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

Thursday March 28, 2013

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

APPROVED MINUTES

I. Call to Order & Introductions

Vice-ChairpersonKeshishian called the meeting to order @ 9:36 a.m.

A. Members Present:

Gail J. Clarkson RN
Kathleen Cowling, DO
Charles Gayney
Robert Hughes
Marc Keshishian, MD, Vice-Chairperson
Brian Klott
Suresh Mukherji, MD
Luis Tomatis, MD

B. Members Absent

Edward B. Goldman, JD
Gay L. Landstrom, RN
James B. Falahee, Jr., JD, Chairperson

C. Department of Attorney General Staff:

Raymond Howd

D. Michigan Department of Community Health Staff Present:

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

II. Review of Agenda

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of January 29, 2013

Motion by Commissioner Gayney, seconded by Commissioner Mukherji, to approve the minutes of January 29, 2013 as presented. Motion Carried.

V. Election of Officers

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to nominate and elect Commissioner Falahee as Chairperson. Motion Carried in a vote of 8- Yes, 0- No, 0- Abstained.

Motion by Commissioner Gayney, seconded by Commissioner Clarkson, to nominate and elect Commissioner Keshishian as Vice- Chairperson. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

VI. Air Ambulance (AA) Services – Follow Up

A. Public Comment:

Dale Berry, MI Association of Ambulances (see Attachment A)
Mary Joe Steffan, St. Mary's Flight Care
Denise Lambis, University of Michigan
Patti Russell, Aero Meds Spectrum Health
Richard Morley, West MI Air Care
Robert Meeker, Spectrum Health
Michael Sandler, Henry Ford Health Systems
Dennis McCafferty, Economic Alliance for Health (EAM)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Hughes, seconded by Commissioner Gayney, to form a workgroup to look at AA issues. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

VII. Magnetic Resonance Imaging (MRI) Standards- Workgroup Final Report

Commissioner Mukherji presented the Workgroup's final report on the MRI Standards (see Attachment B).

A. Public Comment

Robert Meeker, Spectrum Health
Lody Zwarensteyn, Alliance for Health
Melissa Cupp, Weiner Assoc.
Andy Ball, Kheder, Davis, & Assoc.

B. Commission Discussion

None

C. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Cowling, to approve the MRI Standards including the "Meeker Amendment." Motion Failed in a vote of 3-Yes, 5-No, and 0-Abstained.

Motion by Commissioner Hughes, seconded by Commissioner Gayney, to approve the proposed language (see Attachment C) for submission to the Joint Legislative Committee (JLC) and move forward for public hearing, along with the understanding that the Department will review forms CON-220 and CON-220-A. Motion Carried in a vote of 8-Yes, 0-No, and 0-Abstained.

Break @ 11:34 a.m. – 11:44 a.m.

VIII. Megavoltage Radiation Therapy (MRT) Services- February 5, 2013 Public Hearing Summary & Report

Ms. Rogers gave a brief summary from the public hearing comments regarding MRT Services Standards (see Attachment D).

A. Public Comment

Mark Montrose, Oaklawn Hospital (see attachment E)

B. Commission Discussion

None

C. Commission Action

Motion by Commissioner Hughes, seconded by Commissioner Cowling to accept the proposed language (see Attachment F) as presented by the Department and move it forward to the JLC and Governor for the 45-day review period . Motion Carried in a vote of 8-Yes, 0-No, and 0-Abstained.

IX. Open Heart Surgery (OHS) Services

Ms. Rogers gave a brief summary regarding OHS Services Standards (see Attachment G).

A. Public Comment:

Robert Meeker, Spectrum Health
Dennis McCafferty, EAM

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Tomatis to place a moratorium on new programs for the next three years. Motion Failed Due to Lack of a Second.

Motion by Commissioner Clarkson, seconded by Commissioner Mukherji, to accept the proposed language as presented including the Department's recommended language on annual maintenance volume (see Attachment H). Motion Failed in a vote of 5-Yes, 3-No, and 0-Abstained.

Commissioner Tomatis, seconded by Commissioner Gayney, to table the discussion and voting on the OHS Standards so that Commissioner Tomatis may consult with the Society of Thoracic Surgeons (STS) on maintenance volume numbers. Motion Carried in a vote of 7-Yes, 1-No, and 0-Abstained.

X. NICU Work Group- Status Update (Written only)

See attachment H.

XI. Legislative Report

Mr. Blakeney gave an overview of the Legislative Activity.

XII. Administrative Update

A. Planning & Access to Care Section Update

Ms. Nagel gave a verbal update on the workgroups that are currently meeting and the current open nomination period for the Nursing Home/Hospital Long-Term Care Unit Standard Advisory Committee.

B. CON Evaluation Section

1. Compliance Report (see Attachment I)
2. Quarterly Performance Measures (see Attachment J)

XIII. Legal Activity Report

Mr. Howd provided a brief report (See Attachment K).

XIV. Future Meeting Dates- June 13, 2013, September 26, 2013, & December 12, 2013

XV. Public Comment

Anne Mitchell, citizen (see Attachment L)
Robert Meeker, Spectrum Health
Dennis McCafferty, EAM

XVI. Review of Commission Work Plan

Ms. Rogers gave a brief summary of the work plan (see Attachment M).

A. Commission Discussion

B. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Mukherji, to accept the Work Plan as amended at the meeting. Motion Carried in a vote of 8- yes, 0- No, 0- Abstained.

XVII. Adjournment

Motion by Commissioner Klott, seconded by Commissioner Tomatis, to adjourn the meeting @ 1:13 p.m. Motion Carried in a vote of 8- Yes, 0- No, and 0- Abstained.

Attachment A

maas **Representing Pre-Hospital Care Providers**

March 27, 2013

Michigan CON Commission
Michigan Department of Community Health
Capitol View Building
201 Townsend St.
Lansing, MI 48913

RE: Michigan CON for Air Ambulance

Dear Commission Members:

The Michigan Association of Ambulance Services (MAAS) supports the continued application of Certificate of Need (CON) for air ambulance services in Michigan.

CON has effectively safeguarded patient safety and avoided unnecessary healthcare costs in Michigan by protecting the State from the proliferation of helicopters that has occurred in many states. There is currently sufficient coverage in the Lower Peninsula and increasing the number of helicopters without the requirement to show need results in pressure to fly more patients in order to maintain financial viability. This simply results in transferring patients from a safer, less expensive means of transport by ground ambulance to a more risky and higher cost mode.

With today's limited healthcare dollars, it is important that we avoid using them for unnecessary and expensive modes of transport. Overutilization increases the cost of healthcare for everyone and has the potential of necessitating increased subsidies from local governments, which are already strained in these difficult financial times. The State Medicaid program is already reimbursing ground ambulance well below the cost of providing pre-hospital care.

Increasing the number of helicopters may increase the risk of accidents and the potential for overutilization. The air medical CON assures patient safety and without it the State would be open to additional helicopters, regardless of need, as we currently see in neighboring states.

We urge you to side with Michigan's patients and support the continued use of CON in Michigan.

Sincerely,

Brian P. Lovellette

Brian P. Lovellette
Executive Director

cc: Robin Shivley
James Haveman

Michigan Association of Ambulance Services
412 W. Ottawa St • Lansing, Michigan 48933-1518 • (517) 485-3376 • Fax (517) 372-1731
www.miambulance.org • e-mail execdir@miambulance.org

Attachment B

MR Workgroup Report

Suresh K. Mukherji, MD, FACR

Chief of Neuroradiology and Head & Neck Radiology
Professor of Radiology, Otolaryngology Head and Surgery,
Radiation Oncology,
University of Michigan Health System

Professor of Periodontics and Oral Medicine
University of Michigan School of Dentistry

MDCH Certificate of Need Commissioner

Charge

1. Review and update, if necessary, the methodologies to assure they accurately reflect community need for MRI services.

2. Review and update, if necessary, the methodology set forth within the Standards for computing the number of available MRI adjusted procedures

3. Review and update, if necessary, the weighting of scans and the process for documenting and reporting actual MRI procedures.

4. Consider eliminating the volume requirements for replacement of MRI equipment, similar to the PET & CT standards. Consider whether upgrades to existing MRI equipment, without replacement of the equipment, would require CON review/approval.

Charge

5. Review existing criteria, volume requirements, and MRI utilization to determine necessary modifications, if any, related to imaging technology and bundling payments.

6. Review project delivery requirements to assure quality, measurability, and affordability for both the provider and consumer.

7. Consider any necessary technical or other changes from the Department, Commission, or SAC, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

Participants

27 MRI Stakeholders
5 MDCH Staff
1 CON Commissioner
33 Total Workgroup Participants

- Rogers, Brenda (DCH) (RogersB1@michigan.gov);
- Meeker, Bob (Spectrum) Robert.Meeker@spectrum-health.org
- Melissa Cupp (Weiner Associates) (melissacupp@wienerassociates.com)
- Karen Kippen (Henry Ford) kkippen1@hfhs.org
- Will, Geri (UMHS) (gwill@med.umich.edu
- Mukherji, Suresh (UMHS) mukherji@med.umich.edu
- Moore, Andrea (DCH) (MooreA20@michigan.gov)
- Flanders, Sallie (DCH) flanderss@michigan.gov
- Fischer, Eric (DMC) efischer@dmc.org
- Natalie Kellogg (DCH) (KelloggN@michigan.gov)
- Dennis McCafferty (EAM) dennismccafferty@eamonline.org
- Monica Harris (Oakwood) Monica.Harrison@oakwood.org
- Nancy List (NList@chs-mi.com
- Brad Betz (Spectrum) brad.betz@helendevoschildrens.org
- toddw@rad.hfh.edu
- rgutierrez@dmc.org
- Rod Zupolski (Mid Michigan) rod.zupolski@midmichigan.org
- stephanie@mihealthdata.com
- Ateequi, Umbrin F. (BCBSM) (UAteequi@bcbsm.com)
- rhoadl@hnv-hnhs.com
- hedegoreg@hnv-hnhs.com
- rchairs@allianceimaging.com
- micallefj@karmanos.org
- Anny Arana (Allegiance Health) (Anny.Arana@allegiancehealth.org)
- Arlene Elliott (Arbor Advisors) arlene@arbor-advisors.com
- david@williamscs.com
- Bhattacharya, Tulika (DCH)bhattacharyat@michigan.gov
- Patty Haupert (Allegiance Health) patty.haupert@allegiancehealth.org
- Allison Myers (MRI of Michigan) allison.myers@mriofmichigan.com
- Walt Wheeler (Wheeler Associate) walterwheeler@walterwheeler.com
- Carrie Linderoth (Kelly-Cawthorne) clinderoth@kelley-cawthorne.com
- Andy Ball (Kheder Davis)
- Steven Szelag (UMHS)

Review and update, if necessary, the methodologies to assure they accurately reflect community need for MRI services.

- Survey

8. Regarding the current MRI requirements for initiating a new fixed MRI service, do you believe the current requirements are?

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Attachment B

	Response Percent	Response Count
Much too onerous	11.5%	3
Mildly too onerous	30.8%	8
Just right	50.0%	13
Mildly too simple	3.8%	1
Much too simple	7.7%	2
answered question		26
skipped question		0

2. Regarding the current MRI Thresholds for expanding a service, do you believe that the current thresholds are?

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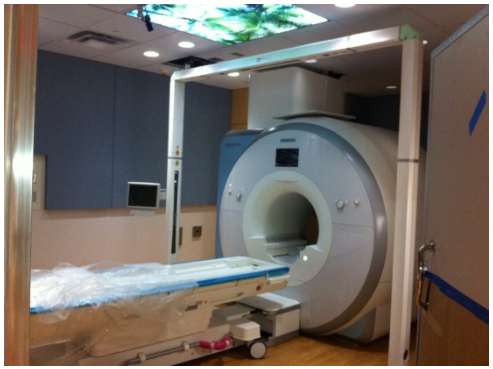
Attachment B

	Response Percent	Response Count
Much too restrictive	15.4%	4
Mildly too restrictive	53.8%	14
Just right	30.8%	8
Mildly too lax	0.0%	0
Much too lax	0.0%	0
answered question		26
skipped question		0

Review and update, if necessary, the methodologies to assure they accurately reflect community need for MRI services.

- Survey (Majority or wait times: same day – 7 days)
- Permit research units to perform 30% clinical studies compared to the number of studies performed on the research unit
- Create MR-simulator standards so that they are similar to the intraoperative MRI standards
  - Inpatient Diagnostic and sedated patients can be performed when the unit is not be used for treatment planning



Review and update, if necessary, the methodologies to assure they accurately reflect community need for MRI services.

9. Is the current 10-mile relocation zone radius for an MRI service and/or unit too restrictive?

Create Chart Download

	Response Percent	Response Count
Yes	42.3%	11
No	57.7%	15
answered question		26
skipped question		0

Review and update, if necessary, the methodologies to assure they accurately reflect community need for MRI services.

- Expanded relocation zone for mobile MRI
  - Metropolitan: 5 miles
  - Rural & Micropolitan: 10 miles

Review and update, if necessary, the methodology set forth within the Standards for computing the number of available MRI adjusted procedures

3. The MRI expansion thresholds for both Hospital Based and Freestanding MRI services are 11,000 adjusted procedures. Which statement below best summarizes your assessment of the 11,000 threshold?

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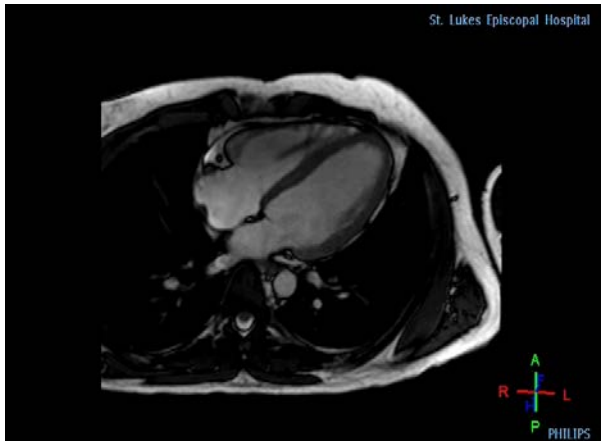
	Response Percent	Response Count
The 11,000 threshold should be increased	4.0%	1
The 11,000 threshold should stay the same	52.0%	13
The 11,000 threshold should be lowered	44.0%	11
Comments Show Responses		5
answered question		25
skipped question		1

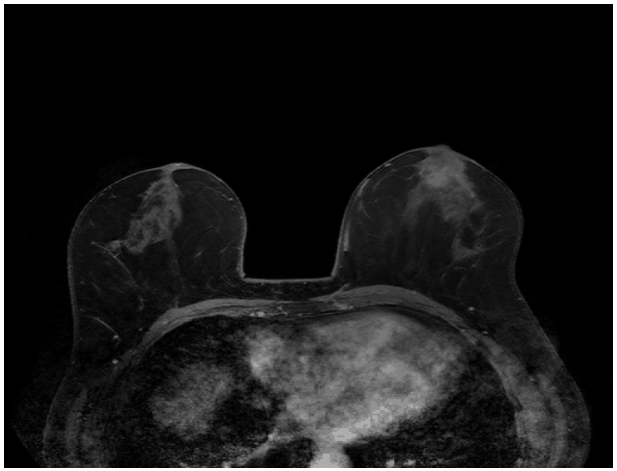
Review and update, if necessary, the methodology set forth within the Standards for computing the number of available MRI adjusted procedures

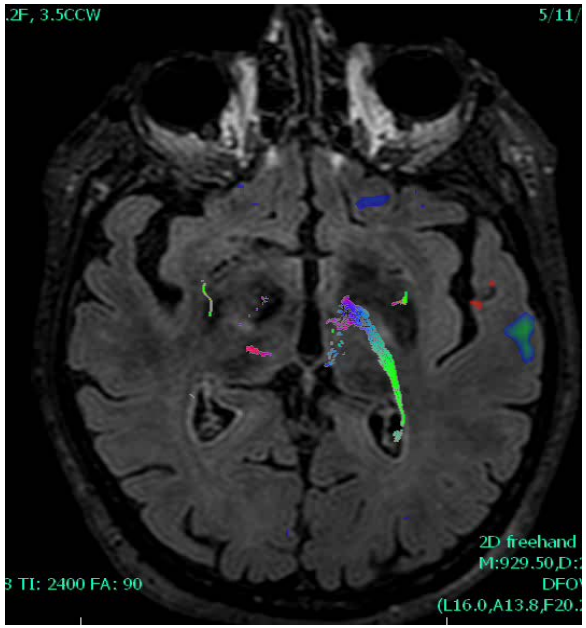
Attachment B

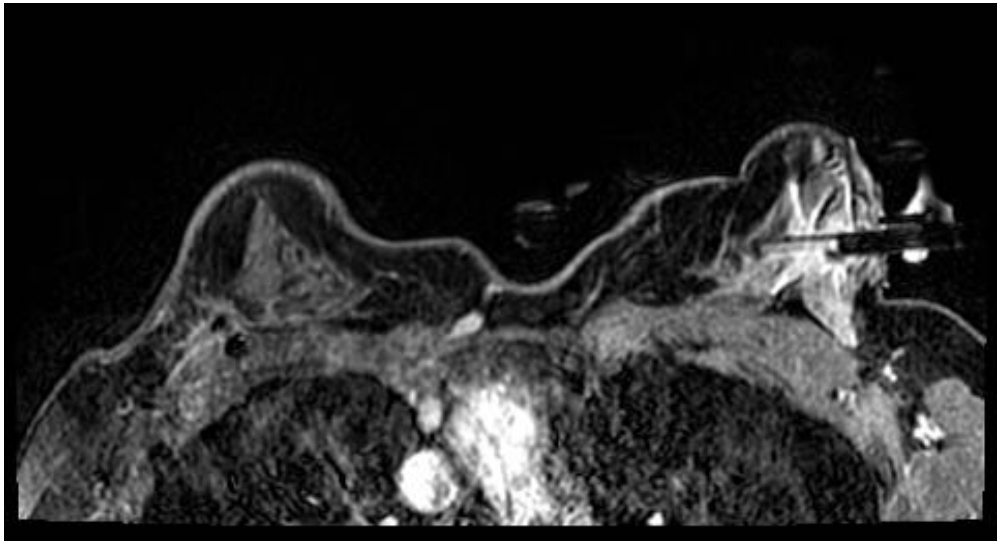
- Very elegant presentation by Tulika Bhattacharya
- No Changes

Review and update, if necessary, the weighting of scans and the process for documenting and reporting actual MRI procedures.









4. Do you currently perform any of the following studies in your MRI practice? Functional MRI of the brain / Breast Biopsies using MR Guidance / Cardiac MRI / Other studies billed as single procedure but routinely take more than 45 minutes to perform Please list these studies below:

Attachment B Download

	Response Count
Show Responses	26
answered question	26
skipped question	0

Complex MR 16/26 (62%)

Review and update, if necessary, the weighting of scans and the process for documenting and reporting actual MRI procedures.

- Add “+1” to the baseline rate of 1 for more complex MRIs (fMRI, MR-guided interventions, Cardiac MRI) by 1

Consider eliminating the volume requirements for replacement of MRI equipment, similar to the PET & CT standards. Consider whether upgrades to existing MRI equipment, without replacement of the equipment, would require CON review/approval

- One time upgrade outside of volume requires to upgrade a unit below 1T to 1T or above
- Allow any component of an MRI units to be repaired if under a service/maintenance agreement

Review existing criteria, volume requirements, and MRI utilization to determine necessary modifications, if any, related to imaging technology and bundling payments.

- There will continue to be standard CPT review and surveys.
- One potential change is the bundling of MR brain/MRA COW/MRA Carotids. Nothing imminent
- No proposed change in thresholds.

Review project delivery requirements to assure quality, measurability, and affordability for both the provider and consumer.

- "Each physician interpreting MR must read 250 MRI"
- Align with ACR language on MR accreditation and ensuring consistent national standards. ---MRI and Breast MRI

Consider any necessary technical or other changes from the Department, Commission, or SAC, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

Questions?

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR MAGNETIC RESONANCE IMAGING (MRI) SERVICES

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

Section 1. Applicability

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

Section 2. Definitions

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

(a) "Acquisition of an existing MRI service or existing MRI unit(s)" means obtaining control or possession of an existing fixed or mobile MRI service or existing MRI unit(s) by contract, ownership, lease, or other comparable arrangement.

(b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 15, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "MRI Service Utilization List," as of the date an application is deemed submitted by the Department.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(p) "Health service area" or "HSA" means the geographic areas set forth in Section 21.

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

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

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

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

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

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

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

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

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

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

(z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section 15.

(aa) "MRI database" means the database, maintained by the Department pursuant to Section 14 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(bb) "MRI-guided electrophysiology intervention" or "MRI-guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.

(cc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an IRB. The capital and operating

costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section ~~8(1)~~7.

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

(ee) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans including FDA-approved positron emission tomography (PET)/MRI scanner hybrids if used for MRI only procedures. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with a~~n~~ MEGAVOLTAGE RADIATION THERAPY (MRT) unit.

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

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

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

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

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

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

(ll) "Pediatric patient" means a patient who is 12 years of age or less, except for Section ~~9~~8.

(mm) "Planning area" means

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

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

(iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section 15(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

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

~~(qq)~~ "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit that does not involve either replacement of the MRI unit, as defined in Section ~~2(1)(rr)(i)~~4, or (ii) a change in the parties to the lease.

(~~rr~~PP) ~~"Replace an existing MRI unit" means (i) any equipment change involving a change in, or replacement of, the magnet resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change other than a change in the magnet that involves a capital expenditure of $750,000 or more in any consecutive 24-month period~~

~~or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.~~

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

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

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

(~~vv~~SS) "Sedated patient" means a patient that meets all of the following:

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

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

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

(~~ww~~TT) "Site" means

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

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

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

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

(~~zz~~WW) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section 15.

(~~aaa~~XX) "Upgrade an existing MRI unit" means any equipment change that

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

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

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

Section 3. Requirements to initiate an MRI service

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

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

(2) An applicant proposing to initiate a fixed MRI service that meets the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is currently an existing host site.

(b) The applicant has received in aggregate, one of the following:

(i) At least 6,000 MRI adjusted procedures.

(ii) At least 4,000 MRI adjusted procedures and the applicant meets all of the following:

(A) Is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted.

(B) The nearest fixed MRI machine is located more than 15 radius miles from the application site.

(iii) At least 3,000 MRI adjusted procedures and the applicant meets all of the following:

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

(B) The applicant hospital operates an emergency room that provides 24-hour emergency care services and at least 20,000 visits within the most recent 12-month period for which data, verifiable by the Department, is available.

(c) All of the MRI adjusted procedures from the mobile MRI service referenced in Section 3(2)(b) shall be utilized even if the aggregated data exceeds the minimum requirements.

(d) The applicant shall install the fixed MRI unit at the same site as the existing host site or within the relocation zone. If applying pursuant to Section 3(2)(b)(iii), the applicant shall install the fixed MRI unit at the same site as the existing host site.

(e) The applicant shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service and its unit becomes operational.

(3) An applicant proposing to initiate a mobile MRI service shall demonstrate 5,500 available MRI adjusted procedures from within the same planning area as the proposed service/unit, and the applicant shall meet the following:

(a) Identify the proposed route schedule and procedures for handling emergency situations.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(c) Identify a minimum of two (2) host sites for the proposed service.

(4) An applicant, whether the central service coordinator or the host site, proposing to initiate a host site on a new or existing mobile MRI service shall demonstrate the following, as applicable:

(a) 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, for a proposed host site that is not located in a rural or micropolitan statistical area county, or

(b) 400 available MRI adjusted procedures from within the same planning area for a proposed host site that is located in a rural or micropolitan statistical area county, and

(c) The proposed host site has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

(5) An applicant proposing to add or change service on an existing mobile MRI service that meets the following requirements shall not be required to be in compliance with subsection (4):

(a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.

(b) Submit copies of all proposed contracts for the proposed host site related to the mobile MRI service.

(6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as applicable, are from the most recently published MRI lists as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

Sec. 4. Replace an existing MRI unit means (i) any equipment change involving a change in, or replacement of, the ENTIRE MRI UNIT resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change~~, other than a change in the magnet,~~ that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. REPLACEMENT ALSO MEANS THE RELOCATION OF AN MRI SERVICE OR UNIT TO A NEW SITE. THE TERM DOES NOT INCLUDE THE REPLACEMENT OF COMPONENTS OF THE MRI SYSTEM, INCLUDING THE MAGNET, UNDER AN EXISTING SERVICE CONTRACT OR REQUIRED MAINTENANCE TO MAINTAIN THE SYSTEM TO OPERATE WITHIN MANUFACTURER SPECIFICATIONS. The term does not include an upgrade TO AN EXISTING MRI UNIT OR REPAIR of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5) have been met.

(1) "Upgrade an existing MRI unit" means any equipment change that
(i) does not involve a change in, or replacement of, the ~~magnet;~~ ENTIRE MRI UNIT, does not result in an increase in the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile MRI unit to a fixed MRI unit); and
(ii) involves a capital expenditure related to the MRI equipment of less than $750,000 in any consecutive 24-month period.

(2) "REPAIR AN EXISTING MRI UNIT" MEANS RESTORING THE ABILITY OF THE SYSTEM TO OPERATE WITHIN THE MANUFACTURER'S SPECIFICATIONS BY REPLACING OR REPAIRING THE EXISTING COMPONENTS OR PARTS OF THE SYSTEM, INCLUDING THE MAGNET, PURSUANT TO THE TERMS OF AN EXISTING MAINTENANCE AGREEMENT THAT DOES NOT RESULT IN A CHANGE IN THE STRENGTH OF THE MRI UNIT.

(3) An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements, as applicable:

(~~1~~a) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department. AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT THAT IS BELOW 1 TESLA WITH AN MRI UNIT THAT IS A 1 TESLA OR HIGHER, SHALL BE EXEMPT ONCE, AS OF *(INSERT EFFECTIVE DATE OF THE STANDARDS)*, FROM THE MINIMUM VOLUME REQUIREMENTS FOR REPLACEMENT:

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

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

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

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

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

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

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

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

(4) AN APPLICANT PROPOSING TO REPLACE AN EXISTING MOBILE MRI HOST SITE TO A NEW LOCATION SHALL DEMONSTRATE THE FOLLOWING:

(a) THE APPLICANT CURRENTLY OPERATES THE MRI MOBILE HOST SITE TO BE RELOCATED.

(b) THE MRI MOBILE HOST SITE TO BE RELOCATED HAS BEEN IN OPERATION FOR AT LEAST 36 MONTHS AS OF THE DATE AN APPLICATION IS SUBMITTED TO THE DEPARTMENT.

(c) THE PROPOSED NEW SITE IS WITHIN A 5-MILE RADIUS OF THE EXISTING SITE FOR A METROPOLITAN STATISTICAL AREA COUNTY OR WITHIN A 10-MILE RADIUS FOR A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY.

(d) THE MOBILE MRI HOST SITE TO BE RELOCATED PERFORMED AT LEAST THE APPLICABLE MINIMUM NUMBER OF MRI ADJUSTED PROCEDURES SET FORTH IN SECTION 14 BASED ON THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.

(e) THE RELOCATION WILL NOT INVOLVE A CHANGE IN THE CURRENT CENTRAL SERVICE COORDINATOR UNLESS THE REQUIREMENTS OF SECTION 3(5) ARE MET.

(5) An applicant proposing to ~~relocate~~REPLACE an existing fixed MRI service and its unit(s) to a new site shall demonstrate the following:

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

(b) The proposed new site is ~~in the relocation zone~~ within a 10-mile radius of the existing site.

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

(6) An applicant proposing to ~~relocate~~REPLACE a fixed MRI unit of an existing MRI service TO A NEW SITE shall demonstrate the following:

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

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

(c) The proposed new site is ~~in the relocation zone~~within a 10-mile radius of the existing site.

(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

Section 5. Requirements to expand an existing MRI service

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

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

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

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

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

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

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

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

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

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

~~(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.~~

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

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

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

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

~~(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.~~

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

Section ~~7~~6. Requirements to acquire an existing MRI service or an existing MRI unit(s)

Sec ~~7~~6. (1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) shall demonstrate the following:

(a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs. The MRI service shall be operating at the applicable volume requirements set forth in Section 14 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except the first application approved pursuant to subsection (a), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 14 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

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

(a) The project will not change the number of MRI units at the site of the MRI service being acquired, subject to the applicable requirements under Section ~~6~~4(~~2~~6), unless the applicant demonstrates that the project is in compliance with the requirements of the initiation or expansion Section, as applicable.

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

Section ~~8~~7. Requirements to establish a dedicated research MRI unit

Sec. ~~8~~7. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the following:

(1) THE APPLICANT AGREES THAT THE DEDICATED RESEARCH MRI UNIT WILL BE USED PRIMARILY (70% OR MORE OF THE PROCEDURES) FOR RESEARCH PURPOSES ONLY.

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

(~~2~~3) Submit copies of documentation demonstrating that the MRI unit shall operate under a protocol approved by the applicant's IRB.

(~~3~~4) An applicant meeting the requirements of this section shall be exempt from meeting the requirements of sections to initiate and replace.

Section ~~9~~8. Requirements to establish a dedicated pediatric MRI unit

Sec. ~~9~~8. ~~(1)~~ An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

(~~a~~1) The applicant shall have experienced at least 7,000 pediatric (< 18 years old) discharges (excluding normal newborns) in the most recent year of operation.

(~~b~~2) The applicant shall have performed at least 5,000 pediatric (< 18 years old) surgeries in the most recent year of operation.

(~~c~~3) The applicant shall have an active medical staff that includes, but is not limited to, physicians who are fellowship-trained in the following pediatric specialties:

(~~i~~a) pediatric radiology (at least two)
(~~ii~~b) pediatric anesthesiology
(~~iii~~c) pediatric cardiology
(~~iv~~d) pediatric critical care
(~~v~~e) pediatric gastroenterology
(~~vi~~f) pediatric hematology/oncology
(~~vii~~g) pediatric neurology
(~~viii~~h) pediatric neurosurgery
(~~ix~~i) pediatric orthopedic surgery
(~~x~~j) pediatric pathology
(~~xi~~k) pediatric pulmonology
(~~xii~~l) pediatric surgery
(~~xiii~~m) neonatology

(~~d~~4) The applicant shall have in operation the following pediatric specialty programs:

(~~i~~a) pediatric bone marrow transplant program
(~~ii~~b) established pediatric sedation program
(~~iii~~c) pediatric open heart program

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

Section ~~10~~9. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. ~~10~~9. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate each of the following, as applicable to the proposed project.

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

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

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

(4) The applicant has achieved one of the following:
(a) at least 1,500 oncology discharges in the most recent year of operation; or
(b) at least 1,000 neurological surgeries in the most recent year of operation; or
(c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

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

(6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this section unless the patient meets one of the following criteria:
(a) the patient has been admitted to an inpatient unit; or
(b) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

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

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

Section ~~11~~10. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service

Sec. ~~11~~10. An applicant proposing to initiate, replace, or acquire a hospital based MRI-guided EPI service shall demonstrate each of the following, as applicable to the proposed project.

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

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

(3) The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its minimum volume requirements pursuant to the CON review standards for cardiac catheterization services and open heart surgery services.

(4) The proposed MRI-guided EPI unit must be located in a cardiac catheterization lab containing a flouroscopy unit with an adjoining room containing an MRI scanner. The rooms shall contain a patient transfer system allowing for transfer of the patient between the cardiac catheterization lab and the MRI unit, utilizing one of the following:
(a) moving the patient to the MRI scanner, or

(b) installing the MRI scanner on a sliding gantry to allow the patient to remain stationary.

(5) Non-cardiac MRI diagnostic studies shall not be performed in an MRI-guided EPI unit approved under this section unless the patient meets one of the following criteria:

(a) The patient has been admitted to an inpatient unit; or

(b) The patient is having the study performed on an outpatient basis as follows:

(i) is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists, or

(ii) has an implantable cardiac device.

(6) The approved MRI-guided EPI unit shall not be subject to MRI volume requirements.

(7) The applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 11. Requirements for all applicants proposing to initiate, replace, or acquire an MRI SIMULATOR THAT WILL NOT BE USED SOLELY FOR MRT TREATMENT PLANNING PURPOSES

Sec. 11. MRI SIMULATION IS THE USE OF MRI TO HELP SIMULATE (OR PLAN) A PATIENT'S MRT TREATMENT AND TO INCORPORATE SUPERIOR DELINEATION OF SOFT TISSUES FOR MRT TREATMENT PLANS. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE AN MRI SIMULATOR SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS APPLICABLE TO THE PROPOSED PROJECT.

(1) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS.

(2) THE PROPOSED SITE HAS AN EXISTING AND OPERATIONAL MRT SERVICE AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS PURSUANT TO THE CON REVIEW STANDARDS FOR MRT SERVICES/UNITS.

(3) MRI DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED USING AN MRI SIMULATOR APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE FOLLOWING CRITERIA:

(A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR

(B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS, BUT IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS.

(4) THE APPROVED MRI SIMULATOR WILL NOT BE SUBJECT TO MRI VOLUME REQUIREMENTS.

(5) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE MRI SIMULATOR TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS REQUIREMENTS.

Section 12. Requirements for approval of an FDA-approved PET/MRI scanner hybrid for initiation, expansion, replacement, and acquisition

Sec. 12. An applicant proposing to initiate, expand, replace, or acquire an FDA-approved PET/MRI scanner hybrid shall demonstrate that it meets all of the following:

(1) There is an approved PET CON for the FDA-approved PET/MRI hybrid, and the FDA-approved

PET/MRI scanner hybrid is in compliance with all applicable project delivery requirements as set forth in the CON review standards for PET.

(2) The applicant agrees to operate the FDA-approved PET/MRI scanner hybrid in accordance with all applicable project delivery requirements set forth in Section 14 of these standards.

(3) The approved FDA-approved PET/MRI scanner hybrid shall not be subject to MRI volume requirements.

(4) An FDA-approved PET/MRI scanner hybrid approved under the CON review standards for PET scanner services and the review standards for MRI scanner services may not utilize MRI procedures performed on an FDA-approved PET/MRI scanner hybrid to demonstrate need or to satisfy MRI CON review standards requirements.

Section 13. Requirements for all applicants

Sec. 13. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section 14. Project delivery requirements – terms of approval

Sec. 14. ~~(1)~~ An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable safety and operating standards.~~

(~~c~~2) Compliance with the following quality assurance standards:

(~~i~~a) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.

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

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

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

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

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

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

(~~A~~i) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:

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

(~~2~~B) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI instrumentation in a program that is part of an imaging program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, and the physician meets the requirements of subdivision (~~i~~1), (~~ii~~2), or (~~iii~~3):

(~~i~~1) Board certification by the American Board of Radiology, the American Osteopathic Board of Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology program completed by a physician in order to become board certified did not include at least two months of MRI training, that physician shall document that he or she has had the equivalent of two months of postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

(~~ii~~2) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, ~~-~~that included two years of training in cross-sectional imaging and six months training in organ-specific imaging areas.

(~~iii~~3) A practice in which at least one-third of total professional time, based on a full-time clinical practice during the most recent 5-year period, has been the primary interpretation of MR imaging.

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

(~~4~~D) The physician ~~interprets, as the primary interpreting physician, at least 250 unadjusted MRI scans annually~~COMPLIES WITH THE "AMERICAN COLLEGE OF RADIOLOGY (ACR) PRACTICE GUIDELINE FOR PERFORMING AND INTERPRETING MAGNETIC RESONANCE IMAGING (MRI)."

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

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

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

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan population, shall

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

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

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

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

(~~d~~4) Compliance with the following ~~terms of approval, as applicable~~MONITORING AND REPORTING REQUIREMENTS:

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

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

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

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

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

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

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

(~~E~~v) In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section ~~8~~7~~(1)~~ or for an IMRI unit approved pursuant to Section ~~10~~9.

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

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

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

(~~iii~~b) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, operating schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to SECTION 7, Section 8~~(1)~~, Section 9, Section 10, or Section 11 shall be reported separately.

For purposes of Section ~~10~~9, the data reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic. For purposes of Section ~~11~~10, the data reported shall include, at a minimum, how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic. FOR PURPOSES OF SECTION 11, THE DATA REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE MRI SIMULATOR IS USED AND FOR WHAT TYPE OF SERVICES, I.E., TREATMENT PLANS OR DIAGNOSTIC SERVICES.

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

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

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

(~~2~~5) An applicant for an MRI unit approved under Section ~~8~~7~~(1)~~ shall agree that the services provided by the MRI unit are delivered in compliance with the following terms.

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

(b) The MRI unit shall not be used for any purposes other than as approved by the IRB unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section ~~8~~7.

(C) THE DEDICATED RESEARCH MRI UNIT WILL BE USED PRIMARILY (70% OR MORE OF THE PROCEDURES) FOR RESEARCH PURPOSES ONLY.

(6) THE DEDICATED PEDIATRIC MRI UNIT APPROVED UNDER SECTION 8 SHALL INCLUDE AT LEAST 80% OF THE MRI PROCEDURES THAT ARE PERFORMED ON PATIENTS UNDER 18 YEARS OF AGE.

(~~7~~3) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 15. MRI procedure adjustments

Sec. 15. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

(a) The base value for each MRI procedure is 1.0. FOR FUNCTIONAL MRI (fMRI) PROCEDURES, MRI-GUIDED INTERVENTIONS, AND CARDIAC MRI PROCEDURES, THE BASE VALUE IS 2.0.

(i) fMRI MEANS BRAIN ACTIVATION STUDIES.

(ii) MRI-GUIDED INTERVENTIONS MEANS ANY INVASIVE PROCEDURE PERFORMED REQUIRING MRI GUIDANCE PERFORMED IN THE MRI SCANNER.

(iii) CARDIAC MRI PROCEDURE MEANS DEDICATED MRI PERFORMED OF THE HEART DONE FOR THE SOLE PURPOSE OF EVALUATION OF CARDIAC FUNCTION, PHYSIOLOGY, OR VIABILITY.

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

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

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

(e) For each MRI procedure performed on a re-sedated patient, 0.25 shall be added to the base value.

(f) For each MRI procedure performed on a special needs patient, 0.25 shall be added to the base value.

(g) For each MRI visit that involves both a clinical and research scan on a single patient in a single visit, 0.25 shall be added to the base value.

(h) For each contrast MRI procedure performed after use of a contrast agent, and not involving a procedure before use of a contrast agent, 0.35 shall be added to the base value.

(i) For each contrast MRI procedure involving a procedure before and after use of a contrast agent, 1.0 shall be added to the base value.

(j) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value.

(k) The results of subsections (a) through (j) shall be summed, and that sum shall represent an MRI adjusted procedure.

(2) The Department shall apply not more than one of the adjustment factors set forth in this subsection, as applicable, to the number of MRI procedures adjusted in accordance with the applicable provisions of subsection (1) that are performed by an existing MRI service or unit.

(a) For a site located in a rural or micropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.4.

(b) For a mobile MRI unit that serves hospitals and other host sites located in rural, micropolitan statistical area, and metropolitan statistical area counties, the number of MRI adjusted procedures for a site located in a rural or micropolitan statistical area county, shall be multiplied by a factor of 1.4 and for a site located in a metropolitan statistical area county, the number of MRI adjusted procedures shall be multiplied by a factor of 1.0.

(c) For a mobile MRI unit that serves only sites located in rural or micropolitan statistical area counties, the number of MRI adjusted procedures shall be multiplied by a factor of 2.0.

(d) For a mobile MRI unit that serves only sites located in a health service area with one or fewer fixed MRI units and one or fewer mobile MRI units, the number of MRI adjusted procedures shall be multiplied by a factor of 3.5.

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

(3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of the results of subsections (1) and (2).

Section 16. Documentation of actual utilization

Sec. 16. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified by the Department and as verified for the 12-month period reported on the most recently published "MRI

Service Utilization List" as of the date an application is deemed submitted by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 17. The Department may elect to verify the data through on-site review of appropriate records.

Section 17. Methodology for computing the number of available MRI adjusted procedures

Sec. 17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed submitted by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 15.

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section ~~8(1)~~7 and dedicated pediatric MRI approved pursuant to Section ~~9~~ 8 shall be excluded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 18. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 18. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

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

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

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

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

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

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

(a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section 17, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A doctor shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the doctor in the data commitment form provided by the Department and submitted by the applicant in support of its application.

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

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

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

(i) The approved CON is withdrawn or expires.

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

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

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

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

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

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

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

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

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

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

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

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

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

Section 19. Lists published by the Department

Sec. 19. (1) On or before May 1 and November 1 of each year, the Department shall publish the following lists:

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

(i) The number of actual MRI adjusted procedures;

(ii) The number of available MRI adjusted procedures, if any; and

(iii) The number of MRI units, including whether each unit is a clinical, research, or dedicated pediatric.

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

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 17(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 17(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

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

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

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

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 14, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 14, and no data will be shown for that service on either list.

Section 20. Effect on prior CON Review Standards; Comparative reviews

Sec. 20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on ~~September 22, 2011~~JUNE 14, 2012 and effective ~~November 21, 2011~~SEPTEMBER 28, 2012.

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

Section 21. Health Service Areas

Sec. 21. Counties assigned to each of the health service areas are as follows:

HSA		COUNTIES	
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw

1021		Wayne		
1022				
1023	2	Clinton	Hillsdale	Jackson
1024		Eaton	Ingham	Lenawee
1025				
1026	3	Barry	Calhoun	St. Joseph
1027		Berrien	Cass	Van Buren
1028		Branch	Kalamazoo	
1029				
1030	4	Allegan	Mason	Newaygo
1031		Ionia	Mecosta	Oceana
1032		Kent	Montcalm	Osceola
1033		Lake	Muskegon	Ottawa
1034				
1035	5	Genesee	Lapeer	Shiawassee
1036				
1037	6	Arenac	Huron	Roscommon
1038		Bay	Iosco	Saginaw
1039		Clare	Isabella	Sanilac
1040		Gladwin	Midland	Tuscola
1041		Gratiot	Ogemaw	
1042				
1043	7	Alcona	Crawford	Missaukee
1044		Alpena	Emmet	Montmorency
1045		Antrim	Gd Traverse	Oscoda
1046		Benzie	Kalkaska	Otsego
1047		Charlevoix	Leelanau	Presque Isle
1048		Cheboygan	Manistee	Wexford
1049				
1050	8	Alger	Gogebic	Mackinac
1051		Baraga	Houghton	Marquette
1052		Chippewa	Iron	Menominee
1053		Delta	Keweenaw	Ontonagon
1054		Dickinson	Luce	Schoolcraft

APPENDIX A

CON REVIEW STANDARDS FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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

Date: February 15, 2013

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Megavoltage Radiation Therapy (MRT) Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the MRT Standards at its December 13, 2013 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRT Standards on February 5, 2013. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from (7) seven organizations and is summarized as follows:

Daniel George, Covenant Healthcare

- Supports the "rural provision" for HSA 8.
- Covenant has concerns regarding the new initiation methodology, in particular, the change from a facility methodology to one based upon a "physician commitment" methodology.
- Putting control of Tumor Registry Data/Cancer Surveillance data into the hands of a few "Staff/Treating" physicians' control becomes complicated, and opens the door to fragmented care for the citizens of Michigan.
- MRT is part of a continuum of care that can encompass imaging, staging, oncological services, infusion, blood transfusions, radiation therapy and often hospitalization.

Kenneth Chu, Marquette General Hospital

- Propose change to lines 467-468 to be modified to include: "One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, available (by telephone, telecommunication, or radio) during hours of operation."

Robert Meeker, Spectrum Health

- In general, Spectrum supports the proposed changes to the MRT Services Standards.
- Specifically, Spectrum supports the proposed utilization-based need methodology, whereby "excess" MRT procedures will be committed to a proposed new program by treating radiation oncologists at existing centers.
- Spectrum supports the proposed revision that would allow an MRT program in the eastern Upper Peninsula.
- Supports the recommended requirements that new MRT programs be accredited within 3 years of operation.

Cory Knill, Karmanos Cancer Center

- Has a concern with the term "immediately available," with which it's used to describe the required physics and physician presence during treatments and machine operation.
    1. The term could be interpreted to mean the responsible person needs to be: 1) Near the machine, 2) Present in the building, 3) available by phone.
    2. To alleviate any confusion, an additional description of the term is needed in the Definitions section to clarify the exact meaning of the term as it applies to the responsible person's proximity to the treatment unit.

Gregory S. Dobis, McLaren Health Care

- Requests that Healthcare Facilities Accreditation Program (HFAP) be included in Section 14 (e) (I) as a qualifying organization, OR not naming specific accrediting organizations but by simply stating that the applicant must be accredited by a recognized CMS authority.

Brian Rasmussen, Dickinson County Healthcare System- Marquette General

- Suggests that lines 467-468 be changed to read: "One FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, available (physically, by telephone, telecommunication, or radio) during hours of operation."
- Suggests that requiring immediate availability would put unreasonable man-hour requirements on some physicists at some centers and centers this opinion on the legal definition "without interval of time, instantly."

Keith Crowell, Oaklawn Hospital

- Suggests that the Commission consider updating the MRT standards by defining the planning area for this service by a mileage radius from the applicant site rather than the Health Service Area (HSA).

- Suggests the Commission consider the possibility of using the location of the patient, rather than the existing MRT service where they were treated, to determine need within the planning area.
    - By looking at the patient's zip code relative to the proposed MRT service location, rather than the location of the MRT service where they received MRT services (knowing many patients travel long distances from home for this service), will be able to locate new services in areas that will most drastically improve patient access rather than continuing status quo.

Recommendations

The Department received testimony to include HFAP, a nationally recognized accreditation organization to satisfy Section 11(2)(e)(i) of the project delivery requirements within the standards. The Department supports this addition as HFAP has deeming authority from the Centers for Medicare and Medicaid Services (CMS).

The Department also received testimony proposing clarification to lines 467-468 which read: "(ii) One (1) FTE board-certified or board-qualified radiation physicist, certified in therapeutic radiologic physics, immediately available during hours of operation." The Department does not propose a change to this language.

OaklawnHospital

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Advancing medicine.
Compassionate care.

March 28, 2013

Mr. James B. Falahee, Jr., J.D.
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend Street, 7th Floor
Lansing, Michigan 48913

Dear Chairman Falahee,

On behalf of Oaklawn Hospital in Marshall, Michigan, we appreciate this opportunity to provide comments on the proposed changes to the MRT standards up for final action today. We are following up to our written comments provided during the public hearing period last month and wanted to take this opportunity to expand upon our suggestions.

We commend the workgroup for accomplishing such significant changes in just three meetings, yet we are concerned that the workgroup may not have had adequate opportunity to consider some of the ramifications of the proposed changes. The workgroup recommendations modify the methodology for demonstrating need for a new MRT service to make it very similar to the methodologies used in CT, MRI, and surgical services. The proposed methodology determines need based on the volumes at existing services rather than the collection of new cancer case data.

Radiation therapy is a modality that requires multiple treatments, often on a daily basis, for weeks at a time. When a patient has access to an MRT service nearby, they are often able to continue their normal routine, with little interruption, such as working, taking care of their children, etc. However, if the patient has to travel, even as little as 45 minutes or an hour, to receive treatment, their ability to maintain their routine and responsibilities significantly decreases. It is commonly believed that patients who continue to work and maintain their routine have improved outcomes.

For this reason, 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 services currently exist. We are concerned, however, that the proposed revisions do the opposite. 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 do not already have it. This is not in the best interests of the patients being served by this treatment modality.

The workgroup recognized this problem to an extent, and has already recommended an exception for the Upper Peninsula to try to alleviate the concerns specifically voiced by providers there. However, exceptions may not be the best way to address the concern. Instead we would like to suggest two additional changes that we believe would resolve the problem for all patients in the State of Michigan, without utilizing exceptions.

The first suggestion is to utilize a mileage radius planning area, instead of the Health Service Area (groupings of counties). As they relate to the description of a Planning Area, Health Service Areas (HSA's) are effectively just arbitrary lines on a map. If a proposed service is near an HSA boundary, it may be much farther from a patient on the opposite side of their HSA than they are to a patient just on the other side of the HSA boundary.

In the alternative, a mileage radius is much more true to a provider's market area. There is considerable precedent for this approach as well. Most other covered clinical services use mileage radius for the planning area and set the radius at a mileage relative to the distance a patient would reasonably travel for the service. The larger the radius, the less restrictive as it relates to collecting data for initiating new service, allowing for greater flexibility in initiating new services in geographic areas that are not yet served.

Because MRT services are not nearly as prevalent as surgical services, CT, or MRI, we believe that a larger radius would be appropriate. The current standards already recognize that more than 60 miles is too far to travel for MRT services (a lower initiation threshold is allowed for a proposed service located more than 60 miles from the nearest existing service), therefore we would suggest a planning area of 60 miles.

The second suggestion is to look at the location of the patient being treated rather than the location where they receive their treatment. We recommend the proposed site of the new MRT service be within the same planning area as the facility where the excess volume was generated. However, if a patient had to travel a significant distance to receive that treatment, the proposed changes do nothing to help initiate a service closer to those traveling patients. If patients in the UP currently have to travel to Traverse City for treatment, under the workgroup proposal, those patients could potentially count toward the initiation of a new service in the Traverse City planning area, but not in the UP planning area, even though that is where the service may be needed more. However, if we looked at where the patient lives instead of where they are treated, the patient traveling from the UP would count toward the initiation of a new service in the UP.

We understand that these standards are slated for a final vote today. However, we believe these concerns are vitally important to the new standards functioning effectively for cancer patients in the State of Michigan and ask that you direct the Department to work with us over the coming months to develop language to address these issues with the intent of putting this back on the agenda for the June meeting. I apologize for not being able to attend today's meeting in person, and have asked a representative to attend and answer any questions in my absence. Thank you for your time in considering this matter.

Sincerely,

Ginger Williams, MD, FACEP, FACHE
President and CEO

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) "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).

(g) "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.

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

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

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

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

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

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

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

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

~~(r) "New cancer case," means a person with any newly diagnosed cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area.~~

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

(t) "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.

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

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

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

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

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

Section 3. ~~Modification of the Appendices~~

~~Sec. 3. The Commission may modify the appendices as follows.~~

~~(1) The Commission may modify the Duplication Rates and the Duplication Factors set forth in Appendix A based on data obtained from the Michigan Cancer Surveillance Program and presented by the Department.~~

~~(2) The Commission may modify the Distribution of MRT Courses by Treatment Visit Category set forth in Appendix B based on data obtained from the Department Annual Survey of MRT providers and presented by the Department.~~

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

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

~~Section 4.~~ Requirements to initiate an MRT service

Sec. ~~4~~3. Initiate means the establishment of an MRT service where an MRT service is not currently provided. The term does not include replacement of an existing MRT service. An applicant proposing to initiate an MRT service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to initiate an MRT service shall demonstrate the following:
(a) The applicant projects 8,000 equivalent treatment visits for each proposed unit.
(b) The proposed MRT unit is not a special purpose MRT unit.

(2) An applicant that demonstrates all of the following shall not be required to be in compliance with the requirement in subsection (1):
(a) The site of the proposed MRT service is located in a rural or micropolitan statistical area county.
(b) The site of the proposed MRT service is 60 driving miles or more, verifiable by the Department, from the nearest MRT service.
(c) The applicant projects 5,500 equivalent treatment visits for each proposed unit.
(d) The proposed MRT unit is not a special purpose MRT unit.

(3) AN APPLICANT THAT DEMONSTRATES ALL OF THE FOLLOWING SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH THE REQUIREMENT IN SUBSECTION (1):
(A) THE APPLICANT IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.
(B) THE SITE OF THE PROPOSED MRT SERVICE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE AND LOCATED IN PLANNING AREA 8.
(C) THE SITE OF THE PROPOSED MRT SERVICE IS 90 DRIVING MILES OR MORE, VERIFIABLE BY THE DEPARTMENT, FROM THE NEAREST MRT SERVICE.
(D) THE APPLICANT PROVIDES COMPREHENSIVE IMAGING SERVICES INCLUDING AT LEAST THE FOLLOWING:
(I) FIXED MAGNETIC RESONANCE IMAGING (MRI) SERVICES,
(II) FIXED COMPUTED TOMOGRAPHY (CT) SERVICES, AND
(III) MOBILE POSITRON EMISSION TOMOGRAPHY (PET) SERVICES.
(~~D~~E) THE PROPOSED MRT UNIT IS NOT A SPECIAL PURPOSE MRT UNIT.

(4) An applicant proposing to initiate an MRT service with an HMRT unit shall demonstrate the following:
(a) The applicant is a single legal entity authorized to do business in the State of Michigan.
(b) The applicant is a collaborative that consists of at least 40% of all Michigan-based hospital MRT services with more than 30,000 equivalent treatment visits based on the most current data available to the Department. Hospital MRT service means an MRT service owned by a hospital or owned by a corporation that is itself wholly owned by hospital(s).
(c) The applicant shall include hospital MRT services from more than one planning area from one or both of the following:
(i) Hospital MRT services qualified under subsection (b).
(ii) Hospital MRT services with the highest number of equivalent treatment visits in a planning area.
(d) Equivalent treatment visits for this subsection shall be those from the most recent CON Annual Survey.
(e) An application shall not be approved if it includes an MRT service described in subsection (i) or (ii) except as provided in subsections (iii) or (iv).
(i) An MRT service that was part of another application under this subsection.

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

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

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

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

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

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

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

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

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

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

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

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

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

(~~4~~5) Applicants under this section shall demonstrate the following staff will be provided:

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

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

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

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

(e) One (1) program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (~~4~~5)(a).

Section ~~5~~4. Requirements to replace an existing MRT unit or service

Sec. ~~5~~4. Replacement of an existing MRT unit means an equipment change that results in a new serial number or requiring the issuance of a new radiation safety certificate from the State of Michigan Radiation Safety Section. Replacement also means the relocation of an MRT service or unit to a new site. Replacement does not include an upgrade to an existing MRT unit with the addition or modification of equipment or software; the replacement components; or change for the purpose of maintaining or improving its efficiency, effectiveness, and/or functionality. An applicant requesting to replace an existing MRT unit(s) or MRT service shall demonstrate the following, as applicable to the proposed project.

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

(a) The replacement unit(s) is the same type as the MRT unit(s) to be replaced.

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

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

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

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

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

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

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

(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section ~~4~~3(2) OR 3(3).

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

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

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

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

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

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

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

(e) The proposed site meets the requirements of Section ~~4~~3(4).

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

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

Section ~~6~~5. Requirements to expand an existing MRT service

Sec. ~~6~~5. An applicant proposing to expand an existing MRT service by adding an MRT unit(s) shall demonstrate the following, as applicable to the proposed project.

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

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

(a) An average of 8,000 equivalent treatment visits was performed in the most recent 12-month period on each of the applicant's existing and approved non-special MRT units.

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

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

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

Section ~~7~~6. Requirements to acquire an existing MRT service

Sec. ~~7~~6. Acquiring an existing MRT service means obtaining possession and control by contract, ownership, lease, or another comparable arrangement and renewal of lease for an existing MRT unit(s). An applicant proposing to acquire an MRT service shall demonstrate the following, as applicable to the proposed project.

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

(2) an applicant proposing to acquire an existing MRT service shall demonstrate the following:
(a) The existing MRT unit(s) shall be operating at the following volumes, as applicable to the proposed project:
(i) Non-special MRT unit(s) at 8,000 equivalent treatment visits per unit or 5,500 for a unit approved under Section ~~4~~3(2) OR 3(3).
(ii) HMRT unit(s) at 8,000 equivalent treatment visits per unit.
(iii) Special purpose unit(s) at 1,000 equivalent treatment visits per unit.

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

Section ~~8~~7. Requirements for a dedicated research MRT unit(s)

Sec. ~~8~~7. An applicant proposing to add a dedicated research MRT unit shall demonstrate the following:

(1) The applicant is an existing MRT service.

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

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

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

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

Section ~~9~~8. Requirements for Medicaid participation

Sec. ~~9~~8. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services, if a CON is approved.

Section ~~10~~9. Methodology for projecting equivalent treatment visits

Sec. ~~10~~9. An applicant being reviewed under Section ~~4~~ 3 shall apply the methodology set forth in this section in computing the projected number of equivalent treatment visits.

(1) ~~Identify the number of new cancer cases under Section 13.~~ AN APPLICANT SHALL DEMONSTRATE THAT THE PROJECTION IS BASED ON THE COMMITMENTS OF THE TREATMENTS PROVIDED BY THE TREATING PHYSICIAN(S) FOR THE MOST RECENT 12-MONTH PERIOD IMMEDIATELY PRECEDING THE DATE OF THE APPLICATION. THE COMMITMENTS OF

THE TREATING PHYSICIAN(S) WILL BE VERIFIED WITH THE DATA MAINTAINED BY THE DEPARTMENT THROUGH ITS "CON ANNUAL SURVEY."

(A) FOR THE PURPOSES OF THIS SECTION, TREATING PHYSICIAN MEANS THE STAFF PHYSICIAN OF THE MRT SERVICE DIRECTING AND PROVIDING THE MRT TREATMENT, NOT THE REFERRING PHYSICIAN.

(2) ~~Multiply the number of new cancer cases identified in subsection (1) by the duplication factor identified in Appendix A, for the planning area in which the proposed unit will be located.~~ AN APPLICANT SHALL DEMONSTRATE THAT THE PROJECTED NUMBER OF COMMITMENTS TO BE PERFORMED AT THE PROPOSED SITE UNDER SUBSECTION (1) ARE FROM AN EXISTING MRT SERVICE THAT IS IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE, AND WILL CONTINUE TO BE IN COMPLIANCE WITH THE VOLUME REQUIREMENTS APPLICABLE TO THAT SERVICE SUBSEQUENT TO THE INITIATION OF THE PROPOSED MRT SERVICE BY AN APPLICANT. ONLY EXCESS ETVS EQUAL TO OR GREATER THAN WHAT IS BEING COMMITTED PURSUANT TO THIS SUBSECTION MAY BE USED TO DOCUMENT PROJECTIONS UNDER SUBSECTION (1). IN DEMONSTRATING COMPLIANCE WITH THIS SUBSECTION, AN APPLICANT SHALL PROVIDE EACH OF THE FOLLOWING:

(A) A WRITTEN COMMITMENT FROM EACH TREATING PHYSICIAN THAT HE OR SHE WILL TREAT AT LEAST THE VOLUME OF MRT TREATMENTS TO BE TRANSFERRED TO THE PROPOSED MRT SERVICE FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE MRT SERVICE PROPOSED BY AN APPLICANT.

(B) THE NUMBER OF TREATMENTS COMMITTED MUST HAVE RESULTED IN AN ACTUAL TREATMENT OF THE PATIENT AT THE EXISTING MRT SERVICE FROM WHICH THE TREATMENT WILL BE TRANSFERRED. THE COMMITTING PHYSICIAN MUST MAKE AVAILABLE HIPAA COMPLIANT AUDIT MATERIAL IF NEEDED UPON DEPARTMENT REQUEST TO VERIFY REFERRAL SOURCES AND OUTCOMES. COMMITMENTS MUST BE VERIFIED BY THE MOST RECENT DATA SET MAINTAINED BY THE DEPARTMENT THROUGH ITS "CON ANNUAL SURVEY."

(C) THE PROJECTED COMMITMENTS ARE FROM AN EXISTING MRT SERVICE WITHIN THE SAME PLANNING AREA AS THE PROPOSED MRT SERVICE.

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

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

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

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

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

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

~~(9) Multiply the estimated number of treatment visits in the IMRT category produced in subsection (5) by 2.0.~~

~~(10) Sum the numbers produced in subsections (6) through (9) to determine the total number of estimated equivalent treatment visits.~~

Section ~~11~~10. Equivalent treatment visits

Sec. ~~11~~10. Equivalent treatment visits shall be calculated as follows:

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

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

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

TABLE 1
Equivalent Treatments

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* (non-gamma knife and cyber knife**)	8.00	8.00
Gamma Knife**		8.00
IORT		20.00

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

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

**After the first isocenter, each additional isocenter receives 4 additional equivalent treatment visits.

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

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

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

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

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

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

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

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

~~**Section 12. Commitment of new cancer cases**~~

~~Sec. 12. An applicant using new cancer cases to demonstrate need shall meet the following:~~

~~(1) Each entity contributing new cancer case data provides a signed governing body resolution that states that the number of new cancer cases committed to the application shall not be used in support of any other application for an MRT unit(s) for the duration of the MRT service for which the data are being committed.~~

~~(2) The locations of all entities contributing new cancer case data are in the same planning area as the proposed MRT service.~~

~~(3) An entity currently operating or approved to operate an MRT service shall not contribute new cancer cases to initiate any MRT service nor shall new cancer cases treated or reported by an existing MRT service be used by an applicant to support a new MRT service.~~

~~**Section 13. Documentation of new cancer case data**~~

~~Sec. 13. An applicant shall submit documentation from the Michigan Cancer Surveillance Program, within the Department, verifying the number of new cancer cases provided in support of the application for the most recent calendar year for which verifiable data is available. New cancer case data supporting an application shall be submitted to the Michigan Cancer Surveillance Program using a format and media specified in instructions from the Department.~~

Section ~~14~~11. Project delivery requirements terms of approval for all applicants

Sec. ~~14~~11. An applicant shall agree that, if approved, the MRT service, including all existing and approved MRT units, shall be delivered in compliance with the following:

(1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:

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

(b) An applicant shall have the following staff:

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

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

(iii) One (1) dosimetrist for every 300 patients treated with MRT annually.

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

(v) One (1) FTE program director who is a board-certified physician trained in radiation oncology who may also be the physician required under subsection (i). The Department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in radiation oncology and/or therapeutic radiology.

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

(d) An applicant shall have equipment and supplies to handle clinical emergencies that might occur. Staff will be trained in CPR and other appropriate emergency interventions and shall be on-site in the MRT unit at all times when patients are treated. A physician shall be on-site or immediately available to the MRT unit at all times when patients are treated.

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

(I) AN APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION BY THE AMERICAN COLLEGE OF SURGEONS COMMISSION ON CANCER ~~OR,~~ THE JOINT COMMISSION ON THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS (JCAHO), OR THE HEALTHCARE FACILITIES ACCREDITATION PROGRAM (HFAP) WITHIN THE FIRST THREE YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

(II) AN APPLICANT SHALL SUBMIT EVIDENCE OF ACCREDITATION BY THE AMERICAN COLLEGE OF RADIOLOGY/AMERICAN SOCIETY FOR RADIATION ONCOLOGY (ACR/ASTRO) OR THE AMERICAN COLLEGE OF RADIATION ONCOLOGY (ACRO) WITHIN THE FIRST THREE YEARS OF OPERATION AND CONTINUE TO PARTICIPATE ANNUALLY THEREAFTER.

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

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

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

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

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

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

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

(a) The applicant shall accept referrals for MRT services from all appropriately licensed health care practitioners.

(b) To assure that the MRT service and its unit(s) will be utilized by all segments of the Michigan population, the applicant shall:

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

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

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

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

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

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

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

(c) An applicant is not required to be in compliance with subsections (4)(a) or (b) if the applicant is replacing an MRT unit under section ~~5~~4(1).

(d) An applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources and other data requested by the Department. Data shall be provided by each type of MRT unit in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

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

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

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

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

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

Section ~~15~~12. Effect on prior CON review standards; comparative reviews

Sec. ~~15~~12. proposed projects reviewed under these standards shall not be subject to comparative review. These standards supersede and replace the CON Review Standards for MRT Services/Units approved by the CON Commission on September ~~16~~22, ~~2008~~ 2011 and effective November ~~13~~21, ~~2008~~2011.

~~APPENDIX A~~

~~DUPLICATION RATES AND FACTORS~~

~~The following Duplication Rates and Factors are effective November 21, 2011 and remain in effect until otherwise changed by the Commission. Duplication factor means the number derived by subtracting the duplication rate from 1. Duplication rate means the percent of new cancer cases in each planning area determined by the Department, Vital Records and Health Data Development Section, that have been reported more than one time to the Michigan Cancer Surveillance Program.~~

~~PLANNING AREA~~	~~DUPLICATION RATE~~	~~DUPLICATION FACTOR~~
~~1~~	~~0.123~~	~~0.877~~
~~2~~	~~0.152~~	~~0.848~~
~~3~~	~~0.113~~	~~0.887~~
~~4~~	~~0.162~~	~~0.838~~
~~5~~	~~0.167~~	~~0.833~~
~~6~~	~~0.270~~	~~0.730~~
~~7~~	~~0.126~~	~~0.874~~
~~8~~	~~0.193~~	~~0.807~~

APPENDIX B

DISTRIBUTION OF MRT COURSES BY TREATMENT VISIT CATEGORY

The following Distribution of MRT Courses by Treatment Visit Category is effective November 21, 2011 and remains in effect until otherwise changed by the Commission.

Treatment Visit Category	Statewide Percent
Simple	0.7%
Intermediate	0.1%
Complex	52.2%
IMRT	47.0%

Source: 2010 CON Annual Survey

APPENDIX ~~C~~A

PLANNING AREAS BY COUNTY

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

APPENDIX ~~DB~~

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR OPEN HEART SURGERY (OHS) SERVICES

(By the 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 OR ACQUISITION OF OHS SERVICES, and delivery of THESE services ~~for all projects approved and certificates of need issued~~ under Part 222 of the Code ~~which involve open heart surgery services~~. PURSUANT TO PART 222 OF THE CODE,

~~(2)~~OHS~~pen heart surgery~~ is a covered clinical service ~~for purposes of Part 222 of the Code~~.

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

~~(4)The Department shall use Section 7 in applying~~ Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

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

Section 2. Definitions

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

(a) "Adult ~~open heart surgery~~ OHS" means ~~open heart surgery~~OHS offered and provided to individuals age 15 and older as defined in subsection (i).

(b) "Cardiac surgical team" means the designated specialists and support personnel who consistently work together in the performance of ~~open heart surgery~~OHS.

(c) "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.

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

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

(F) "HOSPITAL" MEANS A HEALTH FACILITY LICENSED UNDER PART 215 OF THE CODE.

(G) "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.

(~~g~~H) " Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396~~r~~ TO 1396G and1396~~r-8~~I to ~~1396v~~1396U.

(~~h~~I) "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.

(~~i~~J) "Open heart surgery" means any cardiac surgical procedure involving the heart and/or thoracic great vessels (excluding organ transplantation) that is intended to correct congenital and acquired cardiac and coronary artery disease and/or great vessels and often uses a heart-lung pump (pumps and oxygenates the blood) or its equivalent to perform the functions of circulation during surgery. These

procedures may be performed off-pump (beating heart), although a heart-lung pump is still available during the procedure.

(~~j~~K) "Open heart surgical case" means a single visit to an operating room during which one or more ~~open heart surgery~~OHS procedures are performed. THE LIST OF OHS PROCEDURES SHALL BE MAINTAINED BY THE DEPARTMENT.

(~~k~~L) "~~Open heart surgery~~OHS service" means a hospital program that is staffed with surgical teams and other support staff for the performance of open heart surgical procedures. An ~~open heart surgery~~OHS service performs ~~open heart surgery~~OHS procedures on an emergent, urgent and scheduled basis.

(~~l~~M) "Pediatric ~~open heart surgery~~OHS" means ~~open heart surgery~~OHS offered and provided to infants and children age 14 and younger, and to other individuals with congenital heart disease as defined by the ICD-9-CM codes of 745.0 through 747.99.

(~~m~~N) "Planning area" means the groups of counties shown in Section 10.

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

Section 3. Requirements ~~for all applicants proposing~~ to initiate ~~open heart surgery~~OHS services

Sec. 3. (1) An applicant proposing to initiate either adult or pediatric ~~open heart surgery~~OHS as a new service shall be A HOSPITAL AND operating or approved to operate a diagnostic and therapeutic adult or pediatric cardiac catheterization service, respectively.

(2) A hospital proposing to initiate ~~open heart surgery~~OHS as a new service shall have a written consulting agreement with a hospital which has an existing active ~~open heart surgery~~OHS service performing a minimum of 400 open heart surgical cases per year for 3 consecutive years. The agreement must specify that the existing service shall, for the first 3 years of operation of the new service, provide the following services to the applicant hospital:

(a) Receive and make recommendations on the proposed design of surgical and support areas that may be required;

(b) Provide staff training recommendations for all personnel associated with the new proposed service;

(c) Provide recommendations on staffing needs for the proposed service; and

(d) Work with the medical staff and governing body to design and implement a process that will annually measure, evaluate, and report to the medical staff and governing body the clinical outcomes of the new service, including: (i) Mortality rates, (ii) Complication rates, (iii) Success rates, and (iv) Infection rates.

(3) An applicant proposing to initiate adult ~~open heart surgery~~OHS as a new service shall demonstrate 300 adult open heart surgical cases based on the methodology set forth in Section 8.

(4) An applicant proposing to initiate pediatric ~~open heart surgery~~OHS as a new service shall demonstrate 100 pediatric open heart surgical cases based on the methodology set forth in Section 9.

Section 4. Requirements ~~for approval for applicants proposing~~ to acquire an existing open heart surgery service

Sec. 4. An applicant proposing to acquire a hospital that has been approved to perform ~~open heart surgery~~OHS services may also acquire the existing ~~open heart surgery~~OHS service if it can demonstrate that the proposed project meets all of the following:

(1) An application for the first acquisition of an existing ~~open heart surgery~~OHS service after ~~the effective date of these standards~~FEBRUARY 25, 2008 shall not be required to be in compliance with the applicable volume requirements on the date of acquisition. The ~~open heart surgery~~OHS service shall be

operating at the applicable volume requirements set forth in Section 7 of these standards in the second 12 months after the date the service is acquired, and annually thereafter.

(2) Except as provided for in subsection (1), an application for the acquisition of an existing ~~open heart surgery~~OHS service after ~~the effective date of these standards~~ FEBRUARY 25, 2008 shall be required to be in compliance with the applicable volume requirements, as set forth in the project delivery requirements, on the date an application is submitted to the Department.

(3) The applicant agrees to operate the ~~open heart surgery~~OHS service in accordance with all applicable project delivery requirements set forth in Section 7 of these standards.

Section 5. Requirements for ~~all applicants~~MEDICAID PARTICIPATION

Sec 5**.** An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services~~,~~ if a CON is approved.

Section 6. Requirements for MIDB data commitments

Sec. 6. In order to use MIDB data in support of an application for either adult or pediatric ~~open heart surgery~~OHS services, an applicant shall demonstrate or agree, as applicable, to all of the following:

(1) A hospital(s) whose adult MIDB data is used in support of a CON application for adult ~~open heart surgery~~OHS services shall not use any of its adult MIDB data in support of any other application for adult ~~open heart surgery~~OHS services prior to 7 years after the initiation of the ~~open heart surgery~~OHS service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its adult MIDB data in support of another application for adult ~~open heart surgery~~OHS services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate ~~open heart surgery~~OHS services.

(2) A hospital(s) whose pediatric MIDB data is used in support of a CON application for pediatric ~~open heart surgery~~OHS services shall not use any of its pediatric MIDB data in support of any other application for pediatric ~~open heart surgery~~OHS services prior to 7 years after the initiation of the ~~open heart surgery~~OHS service for which MIDB data were used to support. After the 7-year period, a hospital(s) may only commit its pediatric MIDB data in support of another application for pediatric ~~open heart surgery~~OHS services if they have experienced an increase from the previously committed MIDB data. Only that additional increase in MIDB data can be committed to another applicant to initiate ~~open heart surgery~~OHS services.

(3) The hospital(s) committing MIDB data does not currently operate an adult or pediatric ~~open heart surgery~~OHS service or have a valid CON issued under Part 222 to operate an adult or pediatric ~~open heart surgery~~OHS service.

(4) The hospital(s) committing MIDB data is located in the same planning area as the hospital to which MIDB data is being proposed to be committed.

(5) The hospital(s) committing MIDB data to a CON application has completed the departmental form(s) which (i) authorizes the Department to verify the MIDB data, (ii) agrees to pay all charges associated with verifying the MIDB data, and (iii) acknowledges and agrees that the commitment of the MIDB data is for the period of time specified in subsection (1) or (2), as applicable.

(6) The hospital(s) committing MIDB data to an application is regularly admitting patients as of the date the Director makes the final decision on that application, under Section 22231 of the Code, being Section 333.22231 of the Michigan Compiled Laws.

Section 7. Project delivery requirements ~~--~~AND terms of approval for all applicants

Sec. 7. ~~(1)~~ An applicant shall agree that, if approved, the OHS services shall be delivered in compliance with the following terms of CON approval:

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable operating standards.~~

(~~c~~2) Compliance with the following quality assurance standards:

(~~i~~A) ~~The open heart surgery service shall be operating at an annual level of 300 adult open heart surgical cases or 100 pediatric open heart surgical cases, as applicable, by the end of the third 12 full months of operation, and annually thereafter.~~

~~(ii~~B) ~~-~~Each physician credentialed by the ~~applicant -~~hospital to perform adult ~~open heart surgery~~OHS cases, as the attending surgeon, shall perform a minimum of ~~75~~ 50 adult ~~open heart surgery~~OHS cases per year. The annual case load for a physician means adult ~~open heart surgery~~OHS cases performed by that physician, as the attending surgeon, in any hospital or combination of hospitals.

~~(iii) The service shall be staffed with sufficient medical, nursing, technical and other personnel to permit regular scheduled hours of operation and continuous 24 hour on-call availability.~~

(~~iv~~B) The service shall have the ~~capability for rapid mobilization of a~~ cardiac surgical team ~~for~~ AVAILABLE ON CALL FOR emergency cases 24 hours a day, 7 days a week.

(C) THE APPLICANT HOSPITAL SHALL PARTICIPATE WITH THE SOCIETY OF THORACIC SURGEONS (STS) NATIONAL DATABASE AND THE MICHIGAN SOCIETY OF THORACIC AND CARDIOVASCULAR SURGEONS (MSTCVS) QUALITY COLLABORATIVE AND DATABASE OR A DESIGNEE OF THE DEPARTMENT THAT MONITORS QUALITY AND RISK ADJUSTED OUTCOMES.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

(~~v~~A) ~~An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.~~ THE SERVICE SHALL ACCEPT REFERRALS FOR OHS FROM ALL APPROPRIATELY LICENSED PRACTITIONERS.

(~~d~~B) THE APPLICANT HOSPITAL shall participate in Medicaid at least 12 consecutive months within the first two years of operation and annually thereafter.~~The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~

(~~i~~C) ~~provide open heart surgery~~ THE ~~service~~APPLICANT HOSPITAL~~s to all individuals based on the clinical indications of need for the~~ SHALL NOT DENY OHS serviceS TO ANY INDIVIDUAL ~~and not~~BASED on THE ability to pay or source of payment~~; and~~.

~~(ii) maintain information by source of payment to indicate the volume of care from each source provided annually.~~

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

(D) THE OPERATION OF AND REFERRAL OF PATIENTS TO THE OHS SERVICES SHALL BE IN CONFORMANCE WITH 1978 PA 368, SEC. 16221, AS AMENDED BY 1986 PA 319; MCL 333.1621; MSA 14.15 (16221).

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

(~~e~~A) The OHS service shall be operating at an annual level of ~~300~~150 adult open heart surgical cases or 100 pediatric open heart surgical cases, as applicable, AS SUBMITTED TO THE STS DATABASE, by the end of the third 12 full months of operation, and annually thereafter.

(B) The applicant HOSPITAL shall prepare and present to the medical staff and governing body reports describing activities in the ~~open heart surgery~~OHS service including complication rates and other morbidity and mortality data.

(~~f~~C) The applicant HOSPITAL shall participate in a data collection network established and administered by the Department or its designee. The data may include but is not limited to annual budget and cost information, operating schedules, ~~and~~ PATIENT demographicS, diagnostic, morbidity and mortality information, ~~as well as~~AND the volume of care provided to patients from all payor sources. The applicant~~.~~ HOSPITAL shall provide the required data in a format established by the Department and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~g~~D) The applicant HOSPITAL shall participate in a data registry administered by the Department or its designee AS A MEANS TO MEASURE QUALITY AND RISK ADJUSTED OUTCOMES WITHIN OHS PROGRAMS. THE DEPARTMENT SHALL USE THE STS COMPOSITE STAR RATING SYSTEM WHICH CURRENTLY INCLUDES CORONARY ARTERY BYPASS GRAFT COMPOSITE (CABG), AORTIC VALVE REPLACEMENT COMPOSITE, AND PLANS TO ADD ADDITIONAL CARDIAC SURGICAL COMPOSITES EACH YEAR.~~monitors quality and risk adjusted outcomes.~~ The Department or its designee shall require that the applicant HOSPITAL submit a summary report as specified by the Department. The applicant HOSPITAL shall provide the required data in a format established by the Department or its designee. The applicant HOSPITAL shall be liable for the cost of data submission and on-site reviews in order for the Department to verify and monitor volumes and assure quality. The applicant HOSPITAL shall become a member of the data registry specified by the Department upon initiation of the service~~.~~ AND CONTINUE TO ~~Participation~~ PARTICIPATE ~~shall continue~~ annually thereafter FOR THE LIFE OF THAT SERVICE. The outcomes database must undergo statewide auditing.

(~~h~~E) ~~An~~ THE applicant HOSPITAL ~~that fails to comply with the quality assurance standards under subsection (c2) shall be required to provide its quality and risk adjusted outcomes data from the data registry to the Department, or its designee, as part of the Department's enforcement and compliance activities.~~ SHALL UTILIZE AND REPORT THE STS COMPOSITE STAR RATING SYSTEM FOR ALL PROCEDURES AS FOLLOWS:

(I) IF THE PROGRAM RECEIVES A ONE-STAR RATING IN ANY COMPOSITE METRIC, THEY SHALL SUBMIT A REPORT TO THE DEPARTMENT EXPLAINING THE REASON(S) FOR THE UNSATISFACTORY RATING.

(II) IF THE PROGRAM RECEIVES TWO ONE-STAR RATINGS IN A ROW IN THE SAME COMPOSITE METRIC, THEY SHALL SUBMIT AN ACTION PLAN TO THE DEPARTMENT DETAILING SPECIFIC ACTIONS TO RECTIFY THE PROGRAM DEFICIENCIES.

(A) IF THE PROGRAM RECEIVES TWO ONE-STAR RATINGS WITHIN THE SAME COMPOSITE METRIC, THE PROGRAM MAY HAVE TWO YEARS TO OBTAIN A MINIMUM TWO-STAR RATING WITHIN THAT COMPOSITE METRIC. UPON RECEIPT OF A TWO-STAR OR HIGHER RATING, THE PROGRAM MAY BE CONSIDERED IN COMPLIANCE.

(~~f~~F) The applicant HOSPITAL shall provide the Department with ~~a notice stating the date on which the first approved service is performed and such~~TIMELY NOTICE OF THE PROPOSED PROJECT IMPLEMENTATION ~~notice shall be submitted to the Department~~ consistent with applicable statute and promulgated rules.

(5) NOTHING IN THIS SECTION PROHIBITS THE DEPARTMENT FROM TAKING COMPLIANCE ACTION UNDER MCL 333.22247.

(~~2~~56) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 8. Methodology for computing the number of adult open heart surgical cases

Sec. 8. (1) The weights for the adult principal and non-principal diagnoses tables found in Appendix A are calculated using the following methodology. For these two tables, only the MIDB data from licensed hospitals that have operational ~~open heart surgery~~OHS programs in Michigan will be used.

Using ~~a~~ THE hospital~~'~~s' actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, ~~an applicant shall identify~~ the discharges that were from patients aged 15 years and older SHALL BE IDENTIFIED. These discharges shall be known as the "adult discharges."

(a) To calculate the weights for the principal diagnosis, the following steps shall be taken:

(i) For each diagnostic group in the principal weight table, the ~~number of~~ discharges ~~is counted~~ HAVING A PRIMARY DIAGNOSIS MATCHING ANY DIAGNOSIS IN THE DIAGNOSTIC GROUP ARE IDENTIFIED. THE NUMBER OF DISCHARGES ARE COUNTED.

(ii) For the discharges identified in subsection 8(1)(a)(i), any occurrence of an open heart procedure code will be ~~counted~~ CONSIDERED as a single ~~open heart surgery~~OHS case. FOR EACH DIAGNOSTIC GROUP, THE NUMBER OF OHS CASES ARE COUNTED.

(iii) The number of ~~open heart surgery~~OHS cases for each diagnosis category IDENTIFIED IN SUBSECTION 8(1)(A)(II) will be divided by the number of discharges identified in subsection 8(1)(a)(i). This will be the weight for that diagnostic group. This number should show six decimal positions.

(iv) All discharges utilized for the computation of the principal weight table are to be removed from subsequent analyses.

(b) To calculate the weights for the non-principal diagnosis table, the following steps shall be taken, separately, in the sequence ~~shown,~~ OF THE GROUP ORDER FOUND IN THE NON-PRINCIPAL DIAGNOSIS TABLE:

(I) ~~and e~~Each remaining discharge will be examined for any mention of the diagnostic codes from that group. If a match is found, that discharge is assigned to that diagnostic group and removed from subsequent analyses~~:~~. THE NUMBER OF DISCHARGES IN EACH DIAGNOSTIC GROUP IS COUNTED.

(i) For each diagnostic group taken separately, in the sequence shown, any occurrence of an open heart procedure code for each discharge will be counted as a single ~~open heart surgery~~OHS case. If a match is found, the discharge will be ~~counted~~ CONSIDERED as an open heart surgical case for that diagnostic group and removed from subsequent analyses. THE NUMBER OF OPEN HEART SURGICAL CASES IN EACH DIAGNOSTIC GROUP ARE COUNTED.

(ii) The number of ~~open heart surgery~~OHS cases for each non-principal diagnosis category identified in subsection 8(1)(b)(i) will be divided by the number of discharges identified in subsection 8(1)(b)(I). This will result in the non-principal weight for that diagnostic group. This number should show six decimal positions.

(2) An applicant shall apply the methodology set forth in this section for computing the projected number of adult open heart surgical cases using both the principal and non-principal diagnosis tables. The following steps shall be taken in sequence:

(a) For each diagnostic group in the principal weight table in Appendix A, identify the corresponding number of discharges.

(b) Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of ~~open heart surgery~~OHS cases for that group. All discharges identified in subsection 8(2)(a) are removed from subsequent analysis.

(c) The non-principal weight table identifies the sequence that must be followed to count the discharges for the appropriate group. An applicant shall start with the first diagnostic group and shall count the number of discharges with any mention of a non-principal diagnosis corresponding to that specific diagnostic group. When a discharge that belongs in the specific non-principal diagnostic group is identified, it is assigned to that group. This discharge is then removed from the data before counting discharges for the next diagnostic group. The discharges counted for each group will be used only with the non-principal diagnosis weight table in Appendix A and will be entered into its respective diagnostic group. Multiply the number of discharges for each diagnostic group by their respective group weight to obtain the projected number of ~~open heart surgery~~OHS cases for that group.

(d) The total number of projected open heart cases is then calculated by summing the projected number of open heart cases from both principal and non-principal weight tables.

(3) The major ICD-9-CM groupings and Open Heart utilization weights in Appendix A are based on the work of the Bureau of Health Policy, Planning and Access, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a) The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b) Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c) The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d) The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix A and shall be included as an amended appendix to these standards.

(4) Each applicant shall provide access to verifiable hospital-specific data and documentation using a format established by the Department and a mutually agreed upon media.

Section 9. Methodology for computing the number of pediatric open heart surgical cases

Sec. 9. (1) The weights for the pediatric diagnosis table found in Appendix B are calculated using the following methodology. Only the MIDB data from licensed hospitals THAT HAVE OPERATIONAL OHS PROGRAMS in Michigan will be used.

(a) Using ~~a~~ THE hospital~~'~~s' actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, ~~an applicant shall count~~ the discharges that were from patients of any age that have a diagnosis (any mention) of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Appendix B SHALL BE COUNTED. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from subsequent analyses.

(b) For those discharges identified in subsection 9(1)(a), any occurrence of an open heart procedure code will be ~~counted~~ CONSIDERED as a single ~~open heart surgery~~OHS case. THE NUMBER OF OPEN HEART SURGICAL CASES ARE COUNTED.

(c) The number of ~~open heart surgery~~OHS cases for the "Congenital Anomalies" category IDENTIFIED IN SUBSECTION 9(1)(B) will be divided by the number of discharges identified in subsection 9(1)(a). This will be the weight for the "Congenital Anomalies" diagnostic group. This number should show six decimal positions.

(d) Using ~~a~~ THE hospital~~'~~s' remaining inpatient discharges, ~~an applicant shall identify~~ the discharges that were from patients aged 14 years and younger SHALL BE IDENTIFIED. These discharges shall be known as the "pediatric discharges."

(e) Using the "pediatric discharges" identified in ~~subdivision~~ subSECTION 9(1)(d), ~~an applicant shall count~~ the number of discharges that have a diagnosis (any mention) of the ICD-9-CM codes listed in the "All Other Heart Conditions" category in Appendix B SHALL BE COUNTED. Discharge records which do not have one or more of the “All Other Heart Conditions” codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(f) For those discharges identified in subsection 9(1)(e), any occurrence of an open heart procedure code will be ~~counted~~ CONSIDERED as a single ~~open heart surgery~~OHS case. THE NUMBER OF OPEN HEART SURGICAL CASES ARE COUNTED.

(g) The number of ~~open heart surgery~~OHS cases for the "All Other Heart Conditions" category IDENTIFIED IN SUBSECTION 9(1)(F) will be divided by the number of discharges identified in subsection 9(1)(e). This will be the weight for the "All Other Heart Conditions" diagnostic group. This number should show six decimal positions.

(2) An applicant shall apply the methodology set forth in this section for computing the projected number of pediatric open heart surgical cases. In applying discharge data in the methodology, each

applicable inpatient record is used only once. This methodology shall utilize only those inpatient discharges that have one or more of the cardiac diagnoses listed in Appendix B. In applying this methodology, the following steps shall be taken in sequence:

(a) Using a hospital's actual inpatient discharge data, as specified by the most recent MIDB data available to the Department, an applicant shall count the discharges that were from patients of any age that have a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "Congenital Anomalies" category in Appendix B. Each identified record shall be counted only once so that no record is counted twice. An applicant shall remove these cases from the discharge data.

(b) Using a hospital's remaining inpatient discharges, an applicant shall identify the discharges that were from patients aged 14 years and younger. These discharges shall be known as the "pediatric discharges."

(c) Using the "pediatric discharges" identified in Subdivision (b), an applicant shall count the number of discharges with a principal diagnosis or any of the first four non-principal diagnoses of the ICD-9-CM codes listed in the "All Other Heart Conditions" category in Appendix B. Discharge records which do not have one or more of the “All Other Heart Conditions” codes listed in Appendix B shall not be used. Each identified record shall be counted only once so that no record is counted twice.

(d) An applicant shall multiply the count for the "Congenital" and "All Other Heart Conditions" categories by the corresponding Pediatric Open Heart Utilization Weight and add the products together to produce the number of pediatric open heart surgical cases for the applicant.

(3) The major ICD-9-CM groupings and Pediatric Open Heart Utilization Weights in Appendix B are based on the work of the Bureau of Health Policy, Planning and Access, Michigan Department of Community Health, utilizing the most current MIDB data available to the Department.

(a) The Department shall update the open heart utilization weights every 3 years, beginning with the year 2007, according to the methodology described in subsection (1) above, utilizing the most current MIDB data available to the Department.

(b) Updates to the utilization weights made pursuant to this subsection shall not require standard advisory committee action, a public hearing, or submittal of the standard to the legislature and governor in order to become effective.

(c) The Department shall notify the Commission when the updates are made and the effective date of the updated utilization weights.

(d) The updated open heart utilization weights established pursuant to this subsection shall supercede the weights shown in Appendix B and shall be included as an amended appendix to these standards.

(4) Each applicant must provide access to verifiable hospital-specific data and documentation using a format established by the Department and in a mutually agreed upon media.

Section 10. Planning Areas

Sec. 10. Counties assigned to each planning area are as follows:

PLANNING AREA		COUNTIES	
1	LIVINGSTON	MONROE	ST. CLAIR
	MACOMB	OAKLAND	WASHTENAW
	WAYNE		
2	CLINTON	HILLSDALE	JACKSON
	EATON	INGHAM	LENAWEE
3	BARRY	CALHOUN	ST. JOSEPH

	BERRIEN	CASS	VAN BUREN
	BRANCH	KALAMAZOO	
4	ALLEGAN	MASON	NEWAYGO
	IONIA	MECOSTA	OCEANA
	KENT	MONTCALM	OSCEOLA
	LAKE	MUSKEGON	OTTAWA
5	GENESEE	LAPEER	SHIAWASSEE
6	ARENAC	HURON	ROSCOMMON
	BAY	IOSCO	SAGINAW
	CLARE	ISABELLA	SANILAC
	GLADWIN	MIDLAND	TUSCOLA
	GRATIOT	OGEMAW	
7	ALCONA	CRAWFORD	MISSAUKEE
	ALPENA	EMMET	MONTMORENCY
	ANTRIM	GD TRAVERSE	OSCODA
	BENZIE	KALKASKA	OTSEGO
	CHARLEVOIX	LEELANAU	PRESQUE ISLE
	CHEBOYGAN	MANISTEE	WEXFORD
8	ALGER	GOGEBIC	MACKINAC
	BARAGA	HOUGHTON	MARQUETTE
	CHIPPEWA	IRON	MENOMINEE
	DELTA	KEWEENAW	ONTONAGON
	DICKINSON	LUCE	SCHOOLCRAFT

Section 11. Effect on prior planning policies; comparative reviews

Sec. 11. (1) These CON Review Standards supersede and replace the CON Review Standards for ~~Open Heart Surgery~~OHS Services approved by the CON Commission on ~~March 9, 2004~~DECEMBER 11, 2007 and effective on ~~June 4, 2004~~FEBRUARY 25, 2008.

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

Appendix A

DIAGNOSIS GROUPINGS FOR ADULT OPEN HEART SURGICAL CASES
PRINCIPAL DIAGNOSIS

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.~~755521~~730737
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.~~474638~~641457
C	745 – 747.99	Congenital Anomalies	.~~304878~~362101
D	414 – 414.99	Other Chronic Ischemic	.~~175495~~224163
E	410 – 410.99	Acute Myocardial Infarct	.~~119218~~101479
F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.~~013789~~013366

NON-PRINCIPAL DIAGNOSES

GROUP	MAJOR ICD-9-CM CODE GROUP	CATEGORY	ADULT OPEN HEART UTILIZATION WEIGHTS
A	745 – 747.99	Congenital Anomalies	.~~021698~~016876
B	441.01, 441.03 441.1, 441.2 441.6, 441.7	Aortic Aneurysm	.~~020900~~030120
C	410 – 410.99	Acute Myocardial Infarct	.~~014470~~012099
D	394 – 397.9 421 – 421.9 424 – 424.99	Valves	.~~008064~~007648
E	414 – 414.99	Other Chronic Ischemic	.~~001879~~001466

F	212.7 398 – 398.99 411 – 411.99 423 – 423.9 425 – 425.9 427 – 427.9 428 – 428.9 901 – 901.9 996.02, 996.03	All Other Heart Conditions	.~~001190~~001206

Source: Calculated based on the 20~~05~~10 Michigan Inpatient Data Base

Appendix B

DIAGNOSIS GROUPINGS FOR PEDIATRIC OPEN HEART SURGICAL CASES

MAJOR ICD-9-CM CODE GROUP	CATEGORY	PEDIATRIC OPEN HEART UTILIZATION WEIGHTS
745.0 – 747.99	Congenital Anomalies	.~~174027~~234512
164.1, 212.7 390 – 429.99 441.01, 441.03 441.1, 441.2 441.6, 441.7 785.51 786.5-786.59 901.0 – 901.9 996.02	All Other Heart Conditions	.~~018182~~018991

Source: Calculated based on the 20~~05~~10 Michigan Inpatient Data Base

TRINITY HEALTH
Livonia, Michigan

20555 VICTOR PARKWAY | LIVONIA, MI 48152 | p 734-343-1000 | trinity-health.org

March 19, 2013

Chairman Falahee & Commission
Capital View Building
7th Floor
201 Townsend
Lansing, MI 48913

Dear Chairman Falahee:

On March 7, 2013, thirty individuals attended the NICU Workgroup Meeting in Lansing, led by Commissioner Landstrom. The group received a presentation from the Perinatal Regionalization work within the State of Michigan, which concluded with a May 2012 report. The group reached consensus that a need exists to make recommendations to the CON Commission concerning defining Level 2 Special Care Nursery.

At the April meeting, the workgroup will pursue the specifics of the new national standards for Level 2 care from the American Association of Pediatrics and explore options for adding this definitional work to the CON Standards. While possible, it is not anticipated that a recommendation will be ready by the end of the May meeting.

Respectfully submitted,

Gay L. Landstrom, RN
CON Commissioner

CERTIFICATE OF NEED

1st Quarter Compliance Report to the CON Commission

October 1, 2012 through September 30, 2013 (FY 2013)

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	1st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	78	78
Approved projects contacted on or before anniversary date	56	56
Approved projects completed on or before 1-year follow up	72%	72%
CON approvals expired	17	17
Total follow up correspondence sent	218	218
Total approved projects still ongoing	337	

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 is in the process of determining compliance remedies, drafting compliance orders, and arranging meetings with these providers to resolve these investigations.

- 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 is in the process of determining compliance remedies, drafting compliance orders, and arranging meetings with these providers to resolve these investigations.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED

1st Quarter Program Activity Report to the CON Commission

October 1, 2012 through September 30, 2013 (FY 2013)

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	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	92	N/A	92	N/A
Letters of Intent Processed within 15 days	92	100%	92	100%
Letters of Intent Processed Online	92	100%	92	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	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	81	N/A	81	N/A
Applications Processed within 15 Days	81	100%	81	100%
Applications Incomplete/More Information Needed	53	65%	53	65%
Applications Filed Online*	66	100%	66	100%
Application Fees Received Online*	13	20%	13	20%

* 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	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	42	100%	42	100%
Substantive Applications	34	100%	34	100%
Comparative Applications	6	100%	6	100%

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

Measures – continued

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

Activity	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	1	N/A	1	N/A
Decisions Issued within 10 workings Days	1	100%	1	100%

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

Activity	1st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	19	100%	19	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	1st Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	1st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	50	N/A	50	N/A
FOIA Requests Processed on Time	50	100%	50	100%
Number of Applications Viewed Onsite	1	N/A	1	N/A

FOIA – Freedom of Information Act.

Source: Certificate of Need Evaluation Section, Michigan Department of Community Health.

CERTIFICATE OF NEED LEGAL ACTION

(3.28.13)

Case Name	Date Opened	Case Description	Status
Beaumont Hospital v DCH – Oakland County Circuit Court No. 12-125141-CZ	2/28/12	Beaumont filed a five count complaint for declaratory judgment, injunctive and other relief. The counts allege, among other things, APA violations, a due process violation and promissory estoppel. Beaumont seeks an order declaring that its CON to construct a proton beam megavoltage radiation center remains in full force and effect, enjoining MDCH from terminating or otherwise revoking the CON, costs and attorneys' fees.	On January 22, 2013 after the pre-hearing conference, the Administrative Law Judge issued an Order dismissing the administrative case based on lack of jurisdiction, i.e. no hearing authorized for expiration of a CON. William Beaumont has indicated that they will again seek legal remedies to attempt to restore the CON in circuit court, but to date they have not filed.
Case Name	Date Opened	Case Description	Status
Macomb County – Compare Group #95-0225 Includes: *St. Mary's Nursing & RC– CON App # 11-0314* *Lakeside Manor Nursing & RC– CON App # 11-0306* *Shelby Twp Care Center – CON App # 11-0312*	4/25/12	Macomb County – Comparative Review of nursing home beds – Administrative Appeal The three applicants are: (1) St. Mary's Nursing & RC (approved applicant); (2) Lakeside Manor Nursing & RC (denied applicant); (3) Shelby Twp Care Center (denied applicant).	The parties stipulated to resolve the appeals and remand the matters to the Department for entry of amended decisions. This case is ended and we will be closing our file.

CERTIFICATE OF NEED LEGAL ACTION

(3.28.13)

Case Name	Date Opened	Case Description	Status
McLaren Oakland – CON App # 12-0025	08/29/12	McLaren Oakland requested a hearing on the Department's proposed decision disapproving its proposed project to relocate existing nursing home beds. This applicant proposed to relocate existing beds to another location within the same sub-area that has not yet been constructed.	The parties filed cross motions for Summary Disposition. A hearing on the motions was held on 2/25/13.
Case Name	Date Opened	Case Description	Status
McLaren Oakland-Clarkston – CON App #12-0024	08/29/12	McLaren Oakland-Clarkson requested a hearing on the Department's proposed decision disapproving its proposed project to relocate existing nursing home beds to a new site. This applicant proposed to construct a new facility to be licensed as a hospital and add new (relocated) hospital beds.	The parties filed cross motions for Summary Disposition. A hearing on the motions was held on 2/25/13.
Case Name	Date Opened	Case Description	Status
Livingston County Circuit Court *Livingston – Compare Group #95-0214* Includes: *Medilodge of Livingston – CON App # 11-0044* *Livingston Care Center – CON App # 11-0021*	09/14/12	Appeal of the MDCH Director's final decision.	Venue was transferred from Macomb County to Livingston County. The matter has been briefed and we are waiting for the Court to set a date for oral argument.

CERTIFICATE OF NEED LEGAL ACTION

(3.28.13)

Case Name	Date Opened	Case Description	Status
St. Clair County Circuit Court *St. Clair – Compare Group* *#95-0217* Includes: *Medilodge of St. Clair – CON App # 11-0032* *Regency on Lk- Ft. Gratiot – CON App # 11-0034*	09/14/12	Appeal of the MDCH Director's final decision.	The parties will be filing briefs.
Case Name	**Date Opened**	**Case Description**	**Status**
Macomb County Circuit Court *Oakland – Compare Group* *#95-0217* Includes: *Medilodge of Oxford – CON App # 11-0045* *Medilodge of Clarkston – CON App # 11-0043* *Medilodge of Square Lk – CON App # 11-0041* *Regency on the Lk – CON App # 11-0033* *Manor of Farm. Hills – CON App # 11-0024* *Bloomfield Orchard – CON App # 11-0028* *Sen. Com. Of Auburn Hills – CON App # 11-0023* *Sen. Com. Of Prov. Pk. – CON App # 11-0022*	08/10/12	Appeal of the MDCH Director's final decision.	The Court held oral argument on 1/28/13. After the argument, Medilodge filed a motion for reversal or remand arguing that the new Oakland County bed need report constituted a change in law. The parties argued that motion on 3/11/13 On 3/12/13, the Court entered an order affirming the Department's decision and dismissing the appeal.

CERTIFICATE OF NEED LEGAL ACTION

(3.28.13)

Case Name	Date Opened	Case Description	Status
Oakland County – *Regency at Independence Township – CON App # 12-0030*	8/16/12	Oakland County – Denial of application seeking nursing home beds – Administrative Appeal	Status conference held on 2/12/13. Parties are waiting to see if other Oakland County matters are resolved to determine if this one can be resolved. Next status conference is 4/9/13.
Case Name	Date Opened	Case Description	Status
Oakland County – Compare Group #95-0227 Includes: *Oakland Health Campus– CON App # 12-0145* *Bloomfield Orchard Villa – CON App # 12-0116*	1/15/13	Oakland County – Comparative Review of nursing home beds – Administrative Appeal Both applications were denied.	Pre-hearing/status conference scheduled for 2/28/13.
Case Name	Date Opened	Case Description	Status
Macomb County – Compare Group #95-0226 Includes: *St. Mary's Acquisition Co.– CON App # 12-0144* *Shelby Nursing Center – CON App # 12-0119*	1/15/13	Macomb County – Comparative Review of nursing home beds – Administrative Appeal Both applications were denied.	The parties stipulated to resolve the appeals and remand the matters to the Department for entry of amended decisions. This case is ended and we will be closing our file.

CERTIFICATE OF NEED LEGAL ACTION

(3.28.13)

Case Name	Date Opened	Case Description	Status
Mercy Memorial Nursing Center - CON App # 12-0307	3/11/13	Monroe County – Denial of application seeking nursing home beds – Administrative Appeal	The appeal was recently filed. Nothing has been scheduled.

CON Legal Action; report 3.28.12

Via email

February 26, 2013

c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for your continued dedication to proffering those decisions that ensure access to affordable, quality health care for residents of this great state of Michigan. I hereby submit this letter as formal testimony on behalf of my mother, who is unable to represent herself, but would if she could. My mother is a member of the public you serve, a Michigan resident now receiving Medicare and healthcare benefits under the Michigan Public School Retiree Plan. Though I understand this public testimony is a tad late, it is intended for your sincere consideration during this time while you consider 2013 Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

As one who understands the subject matter of UESWL and your CON review standards implicitly, I strongly support and urge continued regulation of lithotripsy services. In addition, I strongly urge you to carefully discern the most critically important facts and numbers before you prior to taking specific actions affecting performance standards of UESWL service, access to it, and the fair and reasonable cost to real people affected by your decisions. On behalf of my mother, and others who have no active, informed voice in this process, I strongly support several very distinct changes to be made in the standards for UESWL that may require a workgroup or Standards Advisory Committee (SAC) to be established.

Background

It is no secret that the main driver of our national deficits is healthcare. We are staring into the eyes of a monster borne of very near demands on our healthcare system posed by the aging baby boomers and by healthcare reform. The prices paid for healthcare services are too often wildly distorted in a system that bears no resemblance whatsoever to a "free market" system. When a patient/purchaser has no means for knowing what it will cost in advance to receive the care they need, nor the medical knowledge necessary to discern that which is appropriate, mostly during stressful times when sick and vulnerable they must instead trust that others will make these fair and just decisions in their best interest. No "free market" argument is ever remotely accurate in the describing our healthcare circumstance. Michigan CON charter is to protect the public against

unfair, unreasonable, and fraudulent practices in covered services by monitoring cost, quality, and access.

Following a mob-style coup in 2004 by Michigan urologists aided first by the large Chicago Syndicate, and then in 2005 by Spectrum Health and William Beaumont Hospital collaborating with the large Ohio Syndicate, two subsidiaries of large out-state syndicates were formed in Michigan and became the exclusive providers of lithotripsy service in the Lower Peninsula. These subsidiary syndicates are known as *Greater Michigan Lithotripsy* and *Great Lakes Lithotripsy*.

Information is widely available from all the CON Department documents from 2005–2010, reflecting numerous changes throughout the state as a result of this takeover of lithotripsy by the syndicates.

With the hostile takeover, these syndicates and their urologists conspired to gain the power necessary to substantially raise prices for mobile lithotripsy service in Michigan across the board. Their intimidating scheme permitted syndicators and urologists the ability to extract for themselves most fees paid to the facilities by insurance companies, the government, and patients for lithotripsy service. It only requires plain arithmetic to understand what happened. Since they became syndicated, it is easy to conservatively estimate that a couple hundred urologists in Michigan alone have by now extracted at least $50,000,000 in "profit" (derived of payments from patients intended for facilities) for themselves by performing lithotripsy in Michigan <u>in addition</u> to what they already receive in normal professional fees paid to them for performing lithotripsy. This does not even reflect the additional millions paid as well to the Outfit bosses. This profit model was derived via base intimidation.

For lithotripsy service, under CPT billing code 50590, insurance companies, the government, and patients pay Michigan CON-approved facilities money that has been calculated to be fair and reasonable for covering facilities' costs to provide: the lithotripter and technologist, operating room, recovery room, staff, lights, heat, overhead, billing services, insurance, brick and mortar, etc. It, again, merely requires simple arithmetic. When receiving an invoice for lithotripsy service from a facility, it is appropriate for a patient to believe that his payment will be used to cover costs in a transparent, fair, and reasonable manner for the services received. Patient invoices for lithotripsy services, however, do not provide the actual hidden detail when instead a facility turns over highly inflated payments to syndicates for the lithotripter and technologist. These highly inflated payments cause facilities instead to lose money unnecessarily on the transaction, in spite of what the patient is led to believe, which in turn requires a facility to either find money "elsewhere" to cover their own overhead costs for the service, or ultimately demand more money in turn from those who pay them. They rob "Peter" to pay the Outfit. The public deserves transparency in this insidious scheme, and to be respected with honest answers about why this scheme has been wrought upon them, especially in light of being a covered service under Michigan CON

guidelines for cost, quality, and access. Because of the Outfit's act so far of siphoning the $50+ million in Michigan and $$Billions nationally, people like my mother and all those other victims affected by the lithotripsy syndicates must endure cuts in healthcare coverage, loss of coverage, increases in contributions for coverage, loss of pension programs, etc., and even worse, just so that the intimidating Outfit can get paid.

Cost

In the 2007 standards review period for UESWL service, I provided testimony to the Commission that, upon performing simple math, demonstrated the cost per case to provide mobile lithotripsy service with a lithotripter and technologist is $385.00, or an annual cost of $385,000 given a standard performance of 1000 cases/single lithotripsy unit. In the 2010 standards review period for UESWL, Mr. Jorgen Madsen provided these documents once again to the Commission, and stated that the costs for providing UESWL service had not changed since 2007. I can find no reason why these costs have had any legitimate reason to increase in the last three years.

The following table represents the simple math: Current charges for lithotripsy service by the Outfit in Michigan run anywhere from $1500.00 to more than $2300.00 per procedure according to Department documents. Current global facility payments for UESWL by insurance companies and the government aren't much more than this, and if they are, they should be questioned as suspect. It is quite simple to discern profitability, and what should be considered fair and reasonable for Michigan healthcare consumers.

Charge/patient	Patients/day	Patients/year	Total/year	% Net Profit
$ 385.00	4	1000	$ 385,000	Even
$ 385.00	5	1250	$ 481,250	25%
$ 385.00	6	1500	$ 577,500	50%
$ 500.00	4	1000	$ 500,000	30%
$ 500.00	5	1250	$ 625,000	62%
$ 500.00	6	1500	$ 750,000	95%
$2400.00	4	1000	$2,400,000	523%
$2400.00	5	1250	$3,000,000	680%
$2400.00	6	1500	$3,600,000	835%

This is not complicated. It is important to note that a single unit lithotripsy service need only treat four patients each day, five days per week for fifty weeks per year in order to comply with Michigan CON performance standards of 1000 cases. A single procedure takes roughly 45 minutes. Profit increases with efficiency. It is absurd to believe as some do, that cutting those performance standards in half, basically treating only two patients per day, somehow meets CON governance standards for cost, quality, and access. It is easy to see, however, where this is coming from. I strongly urge the Commission to adopt new CON cost standards which serve the people of Michigan by capping the maximum per patient payment made to lithotripsy services at $500.00. A 95% profit by

providing efficient service is more than a fair and reasonable reward in today's desperate climate for healthcare consumers.

The game is clearly rigged where it shouldn't be, and permits the Outfit to skim their take from what everyone can easily discern to be otherwise fair and reasonable payment for covering facilities' costs for lithotripsy. For the inflated $2400 fee, does a facility receive a higher quality mobile service? No. For the inflated fee does some sort of improved quality of service guarantee a lower retreatment rate or a higher success rate? No, and probably the inverse. Does mob syndication provide the patient with a quality standard that improves outcome? No. Does the syndicated urologist have the same patient care responsibility were he not syndicated? Yes. The only difference between a fee of $385.00 and a fee of $2400.00 for mobile lithotripsy is that tens of millions of Michigan dollars in ransom is paid to the Outfit, whom in turn with their tidy take pay off public officials (see FEC Report for Committee ID #C00489419 "AKSM Urology PAC"), and ex-public Department of Justice officials (Thomas E. Zeno, esq.) in order to protect the racket.

Once the Outfit infiltrates the process, there is no means to negotiate fair pricing based on what is known by everyone to be true about cost. Intimidation by the Outfit practically extinguishes performance and often even the legitimate consideration of lower cost alternatives for kidney stone removal, significantly increases the number of patients treated with UESWL (see Michigan CON Activity Reports) in spite of a plummeting Michigan population overall, increases UESWL retreatment rates, and most poignantly silences any statistically significant, actionable research programs that may otherwise address in proper measure the very disturbing known concerns about very real risk for life-altering, harmful adverse effects of UESWL.

Quality

In 1984, UESWL technology sailed through the FDA approval process in a short period of time. Since then, the FDA has required no critical long term follow up reporting about this technology to evaluate safety and efficacy, regardless of deeply grave concerns raised in the medical literature about harmful effects. Adverse events for lithotripsy are only required to be reported to them on a voluntary basis. Simultaneously in 1984, a handful of entrepreneurial American urologists began the process of syndicating their peers, building the Outfit that has become a massive national UESWL enterprise. This was possible by carefully fixing prices for services at highly inflated rates in order to secure a so-called "market value" favorable to the Outfit for paying off urologists, and for eliminating competitors who might come in at legitimate lower price points with better quality service. Since right around that same time, 1984, there has become an exploding epidemic 3,600% increase in the rate of acute kidney failure in the United States, the likes of which we have not seen.

As CON Commissioners you are not practicing medicine, however, as arbiters of cost, quality, and access concerns in Michigan healthcare delivery, I suggest you conduct a

thorough review of the medical literature for kidney disease, UESWL, CDC statistical reports for renal failure, dialysis, etc. This is very important information. There is an urgent need to correlate this information, because there is mind numbing radio silence by urologists, the majority whom are syndicated into the Outfit. The public would otherwise reasonably expect the urology profession to be advocating for real answers about harmful effects by undertaking critical, actionable UESWL research. In fact, not performing this research could legitimately be considered a serious breach of trust and responsibility to patient care. The reason this research is not happening could arguably be due to the massive, controlling multibillion dollar Outfit's interest for protecting their perversely conflicted financial enterprise.

With the Outfit so astutely adept over thirty years at organizing to inflate consumer prices in a closed market, syndicating the majority of urologists in this country, and showing clear and compelling capacity to administrate a crooked financial product for themselves, surely they could organize their time, power, intellect, and energies for the sake of "doing no harm." This would be nice. But it won't happen unless the public makes it happen.

There are very troubling concerns about both the short- and long-term adverse effects of UESWL treatments causing renal and other trauma, life-altering ill effects such as hypertension, diabetes, renal failure, pancreatic failure, cardiac arrhythmias, and yes, death. Death, yes, here in Michigan, caused by UESWL. But there are no studies large enough in the medical literature to warrant actions for limiting UESWL performance in response to what are highly measurable, but instead are carefully concealed, life-threatening risks.

The very distinct smoke signals about renal failure and the adverse effects of UESWL from the few brave academic urologists in the medical literature must be taken very seriously. But their studies are just never large enough to cause actions within the Outfit for altering UESWL practices. These dangerously unexamined risks are not conveyed appropriately to patients. For instance, a review of the literature showed a long-term reduction of function in the individual human kidney after SWL in some cases of a solitary kidney and in some cases with an untreated contralateral kidney. "Because there is no evidence that an untreated contralateral kidney aids the long-term recovery of the function of a treated kidney in all cases, simultaneous or separate bilateral renal SWL would not influence this long-term reduction in renal function, which was felt to occur with multiple renal stones and repeat SWL." (J Endourol 1994. Dec 8(6): 395-9.) Wow. Then, "This acute SW damage can be severe, can lead to scarring with a permanent loss of functional renal volume, and has been linked to potentially serious long-term adverse effects. A recent retrospective study linking lithotripsy to the development of diabetes mellitus has further focused attention on the possibility that SWL may lead to life-altering chronic effects. Thus, it appears that what was once considered to be an entirely safe means to eliminate renal stones can elicit potentially severe unintended consequences." (Semin Nephrol. 2008 Mar; 28(2):200-13)

Following UESWL, blood levels for BUN and Creatinine are tested. However, neither of these tests explains anything of damage that may have been done to the treated kidney, so therefore are false representations for the "safety" of UESWL. It is widely known that the untreated kidney will produce normal blood levels of BUN and Creatinine when the contralateral kidney is absent or non-functioning. This is a deeply flawed representation of "safety." The actual damage caused to the treated kidney is not adequately evaluated, and therefore neither is any longer term adverse effect of the trauma on renal function.

One said in conclusion, "SWL results in a clinically significant long-term reduction in renal function."(J Endourol. 1994 Feb; 8(1); 15-9.) Another, "the safe limits of extracorporeal shock wave lithotripsy in humans have yet to be established. Further study regarding this issue and the potential long-term adverse effects of extracorporeal shock wave lithotripsy is needed urgently."(J Urol. 1989 Mar;141(3 Pt 2):793-7). And yet another, "Both clinical and experimental reports clearly show that shock wave lithotripsy (SWL) causes acute renal effects in a majority, if not all, treated kidneys." And another, "At 19 years of follow up, SWL for renal and proximal ureteral stones was associated with the development of hypertension and diabetes mellitus. The incidence of these conditions was significantly higher than in a cohort of conservatively treated patients with nephrolithiasis." (J Urol. 2006. May; 175(5): 1742-7). But nothing actionable is being published or being done. Diabetes mellitus and hypertension cause renal failure, notwithstanding the pure traumatic events posed by UESWL.

When the study was published by the Mayo Clinic in 2006, the American Urological Association requested a response from within, and published a whitepaper:

http://www.auanet.org/content/media/whitepaper.pdf

This whitepaper was basically a wasted review of the medical literature, because the AUA already knows there is nothing actionable in the literature. It can be argued that actionable research is missing on purpose. Please note the physician (business) disclosures in this official whitepaper.

The cost of renal failure in life and in treasure is staggering in this country, and in Michigan.

It is not rocket science to consider that when there is clear evidence and awareness for a procedure causing the kind of trauma that may necessitate nephrectomy, splenectomy, or cause massive hemorrhage, renal failure, and/or death, our concern should be heightened about what this procedure is really doing to people in the long term. It is a traumatic procedure. Anecdotes are not enough. It is no big secret that money has been covering up that the brains of our national gladiators, the NFL, are permanently damaged by concussive effects. Is there really no concern for taking legitimate action to address renal function after trauma? Apparently there is not.

If a patient has had a kidney stone once, they're at significantly increased risk of having another. If this patient has been treated at first with UESWL and there has been unmeasured harm to the kidney, or other organs for that matter, then what will happen if a kidney stone forms in the patient's contralateral kidney and is then treated again with UESWL? It is important to understand the impact of what are only partially examined effects of lithotripsy trauma on the lives of real people, the other victims who pay the high price for this as well, and what the epidemic of acute renal failure is doing to our country. It is indeed arguable that high cost of UESWL syndicates may be far, far greater than meets the eye at first glance. But we will not get the answers we need to know from the Outfit. Obviously.

When others suggest that UESWL is not "invasive," whereas Ureteroscopy is "invasive," as an argument to double the access to UESWL services, be afraid. There is nothing proven in the medical literature about UESWL being more safe or more effective than Ureteroscopy. In fact, the questions raised in the literature about serious trauma and overall safety of UESWL suggest otherwise. However, badly needed research to address these real concerns has been neglected by urologists over these past 30 syndicated years, arguably on purpose. Why bite the hand that feeds?

I would suggest it is long time to come clean about UESWL. And if the urologists, those very professionals we trust in our society to act honestly and impartially on our own behalves, won't properly or adequately perform the research to fully measure the risk of harm by UESWL, then who will? Who will? Who will be the arbiter, then, of "quality?" Who will care to understand the true cost?

I urge you to conduct your own thorough medical literature and statistical review as I did. You may need to go no further than Michigan's Genessee and Lapeer Counties to see a snapshot of what has been happening.

The neglect by an entire national class of physicians (by no means is this unique to Michigan) to perform the obviously needed UESWL research is not an issue of competence. These are doctors. They were the smartest kids, and medical school was the hardest thing to do. It is an issue of character. They have no problem whatsoever organizing in massive groups of complex syndicates boasting of 2500 urologist members, 2000 urologist members, 1500 urologist members, within an Outfit that spans the entire country in order to drive up the cost of providing lithotripsy service nationwide. But there is a clear, cold, calculated neglect to organize for the purpose of conducting the badly needed research they know is necessary to tell the truth about dangerous risks of UESWL. They have known since at least 1989, and have done practically nothing. Thirty years performing UESWL. What you will find in the medical literature tells the precise story of what you will not find in the medical literature; any actionable research. No studies long-term or large enough in writing to warrant any red flags about their very real concerns. Mind you, there are many concerned urologists. But the vast majority of

them are afraid to speak up. It is practically impossible by now to find any unaffected, unbiased medical leadership on this subject amongst them. The Outfit is too powerful.

Far more than merely capping payments made to mobile lithotripsy service providers, a thorough, impartial, independent review of UESWL will provide you with clearer understanding of what might be known about both the life and treasure involved were UESWL not affected by the Outfit's control over information concerning this traumatic procedure. You simply cannot take the concept of "quality" for granted. I strongly urge you to know the subject matter.

Last year alone, Medicare spent $32,900,000,000 on acute renal failure in the United States. This is an unimaginable annual figure considering these are patients who first suffer in dire misery before facing certain death from their disease. One out of five of these patients die every year from their renal failure. The cost is just staggering. With proper attention, and money spent appropriately, these conditions can more often than not be prevented. Protecting UESWL from well-warranted scrutiny must stop. If the urologists and the Outfit won't be forthright with the answers we need, the public deserves real answers for these failures from our governing authorities. The cost is simply far too high. It is not nothing. There must be impartial, informed oversight for those who are picking winners and losers in life and death circumstances for a very pretty penny.

Were there to be an organized Outfit for every medical procedure, then what? This is not complicated. "Quality" must mean something, and the paying public has a right to be respected and kept clearly informed. It is time for the needle to start moving in the right direction concerning hyper-inflated healthcare costs for no good reason and quality care that can be measured honestly. UESWL must be met with the critical unbiased scrutiny it deserves.

With one hand picking the pockets of Michigan healthcare consumers, the "AKSM Urology PAC" aided by Michigan urologists has used the other hand to feed this money to the likes of Ohio's John Boehner and his "The Freedom Project." My mother, and I would guess many other Michigan residents whose wallets have been emptied, would like an answer to these questions: Who's "Freedom?" And, who's "Freedom" to do what?

Access

Access to UESWL is obviously not a problem in Michigan. One need only examine the CON Activity Reports. Eliminating the costly, inaccessible fixed-based lithotripters solved that problem. Now the question of too much access must be answered. It is time for the paying public to understand in a transparent way who is treated with UESWL, and why they are treated with UESWL instead of lower cost alternatives. The paying public should know answers the urology community refuses to give them about who is harmed by this procedure. I would suggest that a tracking mechanism be adopted for UESWL

similar to that of MRI standards for "Available Adjusted Procedures," which may include a statewide registry. This is a critical problem that must be met with a transparent solution. With increased access, increased responsibility for the facts must be exacted.

Summary

We support and urge capping the charge by lithotripsy service providers to facilities at $500.00/procedure. We support and urge an informed, impartial SAC be formed to address a process for knowing the true cost that UESWL has wrought upon Michigan.

Michigan alone is by far not the "problem" related to what is happening with UESWL syndication in the United States. But, Michigan can be the solution. The choice before you is to reject intimidation by the Outfit in favor of reducing healthcare costs for real people and improving the quality of knowledge we have about a traumatic procedure and its relationship to a deeply catastrophic epidemic of deadly kidney disease. We urge you to find other means to support urologists in legitimate ways to do their good work. We urge you to do the right thing.

Thank you for your service.

Sincerely,

Anne Mitchell
ae_mitchell@comcast.net

Cc: The Public

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

Attachment M

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2012												2013											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Air Ambulance Services										PC	•	•	•R	•	•R									
Bone Marrow Transplantation Services	•R		D	•	•	•	•	•	• R—	•	•P	•▲ F	•	•	•	•	•	•D						
Computed Tomography (CT) Scanner Services										PC	•	•	•R	•	•	•	•	•	•	•	• R—	•	•P	•▲ F
Magnetic Resonance Imaging (MRI) Services	•R	•	•R —S	•S	•PS	•▲ F•S	•S	•	•	•	•	•	•	•	•R —	•	•P	• ▲F						
Megavoltage Radiation Therapy (MRT) Services/Units							•	•	•	•	•	• R—	•	•P	• ▲F									
Neonatal Intensive Care Services/Beds (NICU)										PC	•	•	•R	•	•	•	•	•	•	•	• R—	•	•P	•▲ F
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups										PC	•	•	•R	•	•S	•S	•S	▮	▮	▮	▮	▮	▮	▮
Open Heart Surgery Services	•S	•S	•S	▮	▮	▮	▮	▮	▮	▮	•	•R —	•	•	• R—	•	•P	• ▲F						
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units										PC	•	•	•R	•	•	•	•	•	•	•	• R			
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

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

For Approval March 28, 2013

Updated March 21, 2013

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, Policy & Planning, Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, **www.michigan.gov/con**.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	August 12, 2010	2016
Bone Marrow Transplantation Services	December 3, 2010	2015
Cardiac Catheterization Services	February 27, 2012	2014
Computed Tomography (CT) Scanner Services	February 27, 2012	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2015
Hospital Beds	September 28, 2012	2014
Magnetic Resonance Imaging (MRI) Services	September 28, 2012	2015
Megavoltage Radiation Therapy (MRT) Services/Units	November 21, 2011	2014
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2016
Open Heart Surgery Services	February 25, 2008	2014
Positron Emission Tomography (PET) Scanner Services	September 28, 2012	2014
Psychiatric Beds and Services	November 5, 2009	2015
Surgical Services	February 27, 2012	2014
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	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.

Note: Pancreas Transplantation services are no longer subject to and no longer require CON approval effective September 28, 2012.