients from all payor sources and other data requested by the  
 490 Department. Data shall be provided by each type of MRT unit in a format established by the Department  
 491 and in a mutually agreed upon media. The Department may elect to verify the data through on-site  
 492 review of appropriate records.
- 493 (e) Services provided on a dedicated research MRT unit shall be delivered in compliance with the  
 494 following terms:
- 495 (i) Capital and operating costs for research treatment visits shall be charged only to a specific  
 496 research account(s) and not to any patient or third-party payor.
- 497 (ii) The dedicated research MRT unit shall not be used for any purposes other than as approved by  
 498 the IRB.
- 499 (iii) The treatments on a dedicated research MRT unit shall not be used for any volume purposes.
- 500
- 501 (5) The applicable agreements and assurances required by this section shall be in the form of a  
 502 certification agreed to by the applicant or its authorized agent.

## 504 **Section 12. Effect on prior CON review standards; comparative reviews**

506 Sec. 12. proposed projects reviewed under these standards shall not be subject to comparative  
 507 review. These standards supersede and replace the CON Review Standards for MRT Services/Units  
 508 approved by the CON Commission on ~~September 22, 2014~~MARCH 28, 2013 and effective ~~November 21,~~  
 509 ~~2014~~MAY 24, 2013.

**APPENDIX A**511  
512  
513  
514  
515**PLANNING AREAS BY COUNTY**

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

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**APPENDIX B**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

Allegan	<u>HILLSDALE</u>	<u>MASON</u>
Alpena	Houghton	Mecosta
Benzie	<u>IONIA</u>	Menominee
Branch	Isabella	<u>Midland</u>
Chippewa	Kalkaska	Missaukee
Delta	Keweenaw	St. Joseph
Dickinson	Leelanau	Shiawassee
Grand Traverse	Lenawee	Wexford
Gratiot	Marquette	

Metropolitan statistical area Michigan counties are as follows:

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

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Source:

| 65-75 F.R., p. 82238-37245 (December 27, 2000)  
 | JUNE 28, 2010  
 | Statistical Policy Office  
 | Office of Information and Regulatory Affairs  
 | United States Office of Management and Budget

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

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

**POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES**

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

**Section 1. Applicability**

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

**Section 2. Definitions**

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

- (a) "Central service coordinator" means the legal entity that has operational responsibility for a mobile PET scanner service.
- (b) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.
- (c) "Department" means the Michigan Department of Community Health (MDCH).
- (d) "Existing PET scanner" means an operational PET scanner used to provide PET services on the date an application is submitted to the Department.
- (e) "Existing PET scanner service" means an operational PET scanner service providing PET scanner services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.
- (f) "Health service area" or "HSA" means the groups of counties listed in Appendix A.
- (g) "Hospital" means a health facility licensed under Part 215 of the Code.
- (h) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.
- (i) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396 to 1396g and 1396i to 1396u.
- (j) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.
- (k) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a central service coordinator that serves two or more host sites.
- (l) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON.
- (m) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET procedures are performed.
- (n) "Pediatric patient" means any patient less than 18 years of age.
- (o) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.
- (p) "PET scan" means one (1) or more PET procedures performed during a single patient visit.
- (q) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction. Further, the term does include PET/computed tomography

55 (CT) and FDA-approved PET/magnetic resonance imaging (MRI) scanner hybrids. If the PET/CT  
 56 scanner hybrid will be used for CT scans only in conjunction with the PET scan, then no separate CON is  
 57 required for that CT use. If the FDA-approved PET/MRI scanner hybrid will be used for MRI scans only in  
 58 conjunction with the PET scan, then no separate CON is required for that MRI use. The term does not  
 59 include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic  
 60 resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-  
 61 coincidence or coincidence imaging, or similar technology.

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

64 (s) "SPECT" means single photon emission computed tomography.

65

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

67

### 68 **Section 3. Requirements to initiate a PET scanner service**

69

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

72

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

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

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

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

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

80 (e) cardiac catheterization services,

81 (f) open heart surgery,

82 (g) thoracic surgery,

83 (h) cardiology,

84 (i) oncology,

85 (j) radiation oncology,

86 (k) neurology,

87 (l) neurosurgery, and

88 (m) psychiatry.

89

90 (2) If the proposed site does not provide any of the services listed in subsection (1) on-site, the  
 91 applicant shall provide written contracts or agreements with a hospital(s) located within the same planning  
 92 area or 25-mile radius of the proposed site for the services not provided.

93

94 (3) The applicant shall demonstrate the proposed site has an on-site source of  
 95 radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals,  
 96 the applicant shall provide a written contract or agreement that demonstrates a reliable supply of  
 97 radiopharmaceuticals.

98

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

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

102 (b) The applicant has performed:

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

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

107 (c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a  
 108 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a  
 109 rural or micropolitan statistical area.

110 (d) The applicant agrees to cease operation as a host site and not become a host site for at least  
 111 12 months from the date the fixed PET scanner becomes operational. This requirement shall not apply if  
 112 the applicant is installing an FDA-approved PET/MRI scanner hybrid.

113  
 114 (5) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET  
 115 scanner shall project 2,100 PET data units.

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

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

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

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

124  
 125 (6) An applicant proposing to initiate a host site on a proposed or existing mobile PET scanner  
 126 service shall demonstrate the following:

127 (a) The applicant provides a proposed route schedule.

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

130 (c) The applicant has not initiated fixed PET scanner services under subsection 3(4) within the  
 131 most recent 12-month period as of the date the application is submitted to the Department.

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

134  
 135 (7) An applicant proposing to initiate PET scanner services as an existing host site on a different  
 136 mobile PET scanner service shall demonstrate the following:

137 (a) The applicant provides a proposed route schedule.

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

140 (c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the  
 141 Department from an existing mobile PET scanner service at the existing host site.

#### 142 143 **Section 4. Requirements to replace an existing PET scanner(s) or PET scanner service**

144  
 145 Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the  
 146 service to a new site. An upgrade to software or components of an existing scanner does not constitute  
 147 replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET  
 148 scanner service shall demonstrate the following, as applicable to the proposed project.

149  
 150 (1) An applicant proposing to replace a PET scanner(s) shall demonstrate each of the following:

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

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

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

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

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

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

162 (a) The proposed site is within a 10-mile radius of the existing site for a metropolitan statistical area  
163 county or a 25-mile radius for a rural or micropolitan statistical area county.

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

166 (c) The existing fixed PET scanner service has been in operation for at least 36 months as of the  
167 date of the application submitted to the Department.

#### 168 **Section 5. Requirements to expand a PET scanner service**

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

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

174 (a) 1,900 PET equivalents were performed per existing and approved fixed PET scanner(s) in the  
175 most recent 12-month period verifiable by the Department for an applicant in a metropolitan statistical  
176 area county, or

177 (b) 1,700 PET equivalents were performed per existing and approved fixed PET scanner(s) in the  
178 most recent 12-month period verifiable by the Department for an applicant in a rural or micropolitan  
179 statistical area county.

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

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

183 (a) 2,000 PET equivalents were performed per existing and approved mobile scanner(s) in the  
184 most recent 12-month period verifiable by the Department for an applicant serving at least one existing  
185 host site in a metropolitan statistical area county, or

186 (b) 1,800 PET equivalents were performed per existing and approved scanner(s) in the most recent  
187 12-month period verifiable by the Department for an applicant serving only host sites in rural or  
188 micropolitan statistical area counties.

189 (3) An applicant proposing to add a fixed PET scanner to an existing fixed PET scanner service  
190 that also receives mobile PET scanner services shall demonstrate the following:

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

192 (b) The applicant has performed:

193 (i) An average of 1,900 pet equivalents for the host site and each of the existing and approved  
194 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a  
195 metropolitan statistical area county, or

196 (ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved  
197 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a rural or  
198 micropolitan statistical area county.

199 (c) The applicant agrees to cease operation as a host site and not become a host site for at least  
200 12 months from the date the fixed scanner becomes operational.

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

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

214 (1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner  
 215 service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its  
 216 scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in  
 217 this section. The PET SCANNER SERVICE SHALL BE OPERATING AT THE APPLICABLE VOLUMES  
 218 SET FORTH IN THE PROJECT DELIVERY REQUIREMENTS IN THE SECOND 12 MONTHS OF  
 219 OPERATION OF THE SERVICE BY THE APPLICANT AND ANNUALLY THEREAFTER.

220  
 221 (2) FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING PET SCANNER  
 222 SERVICE, EXCEPT THE FIRST APPLICATION APPROVED PURSUANT TO SUBSECTION (1), AN  
 223 APPLICANT SHALL BE REQUIRED TO DOCUMENT THAT THE PET SCANNER SERVICE TO BE  
 224 ACQUIRED IS OPERATING IN COMPLIANCE WITH THE VOLUME REQUIREMENTS SET FORTH IN  
 225 SECTION 11 OF THESE STANDARDS APPLICABLE TO AN EXISTING PET SCANNER SERVICE ON  
 226 THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT.

227  
 228 (23) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall  
 229 demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents  
 230 per scanner in the most recent 12-month period verifiable by the Department.

231  
 232 (34) An applicant proposing to acquire an existing host site shall demonstrate that the existing host  
 233 site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

234  
 235 (45) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall  
 236 demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

#### 237 **Section 7. Requirements for a dedicated research fixed PET scanner**

238  
 239 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for  
 240 exclusive research use shall demonstrate the following:

241  
 242 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or  
 243 more of the scans) for research purposes only.

244  
 245 (2) The dedicated research PET scanner shall operate under a protocol approved by the applicant's  
 246 Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

247  
 248 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by  
 249 means of electromagnetic fields.

250  
 251 (4) The proposed site can have no more than three dedicated research fixed PET scanners  
 252 approved under this Section.

#### 253 **Section 8. Requirements for a dedicated pediatric PET scanner**

254  
 255 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to  
 256 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

257  
 258 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or  
 259 more of the scans) for patients under 18 years of age.

260  
 261 (2) The applicant shall demonstrate the existing site provided the following for the most recent  
 262 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

263 (a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,

264 (b) at least 5,000 pediatric (< 18 years old) surgeries, and

265 (c) at least 50 new pediatric cancer cases on its cancer registry.

268

269 (3) The applicant shall have an active medical staff at the time the application is submitted to the  
270 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

271 (a) radiology (at least two staff members)

272 (b) anesthesiology

273 (c) cardiology

274 (d) critical care

275 (e) gastroenterology

276 (f) hematology/oncology

277 (g) neurology

278 (h) neurosurgery

279 (i) orthopedic surgery

280 (j) pathology

281 (k) pulmonology

282 (l) surgery

283 (m) neonatology

284

285 (4) The applicant shall have in operation the following pediatric specialty programs at the time the  
286 application is submitted to the Department:

287 (a) bone marrow transplant program

288 (b) sedation program

289 (c) open heart program

290

291 (5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a  
292 PET scanner service with a dedicated pediatric fixed PET scanner.

293

294 (6) The proposed site can have no more than two dedicated pediatric fixed PET scanners approved  
295 under this section.

296

### 297 **Section 9. Requirements for a positron emission mammography (PEM) scanner**

298

299 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service  
300 shall demonstrate the following, as applicable to the proposed project.

301

302 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall  
303 demonstrate the following:

304 (a) The applicant is certified through the American College of Radiology (ACR) as a Breast Imaging  
305 Center of Excellence (BICOE) at the time the application is submitted to the Department.

306 (b) The applicant has a fixed PET scanner service and has performed 1,000 PET equivalents per  
307 scanner at the site in the most recent 12-month period verifiable by the Department, or the applicant  
308 operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with a  
309 facility that has a fixed PET scanner service.

310 (c) The proposed site can have no more than one fixed PEM scanner approved under this section.

311

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

314 (a) The central service coordinator application for a mobile PEM scanner shall be accompanied by  
315 at least five (5) companion host site applications for initiation of mobile PEM scanner services. The  
316 proposed host sites have not received mobile PEM scanner services within the most recent 12-month  
317 period.

318 (b) The applicant has performed an average of 500 PET equivalents per scanner on the existing  
319 mobile PET network in the most recent 12-month period verifiable by the Department.

320 (c) The applicant provides a route schedule for the proposed mobile PEM scanner service.

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

323 (e) The proposed network can have no more than one mobile PEM scanner approved under this  
 324 section.

325  
 326 (3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate  
 327 mobile PEM scanner services as a host site shall demonstrate the following:

328 (a) The applicant is certified through the ACR as a BICOE site at the time the application is  
 329 submitted to the Department.

330 (b) The applicant has a fixed PET scanner site or host site and has performed 100 PET equivalents  
 331 in the most recent 12-month period verifiable by the Department, or the applicant operates a  
 332 comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that  
 333 has a fixed or mobile PET scanner service.

334 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

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

337  
 338 (4) An applicant proposing to add an existing PEM scanner host site to an existing mobile PEM  
 339 scanner service shall demonstrate the following:

340 (a) The host site has performed mobile PEM scanner service within the most recent 12-month  
 341 period as of the date an application is submitted to the Department.

342 (b) The proposed site is certified through the ACR as a BICOE site at the time the application is  
 343 submitted to the Department.

344 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

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

347

#### 348 **Section 10. Requirement for Medicaid participation**

349

350 Sec. 10. An applicant shall provide verification of Medicaid participation. An applicant that is a new  
 351 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided  
 352 to the Department within (6) months from the offering of services if a CON is approved.

353

#### 354 **Section 11. Project delivery requirements and terms of approval for all applicants**

355

356 Sec. 11. An applicant shall agree that, if approved, the PET scanner services shall be delivered in  
 357 compliance with the following terms of approval.

358

359 (1) Compliance with these standards.

360

361 (2) Compliance with the following quality assurance requirements:

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

371 (b) The PET scanner service shall include the following personnel, employed directly or on a  
 372 contractual basis: a technologist with training in PET scanning and a physicist. The physicist must be  
 373 board certified or eligible for certification by the American Board of Radiology or an equivalent  
 374 organization.

- 375 (c) The PET scanner service shall have a physician on-site or immediately available to the PET  
 376 scanner service at all times when patients are undergoing PET procedures.
- 377 (d) The applicant maintains the services and specialties as set forth in Section 3(1) through 3(4).  
 378
- 379 (3) Compliance with the following access to care requirements:
- 380 (a) The PET scanner service shall accept referrals for PET scanner services from all appropriately  
 381 licensed practitioners.
- 382 (b) The PET scanner service shall participate in Medicaid at least 12 consecutive months within the  
 383 first two years of operation and continue to participate annually thereafter.
- 384 (c) The PET scanner service shall not deny PET scanner services to any individual based on ability  
 385 to pay or source of payment.
- 386 (d) The operation of and referral of patients to the PET scanner service shall be in conformance  
 387 with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).  
 388
- 389 (4) Compliance with the following monitoring and reporting requirements:
- 390 (a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during  
 391 the second 12 months of operations, and annually thereafter. This requirement shall be waived during  
 392 review of applications under sections 4(1) and 6(45), if applicable. In meeting these requirements, an  
 393 applicant shall not include any PET scans performed on a PET scanner used exclusively for research  
 394 approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8, or  
 395 for a PEM scanner approved pursuant to Section 9.
- 396 (b) The PET scanner service shall participate in a data collection system established and  
 397 administered by the Department or its designee. The data may include, but are not limited to, clinical scan  
 398 data, annual budget and cost information, operating schedules, through-put schedules, demographic and  
 399 diagnostic information, and the volume of care provided to patients from all payor sources. The applicant  
 400 shall provide the required data on a separate basis for each separate and distinct site, PET scanner, or  
 401 PET scanner service as required by the Department, in a format established by the Department. The  
 402 Department may elect to verify the data through on-site review of appropriate records.
- 403 (c) The PET scanner service shall provide the Department with timely notice of the proposed  
 404 project implementation consistent with applicable statute and promulgated rules.  
 405
- 406 (5) Compliance with the following dedicated research PET scanner requirements, if applicable:
- 407 (a) The capital and operating costs relating to the dedicated research PET scanner shall be  
 408 charged only to a specific research account(s) and not to any patient or third- party payor.
- 409 (b) The dedicated research PET scanner shall not be used for any purposes other than as  
 410 approved by the Institutional Review Board.
- 411 (c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for  
 412 research purposes only.  
 413
- 414 (6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:
- 415 (a) The dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for  
 416 patients under 18 years of age.
- 417 (b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty  
 418 programs as set forth in the section.  
 419
- 420 (7) Compliance with the following PEM scanner requirements, if applicable:
- 421 (a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the  
 422 Department.  
 423
- 424 (8) Compliance with the following mobile PET scanner requirements, if applicable:
- 425 (a) The central service coordinator for a mobile PET scanner service shall notify the Department 30  
 426 days prior to dropping an existing host site.
- 427 (b) Each host site must have at least one physician who is board certified or board eligible in  
 428 nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for

429 establishing patient examination and infusion protocol, and providing for the interpretation of scans  
430 performed.

431 (c) Each host site shall provide a properly prepared parking pad for the mobile PET scanner unit, a  
432 waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an  
433 enclosed canopy or an enclosed corridor).

434 (d) A mobile PET scanner service shall operate under a contractual agreement that includes the  
435 provision of PET services at each host site on a regularly scheduled basis.

436  
437 (9) The agreements and assurances required by this section shall be in the form of a certification  
438 agreed to by the applicant or its authorized agent.

439

## 440 **Section 12. Methodology for computing the projected PET data units**

441

442 Sec. 12. An applicant being reviewed under Section 3 shall apply the methodology set forth in this  
443 section in computing the projected number of PET data units.

444

445 (1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the  
446 requirements of Section 13.

447 (a) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes  
448 C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes (9590-9729), melanoma  
449 (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470  
450 or C490 excluding C440-C444 (skin of head and neck), and additional codes approved by national  
451 coverage determination]. Use the name "combined" for this grouping.

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

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

457

458 (2) Identify the number of diagnosis-specific new cancer cases documented in accord with the  
459 requirements of section 13.

460 (a) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the  
461 estimated probability that a breast cancer case will require a PET scan.

462 (b) Multiply the number resulting from the calculation in subsection (2)(a) by 1.0, which is the  
463 estimated number of PET scans needed for each patient requiring a PET scan.

464

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

468

469 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41,  
470 345.51, 345.61, 345.71, 345.81, or 345.91, see Appendix D for ICD-10-CM Codes) identified in accord  
471 with the requirements of Section 16 by 1.0, which is the estimated probability that a patient having an  
472 intractable epilepsy procedure will require a PET scan. Multiply the number resulting from the calculation  
473 in subsection (3) by 1.0, which is the estimated number of PET scans needed for each patient requiring a  
474 PET scan.

475

476 (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the  
477 total number of projected PET data units.

478

479 (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is  
480 proposing to serve only planning area 6 to determine the total number of projected PET data units.

481

482 (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is  
 483 proposing to serve only planning area 5 to determine the total number of projected PET data units.

### 484 **Section 13. Commitment of diagnosis-specific new cancer cases**

485  
 486  
 487 Sec. 13. An applicant proposing to use diagnosis-specific new cancer cases shall demonstrate all of  
 488 the following:

489 (1) Only those cancer diagnoses identified in Section 12(1) and 12(2) shall be included.

491  
 492 (2) Each entity contributing diagnosis-specific new cancer case data provides, as part of the  
 493 application at the time it is submitted to the Department, a signed governing body resolution that identifies  
 494 the number of diagnosis-specific cancer cases being committed to the application and that states no  
 495 current or future diagnosis-specific new cancer case data will be used in support of any other application  
 496 for a PET unit for a period of five (5) years from the date of start of operations of the approved PET  
 497 scanner service for which data are being committed. If the required documentation for this subsection is  
 498 not submitted with the application on the designated application date, the application will be deemed filed  
 499 on the first applicable designated application date after all required documentation is received by the  
 500 Department.

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

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

507 (c) No entity contributing diagnosis-specific new cancer case data has previously committed or is  
 508 committing data to another service that is less than five (5) years from the start of operations of that  
 509 service.

510  
 511 (3) No entity currently operating or approved to operate a PET scanner service shall contribute  
 512 diagnosis-specific new cancer cases.

513  
 514 (4) The Department may not consider a withdrawal of diagnosis-specific new cancer case data  
 515 during the 120-day application review cycle following the date on which the Department review of the  
 516 application commences or after a proposed decision to approve the application has been issued unless  
 517 the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in  
 518 the form of a governing body resolution that contains the specific CON application number to which the  
 519 data were originally committed, the legal applicant entity, the committing entity, the type of data, the date  
 520 of the meeting in which the governing body authorized the withdrawal of the data, the governing body  
 521 president's signature, and the date of the signature.

### 522 **Section 14. Documentation of diagnosis-specific new cancer case data**

523  
 524  
 525 Sec. 14. An applicant required to document volumes of diagnosis-specific new cancer cases shall  
 526 submit, as part of its application at the time it is submitted to the Department, documentation from the  
 527 Division for Vital Records and Health Statistics verifying the number of diagnosis-specific new cancer  
 528 cases provided in support of the application for the most recent calendar year for which verifiable data are  
 529 available from the state registrar. If the required documentation for this subsection is not submitted with  
 530 the application on the designated application date, the application will be deemed filed on the first  
 531 applicable designated application date after all required documentation is received by the Department.  
 532 Diagnosis-specific new cancer case data supporting an application under these standards shall be  
 533 submitted to the Division for Vital Records and Health Statistics using a format and media specified in  
 534 instructions from the Department of Community Health.

**Section 15. Commitment and documentation of diagnostic cardiac catheterization data**

Sec. 15. An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all of the following:

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

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

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

(c) No entity contributing diagnostic cardiac catheterization data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service.

(d) The diagnostic cardiac catheterization case data is from the most recently completed report(s) of the annual survey produced by the Department, and the contributing entity has CON approval to provide diagnostic cardiac catheterization services.

(2) No entity currently operating or approved to operate a PET scanner service shall contribute diagnostic cardiac catheterization case data.

(3) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been denied unless the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

**Section 16. Commitment and documentation of intractable epilepsy data**

Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the following:

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

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

591 (b) For mobile PET scanner services, the geographic location of each entity contributing intractable  
592 epilepsy case data in the planning area(s) for which the proposed PET scanner service contains a  
593 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical  
594 area counties or 25-mile radius for metropolitan statistical area counties.

595 (c) No entity contributing intractable epilepsy case data has previously committed or is committing  
596 data to another service that is less than five (5) years from the start of operations of that service.

597 (d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB)  
598 available to the Department.

599

600 (2) No entity currently operating or approved to operate a scanner shall contribute intractable  
601 epilepsy case data.

602

603 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the 120-  
604 day application review cycle following the date on which the Department review of the application  
605 commences or after a proposed decision to approve the application unless the application is denied,  
606 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing  
607 body resolution that contains the specific CON application number to which the data were originally  
608 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in  
609 which the governing body authorized the withdrawal of the data, the governing body president's signature,  
610 and the date of the signature.

611

## 612 **Section 17. Methodology for computing PET equivalents**

613

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

615

<b>TABLE 1</b>	
<b>PET EQUIVALENTS</b>	
<b>Scan Category</b>	<b>Weight</b>
Simple <sup>1</sup>	0.75
Standard <sup>2</sup>	1.0
Complex <sup>3</sup>	1.5
<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.	

616

## 617 **Section 18. Department inventory of PET scanners**

618

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

621

## 622 **Section 19. Comparative reviews; effect on prior planning policies**

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624 Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative  
625 review. These CON review standards supersede and replace the CON standards for PET scanner  
626 services approved by the CON Commission on ~~June 14, 2012~~MARCH 18, 2014 and effective ~~September~~  
627 ~~28, 2012~~JUNE 2, 2014.

628

**APPENDIX A**

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631 Counties assigned to each health service area are as follows:

632

**HEALTH SERVICE AREA****COUNTIES**

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635	1	Livingston	Monroe	St. Clair
636		Macomb	Oakland	Washtenaw
637		Wayne		

638

639	2	Clinton	Hillsdale	Jackson
640		Eaton	Ingham	Lenawee

641

642	3	Barry	Calhoun	St. Joseph
643		Berrien	Cass	Van Buren
644		Branch	Kalamazoo	

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646	4	Allegan	Mason	Newaygo
647		Ionia	Mecosta	Oceana
648		Kent	Montcalm	Osceola
649		Lake	Muskegon	Ottawa

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651	5	Genesee	Lapeer	Shiawassee
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653	6	Arenac	Huron	Roscommon
654		Bay	Iosco	Saginaw
655		Clare	Isabella	Sanilac
656		Gladwin	Midland	Tuscola
657		Gratiot	Ogemaw	

658

659	7	Alcona	Crawford	Missaukee
660		Alpena	Emmet	Montmorency
661		Antrim	Gd Traverse	Oscoda
662		Benzie	Kalkaska	Otsego
663		Charlevoix	Leelanau	Presque Isle
664		Cheboygan	Manistee	Wexford

665

666	8	Alger	Gogebic	Mackinac
667		Baraga	Houghton	Marquette
668		Chippewa	Iron	Menominee
669		Delta	Keweenaw	Ontonagon
670		Dickinson	Luce	Schoolcraft

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**APPENDIX B**

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Counties by Health service areas assigned to each planning area are as follows:

**PLANNING AREA 1****COUNTIES**

HSA 1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		

**PLANNING AREA 2**

HSA 2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
HSA 3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	

**PLANNING AREA 3**

HSA 4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa

**PLANNING AREA 4**

HSA 5	Genesee	Lapeer	Shiawassee
HSA 6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	

**PLANNING AREA 5**

HSA 7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford

**PLANNING AREA 6**

HSA 8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

**APPENDIX C**

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725 Rural Michigan counties are as follows:

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727	Alcona	<del>Hillsdale</del>	Oceana
728	Alger	Huron	Ogemaw
729	Antrim	Iosco	Ontonagon
730	Arenac	Iron	Osceola
731	Baraga	Lake	Oscoda
732	Charlevoix	Luce	Otsego
733	Cheboygan	Mackinac	Presque Isle
734	Clare	Manistee	Roscommon
735	Crawford	<del>Mason</del>	Sanilac
736	Emmet	<del>Montcalm</del>	Schoolcraft
737	Gladwin	Montmorency	Tuscola
738	Gogebic	<u>NEWAYGO</u>	

739

740 Micropolitan statistical area Michigan counties are as follows:

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742	Allegan	<u>HILLSDALE</u>	<u>MASON</u>
743	Alpena	Houghton	Mecosta
744	<u>Benzie</u>	<u>IONIA</u>	Menominee
745	Branch	Isabella	<del>Midland</del>
746	<u>Chippewa</u>	Kalkaska	Missaukee
747	Delta	Keweenaw	St. Joseph
748	Dickinson	Leelanau	Shiawassee
749	Grand Traverse	Lenawee	Wexford
750	Gratiot	Marquette	

751

752 Metropolitan statistical area Michigan counties are as follows:

753

754	Barry	<del>onia</del>	<u>MONTCALM</u> <del>Newaygo</del>
755	Bay	Jackson	Muskegon
756	Berrien	Kalamazoo	Oakland
757	Calhoun	Kent	Ottawa
758	Cass	Lapeer	Saginaw
759	Clinton	Livingston	St. Clair
760	Eaton	Macomb	Van Buren
761	Genesee	<u>MIDLAND</u>	Washtenaw
762	Ingham	Monroe	Wayne

763

764 Source:

765

766 | 65-75 F.R., p. 82238-37245 (December 27, 2000) JUNE 28, 2010

767 Statistical Policy Office

768 Office of Information and Regulatory Affairs

769 United States Office of Management and Budget

**APPENDIX D****ICD-9-CM TO ICD-10-CM CODE TRANSLATION**770  
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<b>ICD-9 CODE</b>	<b>DESCRIPTION</b>	<b>ICD-10 CODE</b>	<b>DESCRIPTION</b>
345.01	Intractable Epilepsy Cases	G40.311	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.319	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
		G40.A11	Absence Epileptic Syndrome, Intractable, with Status Epilepticus
345.11	Intractable Epilepsy Cases	G40.311	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, with Status Epilepticus
		G40.319	Generalized Idiopathic Epilepsy and Epileptic Syndromes, Intractable, without Status Epilepticus
345.41	Intractable Epilepsy Cases	G40.211	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Complex Partial Seizures, Intractable, with Status Epilepticus
		G40.219	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Complex Partial Seizures, Intractable, without Status Epilepticus
345.51	Intractable Epilepsy Cases	G40.011	Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic Syndromes with Seizures of Localized Onset, Intractable, with Status Epilepticus
		G40.019	Localization-Related (Focal) (Partial) Idiopathic Epilepsy and Epileptic Syndromes with Seizures of Localized Onset, Intractable, without Status Epilepticus
		G40.111	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, with Status Epilepticus
		G40.119	Localization-Related (Focal) (Partial) Symptomatic Epilepsy and Epileptic Syndromes with Simple Partial Seizures, Intractable, without Status Epilepticus

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775  
776**APPENDIX D continued**

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

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778 "ICD-9-CM CODE" means the disease codes and nomenclature found in the International Classification of  
779 Diseases - 9th Revision - Clinical Modification, prepared by the Commission on Professional and Hospital  
780 Activities for the U.S. National Center for Health statistics.  
781  
782 "ICD-10-CM CODE" means the disease codes and nomenclature found in the International Classification  
783 of Diseases - 10th Revision - Clinical Modification, National Center for Health Statistics.

# Psychiatric Bed Need: 2014 Update

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December 30, 2014

## 1 Summary

The psychiatric bed need was implemented using the current Standards (3/22/13) methodology along with three key datasets: projected population data for 2017 (acquired from the State Demography office), population data for 2012 (from the US Census Bureau), and licensed inpatient bed survey data for 2011 and 2012. Two appendices (A and B) in the standards were also updated using the most recent survey utilization rates and population data. This report briefly outlines the methodology and provides bed need projections for 2017.

## 2 Appendix A

The number of psychiatric hospital beds per 10,000 adults is reported as a table in Appendix A of the Standards. The appendix was updated using 2012 annual survey data and 2012 county population data (see Table 1). For seven of the eight planning areas (HSAs) along with the state overall, the new bed/population rates were quite stable since the previous update. Only HSA 7 had a considerable change, due to the 14 adult psychiatric beds at McLaren Northern Michigan that are no longer in service.

**Table 1. Psychiatric hospital beds per 10,000 adults for Appendix A of the Standards.** “Previous” contains the information from the previous update (performed in 2012) and “Updated” contains the information from the current update.

HSA	Previous	Updated
1	3.0808	3.0914
2	2.4282	2.4060
3	2.4604	2.4446
4	2.5284	2.3917
5	3.0698	3.0791
6	1.5558	1.7505
7	1.2570	0.8384
8	2.2756	2.2665
<i>STATE</i>	<i>2.6633</i>	<i>2.6428</i>

## 3 Appendix B

The Standards contain the pediatric use rate (patient days per 1,000 children and adolescents) in Appendix B. This value increased from 22.8146 in the previous update to 25.6645 using the most recent

data. The raw data (utilization and population) can be found in Table 2, showing that the increased rate is due to both a larger raw number of patient days used and a decreased pediatric and adolescent population.

**Table 2. Pediatric use rate for Appendix B of the Standards.** “Previous” contains the information from the previous update (performed in 2012) and “Updated” contains the information from the current update.

	Previous	Updated
Patient Days	53,479	58,242
Population	2,344,068	2,269,365
Use Rate	22.8146	25.6644

## 4 Pediatric Bed Need

The pediatric and adolescent psychiatric bed need was implemented as detailed in Section 3 of the Standards using 2012 as the base year and 2017 as the planning year, along with the updated value from Appendix B. The results are provided in Table 3. Generally, the bed need figures increased slightly in each planning area, which is most likely due to the overall increase in the pediatric use rate (noted above).

**Table 3. Pediatric Bed Need.** “Previous” contains the information from the previous update (performed in 2012) and “Updated” contains the information from the current update.

HSA	Previous	Updated
1	113	114
2	15	16
3	17	19
4	32	35
5	12	13
6	14	16
7	8	9
8	6	7
<i>STATE</i>	<i>217</i>	<i>229</i>

## 5 Adult Bed Need

The adult psychiatric bed need was implemented as detailed in Section 3 of the Standards using 2012 as the base year and 2017 as the planning year, along with the updated values from Appendix A. The results are provided in Table 4. Statewide, the number of adult beds needed dropped in the most recent update, as six of eight HSAs saw decreases in the projections. However, the projected bed need increased in two HSAs (5 & 6).

**Table 4. Adult Bed Need.** “Previous” contains the information from the previous update (performed in 2012) and “Updated” contains the information from the current update.

<b>HSA</b>	<b>Previous</b>	<b>Updated</b>
1	1,084	1,044
2	169	163
3	188	179
4	300	289
5	143	144
6	95	110
7	48	30
8	64	62
<i>STATE</i>	<i>2,091</i>	<i>2,021</i>

CERTIFICATE OF NEED  
**1<sup>st</sup> Quarter Compliance Report to the CON Commission**  
 October 1, 2014 through September 30, 2015 (FY 2015)

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	1 <sup>st</sup> Quarter	Year-to-Date
Approved projects requiring 1-year follow up	78	78
Approved projects contacted on or before anniversary date	52	52
Approved projects completed on or before 1-year follow up	67%	
CON approvals expired	15	15
Total follow up correspondence sent	193	193
Total approved projects still ongoing	323	

## Compliance Report to CON Commission

FY 2015 – 1<sup>st</sup> Quarter

Page 2

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

The Department has taken the following actions:

- After a statewide review of the Open Heart Surgery data based on the 2010 Annual Survey, the Department opened 6 compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has completed collection of information and investigation of the same. The Department has conducted meetings with all 6 hospitals and is in the process of determining proposed compliance actions. A settlement proposal has been offered to all 6 hospitals with open compliance investigations. The Department is working to finalize the settlement agreements with the 6 hospitals.
- After a statewide review of the Open Heart Surgery data based on the 2013 Annual Survey, the Department opened 5 additional compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. The Department has collected some information and is scheduling meeting with all 5 hospitals to gather additional information.
- After a statewide review of the Psychiatric Beds and Services data based on the 2010 Annual Survey, the Department opened 14 compliance investigations of adult and child/adolescent psychiatric programs not meeting the approved occupancy rates. The Department has completed collection of information and investigation of the same. The Department has closed 4 investigations based on more recent data and updated information. The Department has conducted meetings with the remaining 10 psychiatric hospitals (10 adult programs and 1 child/adolescent program) and has determined proposed compliance actions. The Department is working to finalize settlement agreements with the 10 programs to resolve these investigations.
- Metro Health Hospital – Facility entered into a renewal lease for the fixed MRI unit without CON approval. The facility was required to correct the issue within an active CON and paid a civil fine of \$5,500.
- Orthopaedic Surgical Institute – Facility was approved to purchase the facility, however entered into a lease instead. The facility was required to correct the issue within an active CON and paid a civil fine of \$1,500.
- Allegiance Health – Facility received PET services from a PET Network that was not approved to provide service at this site. The facility was required to file a corrective CON, establish a corrective action plan, and paid a civil fine of \$1,500.
- Michigan Mobile PET CT – Facility provided PET services to a non-approved host site. The facility was required to establish a corrective action plan and paid a civil fine of \$33,000.

**CERTIFICATE OF NEED**  
**1<sup>st</sup> Quarter Program Activity Report to the CON Commission**  
 October 1, 2014 through September 30, 2015 (FY 2015)

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

**Measures**

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

Activity	1 <sup>st</sup> Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	103	N/A	103	N/A
Letters of Intent Processed within 15 days	103	100%	103	100%
Letters of Intent Processed Online	103	100%	103	100%

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	1 <sup>st</sup> Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	74	N/A	74	N/A
Applications Processed within 15 Days	73	99%	73	99%
Applications Incomplete/More Information Needed	54	73%	54	73%
Applications Filed Online*	72	100%	72	100%
Application Fees Received Online*	12	17%	12	17%

\* 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	1 <sup>st</sup> Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	56	100%	56	100%
Substantive Applications	16	100%	16	100%
Comparative Applications	0	N/A	0	N/A

*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.

Program Activity Report to CON Commission  
 FY 2015 – 1<sup>st</sup> Quarter  
 Page 2 of 2

**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	1 <sup>st</sup> Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	0	N/A	0	N/A
Decisions Issued within 10 workings Days	0	N/A	0	N/A

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

Activity	1 <sup>st</sup> Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	15	100%	15	100%

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	1 <sup>st</sup> Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

**Other Measures**

Activity	1 <sup>st</sup> Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	51	N/A	51	N/A
FOIA Requests Processed on Time	48	94%	48	94%
Number of Applications Viewed Onsite	5	N/A	5	N/A

FOIA – Freedom of Information Act.

**DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN**

	2014												2015											
	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 (BMT) Services	•D	•	•R —	•P	•	• ▲F				PC			•R A		DA									
Cardiac Catheterization Services**	•R PA	•S	• ▲F S	•S	•S	■	■	■	■	■	■	■	•	•	• R—	•P	•	• ▲F						
Hospital Beds	•R PA	•	• ▲F R	•	•	•R	•	•	• R—	•P	•	• ▲F												
Magnetic Resonance Imaging (MRI) Services						• R—	•P	•	• ▲F	PC			•R A	•	•	•	•	•						
Megavoltage Radiation Therapy (MRT) Services/Units**	•R A	•S	•S	•S	•S	•S	■	■	■	■	■	•	•	•	• R—	•P	•	• ▲F						
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	•	•	•	•	•	R—	P	•	• R—	•P	•	• F▲												
Positron Emission Tomography (PET) Scanner Services	•R PA	•	• ▲F	•	•	•	•	•	•	•	•	•	•	•	• R—	•P	•	• ▲F						
Psychiatric Beds and Services										PC			•R A	•	•	•	•	•	•	•				
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	•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
  - 1 - ICD-10 Translation
  - 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
  - PC - Public Comment Period for initial comments on review standards for review in the upcoming year
  - R - Receipt of report
  - S - Solicit nominations for standard advisory committee or standing committee membership

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

**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	June 2, 2014	2016
Bone Marrow Transplantation Services	March 22, 2013	2018
Cardiac Catheterization Services	June 2, 2014	2017
Computed Tomography (CT) Scanner Services	December 22, 2014	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	June 2, 2014	2017
Magnetic Resonance Imaging (MRI) Services	December 22, 2014	2018
Megavoltage Radiation Therapy (MRT) Services/Units	May 24, 2013	2017
Neonatal Intensive Care Services/Beds (NICU)	December 22, 2014	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2016
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	June 2, 2014	2017
Psychiatric Beds and Services	March 22, 2013	2018
Surgical Services	December 22, 2014	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2016

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

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