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

Wednesday, June 11, 2008

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

APPROVED MINUTES

I. Call To Order

Chairperson Goldman called the meeting to order at 9:15 a.m.

A. Members Present:

Edward B. Goldman, Chairperson
Bradley Cory
Dorothy E. Deremo
Marc Keshishian, MD
Adam Miller
Michael A. Sandler, MD
Vicky Schroeder
Thomas M. Smith
Michael W. Young, DO

B. Members Absent:

Peter Ajluni, DO
Norma Hagenow, Vice-Chairperson

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Tulika Bhattacharya
Sally Flanders
William Hart
Larry Horvath
Joette Laseur
Irma Lopez
Nick Lyon
Andrea Moore
Taleitha Pytlowanyj
Brenda Rogers
Perry Smith
Gaye Tuttle

II. Review of Agenda

Motion by Commissioner Cory, seconded by Commissioner Young, to accept the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest

Chairperson Goldman clarified that he does have a conflict of interest in regards to Megavoltage Radiation Therapy (MRT). He stated that the University of Michigan has submitted a Letter of Intent (LOI), but it had incorrect information that the Department requested them to fix.

IV. Review of Minutes – April 30, 2008

Commissioner Sandler stated under item VI C, the results of the vote should read as follows, "Motion Carried, 10-0, Commissioner Sandler abstained."

Motion by Commissioner Sandler, seconded by Commissioner Deremo, to approve the minutes as amended. Motion Carried.

V. Public Comments for Action Items (i.e. VII & X)

Magnetic Resonance Imaging (MRI) Services – Intraoperative MRI (IMRI)

Sean Gehle, St. John Health
Bob Meeker, Spectrum Health

Bone Marrow Transplantation (BMT) Services

Patrick O'Donovan, William Beaumont
Carol Christner, Karmanos Cancer Institute
Dennis McCafferty, Economic Alliance for Michigan

VI. Public Comment (i.e., general)

Mini Computed Tomography (CT) Scanners

Dennis McCafferty, Economic Alliance for Michigan

Proton Beam Therapy (PBT)

Elizabeth Palazzolo, Henry Ford Health System
Larry Horwitz, Economic Alliance for Michigan (Attachment A)

VII. MRI Services - IMRI

A. Report

Commissioner Sandler stated that he urges the Commission to take action on the proposed language.

B. Review of Language

Ms. Rogers provided a brief overview of the proposed language (Attachment B).

C. Commission Proposed Action

Motion by Commissioner Sandler, seconded by Commissioner Smith, to accept the proposed language and move forward for a public hearing. Motion Carried, 9-0.

VIII. CT Scanner Services – Mini CT Scanners – Status Report

Ms. Rogers stated a discussion group has been formed and has another meeting scheduled for July. She stated the group will have a report to present to the Commission at the next Commission meeting in September.

IX. BMT Services

A. Review of Language

Ms. Rogers provided a brief overview of the technical changes made to the proposed language (Attachment C).

B. Commission Discussion

Commissioner Goldman and Commissioner Sandler recused themselves from discussion and voting.

C. Commission Proposed Action

Motion by Commissioner Keshishian, seconded by Commissioner Sandler, to approve the proposed language and move forward for public hearing. Motion Carried, 6-0 with Chairperson Goldman and Commissioner Sandler abstaining.

X. Megavoltage Radiation Therapy (MRT) Services/Units – PBT Collaborative – Update

Mr. Lyon provided an overview of the MRT-PBT report (Attachment D). Discussion followed.

Motion by Commissioner Cory, seconded by Commissioner Young, to accept the MRT-PBT report. Motion Carried, 6-0 with Chairperson Goldman and Commissioner Sandler abstaining.

XI. Standing New Medical Technology Advisory Committee (NEWTAC) – Report

Commissioner Keshishian stated there is nothing to report at this time.

XII. Legislative Report

Mr. Lyon stated there is nothing to report at this time.

XIII. Compliance Report

Mr. Lyon provided a brief overview of the compliance report (Attachment E).

XIV. Administrative Update

Mr. Hart stated that Ms. Ateequi and Ms. Amarnath are no longer part of the CON Policy staff.

Chairperson Goldman stated his appreciation for their work.

XV. Program Update

A. Quarterly Performance Measures

Chairperson Goldman stated a written report (Attachment F) is provided in the binders.

Break from 10:23 a.m. to 10:35 a.m.

B. Online Application System – Presentation

Mr. Horvath provided an overview of the CON Program presentation (Attachment G). He also provided a brief tutorial of the online system. Discussion followed.

XVI. Legal Activity Report

Mr. Styka provided a brief overview of the legal activity report (Attachment H).

XVII. Future Meeting Dates

September 16, 2008
December 9, 2008

XVIII. Public Comments

Larry Horwitz, Economic Alliance for Michigan

XIX. Work Plan

A. Commission Discussion

Ms. Rogers provided a brief overview of the Work Plan (Attachment I).

B. Commission Action

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to approve the Work Plan. Motion Carried.

XX. Adjournment

Motion by Commissioner Deremo, seconded by Commissioner Keshishian, to adjourn the meeting at 11:21 a.m. Motion Carried.

HERE IS WHAT NATIONALLY-RECOGNIZED EXPERTS IN THE FIELD OF RADIATION ONCOLOGY SAY ABOUT THE MICHIGAN CON APPROACH TO PROTON BEAM THERAPY:

"The development of new technology to advance the treatment of patients with cancer can be of major benefit to the patients and can also provide wider benefits to the community (by having a new and important technology available), for the prestige of the region, and even as an economic stimulus. Some technologies are inexpensive and can be implemented with minimal planning.

Other types of technologies, of which proton radiation therapy is almost the prototype, require a large amount of resources and need careful medical investigation to assure that the technology is being used appropriately and to the overall benefit of the community.

"Having a proton facility built in Michigan that will serve a very wide group of hospitals and individuals, and in which clinical and developmental research can be carried out throughout the broad medical community, would clearly be in the best interest of the people of the state of Michigan. It makes no sense, medically or economically, to not have such a facility widely available as a joint effort. **Competition makes sense in football, but not in areas of medicine where inappropriate facilities can lead to overuse of the technology and increased costs to the state.**"

Joel Tepper, MD, Former President and Chairman of the Board of ASTRO (American Society of Therapeutic Radiology and Oncology), the leading professional association of radiation oncologists in the world; University of North Carolina School of Medicine: Distinguished Professor of Cancer Research, Professor, Radiation Oncology

"Based upon the scientific literature and my own experience using proton beam, I strongly believe that proton therapy offers considerable advantages over more conventional radiation in certain clinical situations where the morbidity of the alternatives is unacceptable. These include tumors of the eye, skull base, primary spinal tumors, and many pediatric malignancies. **These tumors are, however, relatively rare.**

"I do not feel that the same advantage holds for most of the common malignancies. Prostate cancer, the one in which I have the most experience, is managed just as effectively and with comparable morbidity by other forms of external radiation, brachytherapy [radiation seeds], and surgery. Indeed many patients with this disease need no treatment at all. Huge dosimetric uncertainties exist in the treatment of lung cancer and there is little experience and little potential gain in the treatment of breast cancer.

"I therefore believe that, **bearing in mind the cost of proton facilities, a cost that will be passed on to all the insured and to taxpayers, a limited number of proton facilities geographically well spaced and shared between hospitals will offer the best use of this resource.** It also ensures that proton treatment goes to those who will clearly benefit and not to those who will not. As technological medicine seems to obey 'supply-driven demand' rules, an excess of proton capability can only result in proton over-use."

Anthony Zietman MD, Board of Directors, ASTRO (American Society of Therapeutic Radiology and Oncology), the leading professional association of radiation oncologists in the world; Professor, of Radiation Oncology, Harvard Medical School, Massachusetts General Hospital

"I completely support the notion that combined collaborative efforts on Proton Beam Therapy by leading cancer centers would be the most beneficial for the citizens of Michigan. **I am hoping that a 'good government' model like Michigan's can lead the way.** The consortium idea makes perfect sense. I applaud Michigan's Certificate of Need Commission for its leadership."

W. Robert Lee, M.D. Professor, Radiation Oncology, Duke School of Medicine, M.D., M.S., M. Ed.

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. (1) These standards are requirements for the approval of the initiation, expansion, replacement, relocation, or acquisition of MRI services and the delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code that involve magnetic resonance imaging services.

(2) Magnetic resonance imaging is a covered clinical service for purposes of Part 222 of the Code. An MRI unit approved pursuant to Section 9(1) seeking approval to operate pursuant to sections 3, 4, 5, 6, 7, or 8 shall be considered as a person requesting CON approval to initiate, expand, replace, relocate, or acquire a covered clinical service, as applicable.

(3) The Department shall use sections 3, 4, 5, 6, 7, 8, 9, 10, 13, 14, 15, 16, ~~and~~ 17, AND 18 as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(4) The Department shall use Section ~~12~~13, as applicable, 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 11, as applicable, in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

Section 2. Definitions

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

(a) "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," for purposes of sections ~~15~~ 16 and ~~16~~17, means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section ~~13~~14, 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 "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department.

(c) "Available MRI adjusted procedures," for purposes of Section ~~15~~16, 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 complete by the Department.

In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000 multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or

has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures.

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). It shall be a legal entity authorized to do business in the State of Michigan.

(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 magnetic resonance imaging service" or "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 magnetic resonance imaging unit" or "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," for purposes of Section ~~16~~17(3)(b), 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 19.

(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 of an existing fixed MRI service 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," for purposes of Section ~~13~~ 14 of these standards, 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) "IRB" or "institutional review board" 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 a health facility licensed under Part 215 of the Code. In the case of a single site hospital, it is the location of the facility authorized by license and listed on that licensee's certificate of licensure or in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by the licensee's certificate of licensure.

(~~x~~Y) "Magnetic resonance" or "MR" 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.

(~~y~~Z) "Magnetic resonance imaging adjusted procedure" or "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section ~~13~~14.

(~~z~~AA) "Magnetic resonance imaging database" or "MRI database" means the database, maintained by the Department pursuant to Section ~~12~~ 13 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(~~aa~~BB) "Magnetic resonance imaging procedure" or "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, 8 or 10 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 institutional review board. 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 9(1).

(~~bb~~CC) "Magnetic resonance imaging services" or "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.

(~~cc~~DD) "Magnetic resonance imaging unit" or "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.

(~~dd~~EE) "Magnetic resonance imaging visit" or "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI procedures.

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

(~~ff~~GG) "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.

(~~gg~~HH) "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.

(~~hh~~II) "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.

(~~ii~~JJ) "Ownership interest, direct or indirect," for purposes of these standards, 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.

(~~jj~~KK) "Pediatric patient," for purposes of these standards, except for Section 10, means a patient who is 12 years of age or less.

(~~kk~~LL) "Planning area," for purposes of these standards, 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. For purposes of Section 7(3) of these standards, the planning area shall be measured from the original site at which the MRI service was first initiated.

(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 ~~13~~14(2)(d), the health service area in which all the proposed mobile host sites will be located.

(~~ll~~MM) "Referring doctor," for purposes of these standards, 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.

(~~mm~~NN) "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.

(~~nn~~OO) "Relocation zone," for purposes of these standards, means the geographic area that is within a 10-mile radius of the existing site of the MRI service or unit to be relocated.

(~~oo~~PP) "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)(pp)(i), or (ii) a change in the parties to the lease.

(~~pp~~QQ) "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)(a)-(e), as applicable, have been met.

(~~qq~~RR) “Research scan” means an MRI scan administered under a research protocol approved by the applicant’s institutional review board.

(~~rr~~SS) “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.

(~~ss~~TT) "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.

(~~tt~~UU) "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).

(~~uu~~VV) "Site," for purposes of these standards, 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.

(~~vv~~WW) “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.

(~~ww~~XX) "Teaching facility," for purposes of these standards, 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.

(~~xx~~YY) "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 ~~13~~14.

(~~yy~~ZZ) "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 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 for approval of applicants proposing to initiate an MRI service or mobile MRI host site

Sec. 3. (1) An applicant proposing to initiate a fixed MRI service shall demonstrate that 6,000 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section ~~15~~ 16 of these standards.

(2)(a) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a mobile MRI unit shall demonstrate that a minimum of 5,500 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, per proposed unit result from application of the methodology in Section ~~15~~ 16 of these standards.

(b) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section ~~15~~ 16 of these standards, for each proposed host site that

(i) is not located in a rural or micropolitan statistical area county and

(ii) 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.

(c) The applicant, whether the central service coordinator or the host site, must demonstrate that a minimum of 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section ~~15~~ 16 of these standards for each proposed host site that

(i) is located in a rural or micropolitan statistical area county and

(ii) 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.

(3)(a) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site not in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 600 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section ~~15~~ 16 of these standards for that host site.

(b) An applicant, whether the central service coordinator or a proposed host site, proposing to initiate a mobile MRI host site in a rural or micropolitan statistical area county, that is to be part of an existing mobile MRI service, must demonstrate that at least 400 available MRI adjusted procedures, from within the same planning area as the proposed service/unit, result from the application of the methodology in Section ~~15~~ 16 of these standards for that host site.

(4) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1):

(a) The applicant is proposing to initiate a fixed MRI service.

(b) The applicant is currently a host site being served by one or more mobile MRI units.

(c) The applicant has received, in aggregate, the following:

(i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available or

(ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, 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;

(C) the applicant is a nonprofit licensed hospital site;

(D) the applicant certifies in its CON application, by providing a governing body resolution, that the board of trustees of the facility has performed a due diligence investigation and has determined that the fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access within the community hospital setting.

(d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent 12-month period, referenced in (c) above, by each mobile MRI service/units from which any of the MRI adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000 adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from network 18 do not need to be used to meet the 6,000 minimum.]

(e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site or at the applicant's licensed hospital site as defined in these standards.

(5) Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides each of the following, as applicable:

(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) The addition of a host site to a mobile MRI unit will not increase the number of MRI units operated by the central service coordinator or by any other person.

(c) Notification to the Department of the addition of a host site prior to the provision of MRI services by that mobile MRI unit in accordance with (d).

(d) A signed certification, on a form provided by the Department, whereby each host site for each mobile MRI unit has agreed and assured that it will provide MRI services in accordance with the terms for approval set forth in Section ~~12~~ 13 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, that are served by the mobile route as of the date of the signed certification or are committed in writing to be served by the mobile route.

(e) The central service coordinator requires, as a condition of any contract with a host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

Section 4. Requirements for approval of an application proposing to expand an existing MRI service

Sec. 4. (1) An applicant proposing to expand an existing fixed MRI service shall demonstrate that its existing fixed MRI units (excluding MRI units approved pursuant to Section 10) have performed at least an average of 11,000 adjusted procedures for each fixed unit based on the application of the methodology in Section ~~13~~ 14 and as documented in accordance with Section ~~14~~ 15 of these standards.

(a) The additional unit shall be located at the same site unless the requirements of Section 7(2) have been met.

(2) An applicant proposing to expand an existing fixed MRI service approved pursuant to Section 10 shall demonstrate that its existing fixed MRI units have performed at least an average of 3,500 adjusted procedures for each fixed unit, based on the application of the methodology in Section ~~13~~ 14 and as documented in accordance with Section ~~14~~ 15 of these standards.

(a) The additional unit shall be located at the same site unless the requirements of Section 7(2) have been met.

(3) An applicant proposing to expand an existing mobile MRI service shall demonstrate that 4,000 available MRI adjusted procedures, from within the same planning area as the proposed unit, per proposed additional unit result from application of the methodology in Section ~~15~~ 16 of these standards.

(4) An applicant proposing to expand an existing mobile MRI service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 6(2).

Section 5. Requirements for approval of an applicant proposing to replace an existing MRI unit

Sec. 5. An applicant proposing to replace an existing MRI unit shall demonstrate that the proposed project meets each of the following requirements:

(1) Within the most recent 12-month period for which data, verifiable by the Department, are available, at least the applicable minimum number of MRI adjusted procedures set forth in subdivision (a), (b), or (c) has been performed. In meeting this requirement, an applicant shall not include any procedures conducted by an MRI unit approved pursuant to Section 9(1).

(a) Each existing mobile MRI unit on the network has performed in excess of an average of 5,500 MRI adjusted procedures per MRI unit.

(b) Each existing fixed MRI unit at the current site has performed in excess of an average of 6,000 MRI adjusted procedures per MRI unit.

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

(2) 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.

(3) 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.

(4) An applicant proposing to replace an existing mobile MRI unit must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 6(2).

(5) The replacement unit shall be located at the same site unless the requirements of Section 7(2) have been met.

Section 6. Additional requirements for approval of an applicant proposing to initiate a mobile MRI service

Sec. 6. (1) An applicant proposing to initiate a mobile MRI service that involves beginning operation of a mobile MRI unit shall identify the proposed regular route schedule and the procedures for handling emergency situations.

(2) An applicant proposing a mobile MRI service shall submit copies of all proposed contracts related to the mobile MRI service in the CON application submitted by the central service coordinator. The contract shall include at least the following:

(a) A signed certification, on a form provided by the Department, whereby each host site has agreed and assured that it will provide MRI services for each mobile MRI unit in accordance with the terms of approval set forth in Section ~~12~~ 13 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, as of the date of the signed certification.

(b) A statement that requires compliance with the requirements of these standards by that host site and assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

(c) A signed agreement between the central service coordinator and the host site(s) that states that for any host site applying, at any time in the future, for a fixed MRI unit under Section 3(4), that the mobile services at the host site will not cease until the fixed unit is in operation or upon the request of the host site. Further, the applicant applying for the fixed MRI unit must stipulate in the application at the time it is submitted to the Department that it has notified all affected host sites as well as the central service coordinator at least six months prior to beginning operation of the fixed MRI unit.

Section 7. Requirements for approval of an applicant proposing to relocate an existing MRI service and/or MRI unit(s)

Sec 7. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall demonstrate that the proposed project meets all of 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 of the existing MRI service and its unit(s) to be relocated is in the relocation zone.

(c) The proposed project will not result in the replacement of the existing MRI unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(d) The proposed project will not result in an increase of the number of MRI units operated by the existing MRI service at the proposed site unless the applicant demonstrates that the requirements of Section 4, as applicable, have been met.

(e) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section ~~12~~13(1)(d)(i) of these standards based on the most recent 12-month period for which the Department has verifiable data.

(f) The applicant agrees to operate the MRI service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~12~~ 13 of these standards.

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

(a) 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.

(b) The proposed new site for the MRI unit(s) to be relocated is in the relocation zone.

(c) The proposed project will not result in the replacement of the MRI unit(s) to be relocated unless the applicant demonstrates that the requirements of Section 5, as applicable, have been met.

(d) The proposed project will not result in an increase of the number of MRI units operated by an existing MRI service at the proposed site unless the applicant demonstrates that the requirements of Section 4, as applicable, have been met.

(e) 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 ~~12~~13(1)(d)(i) of these standards based on the most recent 12-month period for which the Department has verifiable data.

(f) The applicant agrees to operate the MRI unit(s) at the proposed site in accordance with all applicable project delivery requirements set forth in Section ~~12~~ 13 of these standards.

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

(3) An applicant that meets all of the following requirements shall be exempt from relocating within the relocation zone:

(a) The licensed hospital site to which the MRI service is to be relocated and the MRI service at the site from which the MRI service is to be relocated are owned by the same person as defined in Section 1106 of this public act or the same governmental entity.

(b) The licensed hospital site to which the MRI service is to be relocated is located within the planning area.

(c) As evidenced in the governing body resolution required in (e), the MRI service to be relocated shall cease at its current location within 24 months after the date the application receives a final decision of approval from the Department or upon the date the service becomes operational at the relocation site, whichever occurs first.

(d) The MRI service shall be relocated and shall be operational within 24 months after the date the application receives a final decision of approval from the Department or the CON to relocate the MRI service shall expire.

(e) The CON application includes a resolution of the applicant's governing body that commits to the provisions of (c) and (d).

(f) The relocation of the MRI service shall not result in the licensed hospital site having more than one fixed MRI unit.

Section 8. Requirements for approval of an applicant proposing to acquire an existing MRI service or an existing MRI unit(s)

(1) An applicant proposing to acquire an existing fixed or mobile MRI service and its unit(s) 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 unless the applicant demonstrates that the project is in compliance with the requirements of Section 3 or 4, 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 Section 5 have been met.

(c) The applicant agrees to operate the MRI service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~12~~ 13 of these standards.

(d) 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 ~~12~~13(1)(d)(i) of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(e) 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 (d), 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 ~~12~~13(1)(d)(i) 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 7(2), unless the applicant demonstrate**s** that the project is in compliance with the requirements of Section 3 or 4, 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 Section 5 have been met.

(c) The applicant agrees to operate the MRI unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~12~~ 13 of these standards.

Section 9. Requirements for approval of an applicant proposing an MRI unit to be used exclusively for research

Sec. 9. (1) An applicant proposing an MRI unit to be used exclusively for research shall demonstrate each of the following:

(a) 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.

(b) The MRI unit shall operate under a protocol approved by the applicant's institutional review board.

(c) The applicant agrees to operate the unit in accordance with the terms of approval in Section ~~12~~13(2).

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements and terms of sections 3, 4, 5, 6, 7, 8, ~~12~~ 13 [with the exception of ~~12~~13(1)(d)(iii)], ~~14~~15, and ~~15~~ 16 of these standards.

Section 10. Requirements for approval of an applicant proposing to establish dedicated pediatric MRI

Sec. 10. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

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

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

(i) pediatric radiology (at least two)
(ii) pediatric anesthesiology
(iii) pediatric cardiology
(iv) pediatric critical care
(v) pediatric gastroenterology
(vi) pediatric hematology/oncology
(vii) pediatric neurology
(viii) pediatric neurosurgery
(ix) pediatric orthopedic surgery
(x) pediatric pathology
(xi) pediatric pulmonology
(xii) pediatric surgery
(xiii) neonatology

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

(i) pediatric bone marrow transplant program

(ii) established pediatric sedation program
(iii) pediatric open heart program

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 4, of these standards.

SECTION 11. PILOT PROGRAM REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED IMRI

SEC. 11. AS A PILOT PROGRAM, AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED IMRI SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING:

(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 SHALL HAVE EXPERIENCED 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.

(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.

(9) THE APPLICANT AGREES TO OPERATE THE IMRI UNIT IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION 13 OF THESE STANDARDS.

(10) THE PROVISIONS OF SECTION 11 ARE PART OF A PILOT PROGRAM APPROVED BY THE CON COMMISSION AND SHALL EXPIRE AND BE OF NO FURTHER FORCE AND EFFECT, AND SHALL NOT BE APPLICABLE TO ANY APPLICATION WHICH HAS NOT BEEN SUBMITTED BY DECEMBER 31, 2010.

Section ~~11~~12. Requirements for approval – all applicants

Sec. ~~11~~12. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section ~~12~~13. Project delivery requirements – terms of approval

Sec. ~~12~~13. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following terms of CON approval for each geographical location where the applicant operates an MRI unit:

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards for the specific MRI unit approved.

(c) Compliance with the following quality assurance standards:

(i) An applicant shall develop and maintain policies and procedures that establish protocols for the following system performance measures. The protocols shall establish the required benchmarks; identify the testing interval, which shall be at least quarterly; and identify the MRI staff person responsible for testing the system performance measures.

(A) Signal-to-noise ratio.

(B) Spatial resolution.

(C) Slice thickness, location, and separation.

(D) Spatial linearity.

(E) Field homogeneity and drift.

(F) System calibration and stability.

(G) Cryogen level and boiloff rate.

(H) Radio frequency power monitor.

(I) Hard copy image quality.

In addition to the designated staff person, the system performance measures in subdivisions (A) through (F) and (H) also shall be evaluated by an appropriately trained MRI physicist or engineer. The physicist/engineer shall conduct tests of these system performance measures when the MRI unit begins to operate, and annually thereafter. The purpose of the physicist/engineer test shall be to certify to the Department that the MRI unit meets or exceeds all of the system performance specifications of the manufacturer of the MRI unit in effect for that MRI unit at the time of installation or most recent upgrade. The physicist/engineer shall make available for review the periodic system performance measures test data established in this subsection.

(ii) An applicant shall develop and maintain policies, procedures, and protocols for assuring the functionality of each of the following MRI accessories. The protocols shall establish the required benchmarks, identify the testing interval for each accessory, and identify the staff person responsible for testing the system performance measures.

(A) All surface coils.

(B) Positioning devices.

(C) Physiologic triggering/monitoring equipment.

(D) Patient communication devices.

(E) Scan table position indicator and drives.

(F) Data network including storage and retrieval.

(G) Emergency rundown/shutdown units.

(H) Hard copy devices.

(iii) 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. Each of the following must be included and the staff person responsible for development and enforcement of these policies shall be indicated.

(A) Access to the MRI service.

(B) Access to the MRI scan room.

(C) Patient safety clearance before imaging and safety during imaging.

(D) Adverse bioeffects, including

(1) acoustic hazard.

(2) radio frequency burn hazard.

(3) specific absorption rates.

(4) peripheral nerve stimulation.

(5) pregnancy.

(6) magnet quench hazard.

(E) Sedation.

(F) Contrast administration.

(G) Treatment of adverse reactions to contrast.

(H) Patient monitoring for sedation, anesthesia, and unstable patients.

(I) Patient resuscitation, management of emergencies, maintenance of cardiopulmonary resuscitation equipment, and certification requirements for personnel for either basic or advanced cardiopulmonary resuscitation.

(J) Screening for metallic implants, pacemakers, and metallic foreign bodies, as well as a list of contraindications.

(K) Mechanism for consultation regarding difficult cases.

(L) Pulse sequence protocols for specific indications.

(M) Institutional review board policies relating to non-FDA approved pulse sequences or investigational procedures.

(N) Staff inservice regarding subdivisions (A) through (M).

(iv) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

(v) An applicant shall maintain records of the results of the periodic test data required by subdivisions (i) and (ii), including the results of the tests performed by the MRI physicist/engineer required in subdivision (i). An applicant, upon request, shall submit annually to the Department a report of the test data results and evidence of compliance with the applicable project delivery requirements.

(vi) 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) An MRI team leader who shall be responsible for

(1) developing criteria for procedure performance.

(2) developing protocols for procedure performance.

(3) developing a clinical data base for utilization review and quality assurance purposes.

(4) transmitting requested data to the Department.

(5) screening of patients to assure appropriate utilization of the MRI service.

(6) taking and interpretation of scans.

(7) coordinating MRI activity at MRI host sites for a mobile MRI unit.

(8) identifying and correcting MRI image quality deficiencies.

(B) 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.

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

(D) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis. An MRI physicist/engineer shall be responsible for at least the following:

(1) providing technical specifications for new equipment and assistance in equipment procurement.

(2) performing or validating technical performance for system acceptance.

(3) establishing preventive maintenance schedules and quality assurance test procedures and recording and reviewing preventive maintenance and quality assurance data.

(4) facilitating the repair of acute system malfunctions.

(5) training personnel in the MRI service with respect to the technical aspects of MRI scanning and patient and staff safety.

(6) assisting in designing and optimizing clinical imaging procedures.

(E) System maintenance personnel who shall be responsible for calibrating the MRI system and preventive maintenance at regularly scheduled intervals and who shall compile and submit quality control data to the MRI team leader.

(vii) An applicant shall document that the MRI team members have the following qualifications:

(A) The MRI team leader is a board-certified or board-eligible radiologist, or other physician trained in MRI, who spends greater than 75 percent of his or her professional time in multiple anatomic site medical imaging. The MRI team leader also shall demonstrate that he or she meets the requirements set forth in subsection (B) for a physician who interprets MRI images.

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

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

(2) 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), (ii), or (iii):

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

(C) 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.

(D) 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.

(E) An applicant shall document that system maintenance personnel are qualified on the basis of training and experience to perform the calibration, preventive maintenance, and quality control functions on the specific MRI unit approved.

(viii) 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.

(ix) In addition to all other applicable terms of approval, each mobile MRI unit shall have an operations committee with members representing each host site, the central service coordinator, and the medical director. This committee shall oversee the effective and efficient use of the MRI unit, establish the normal route schedule, identify the process by which changes shall be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile MRI unit on at least a quarterly basis.

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

(i) MRI units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. 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. 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 9(1) OR FOR AN IMRI UNIT APPROVED PURSUANT TO SECTION 11.

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

(A) provide magnetic resonance 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.

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

(iii) 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 annual budget and cost information, operating schedules, throughout 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. However, the Department shall allow an applicant up to an additional 60 days to submit the required data if reasonable efforts are made by an applicant to provide the required data. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 9(1) ~~or,~~ Section 10, OR SECTION 11 shall be reported separately.

(A)FOR PURPOSES OF SECTION 11, 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.

(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)(i) 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.

(ii) 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) An applicant for an MRI unit under Section 9(1) shall agree that the services provided by the MRI unit approved pursuant to Section 9(1) shall be delivered in compliance with the following terms of CON approval:

(a) The capital and operating costs relating to the research use of the MRI unit approved pursuant to Section 9(1) shall be charged only to a specific research account(s) and not to any patient or third-party payor.

(b) The MRI unit approved pursuant to Section 9(1) shall not be used for any purposes other than as approved by the institutional review board unless the applicant has obtained CON approval for the MRI unit pursuant to Part 222 and these standards, other than Section 9.

(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.

(4) An applicant approved to initiate a fixed MRI service pursuant to Section 3(4) of these standards 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.

Section ~~13~~14. MRI procedure adjustments

Sec. ~~13~~14. (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.

(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 ~~14~~15. Documentation of actual utilization

Sec. ~~14~~15. 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 "Available MRI Adjusted Procedures List" as of the date an application is deemed complete 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 ~~15~~16. The Department may elect to verify the data through on-site review of appropriate records.

Section ~~15~~16. Methodology for computing the number of available MRI adjusted procedures

Sec. ~~15~~16. (1) The number of available MRI adjusted procedures required pursuant to Section 3 or 4(2) of these standards 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 complete 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 ~~13~~14.

(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 9(1) and dedicated pediatric MRI approved pursuant to Section 10 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(4)(d), 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 4(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 (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 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 (iv) above, sum the available adjusted procedures.

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

(vii) For only those doctors identified in (v) above, multiply the result of (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(4).

Section ~~16~~17. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. ~~16~~17. (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 or at the applicant's discretion, on a more current form subsequently provided by the Department, for each doctor committing available MRI adjusted procedures to that application for a new or additional MRI unit pursuant to Section 3 or Section 4(2), respectively.

(b) An applicant also shall submit, at the time the application is filed with 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 filed on the first applicable designated application date after all required documentation is received by the Department.

(3) The Department shall consider a data commitment, on a form provided by the Department in response to the applicant's letter of intent or at the applicant's discretion, on a more current form

subsequently provided by the Department, submitted by the applicant in support of its application, 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 ~~15~~16, is being committed and specifies the CON application number, for the new fixed or mobile MRI unit or for the additional mobile MRI unit proposed to be located within the planning area, 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 that he or she does not have an ownership interest, either direct or indirect, in the applicant entity, except that this requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member.

(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 or 4(2), respectively, 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 or 4(2), respectively, 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 or 4(2), respectively, the Department shall,

(a) if the applications were filed 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 filed 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 filed on different designated application dates, consider the data commitment submitted in the application filed on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications filed 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) filed 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 complete 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 complete only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

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

(a) during the 120-day period following the date on which the Department's review of an application commences.

(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 ~~17~~18. Lists of MRI adjusted procedures published by the Department

Sec. ~~17~~18. (1) At a minimum, 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 unit or an MRI unit used exclusively for research.

(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 ~~15~~16(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 ~~15~~16(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section ~~15~~16(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 ~~12~~13(1)(d)(iii), the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section ~~12~~13(1)(d)(iii), and no data will be shown for that service on either list.

(4) In the case of an MRI service at which MRI services previously were not provided, the Department may use annualized data from at least a consecutive six-month period in publishing the lists pursuant to subsections (a) and (b).

Section ~~18~~19. Effect on prior CON Review Standards; Comparative reviews

Sec. ~~18~~19. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on ~~December 12, 2006~~SEPTEMBER 18, 2007 and effective ~~March 8~~NOVEMBER 13, 2007.

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

Section ~~19~~20. Health Service Areas

Sec. ~~19~~20. Counties assigned to each of the health service areas are as follows:

HSA		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

1104		Cheboygan	Manistee	Wexford
1105				
1106	8	Alger	Gogebic	Mackinac
1107		Baraga	Houghton	Marquette
1108		Chippewa	Iron	Menominee
1109		Delta	Keweenaw	Ontonagon
1110		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

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR BONE MARROW TRANSPLANTATION SERVICES

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve bone marrow transplantation services.

(2) A bone marrow transplantation service is a covered clinical service for purposes of Part 222 of the Code.

(3) A bone marrow transplantation service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic bone marrow transplant procedures.

(4) An existing bone marrow transplantation service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing bone marrow transplantation service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

(5) The Department shall use Sections 3, 7 & 8, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(6) The Department shall use Sections 4, 5 & 6, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

Sec. 2. (1) As used in these standards:

(a) "Acquisition of a bone marrow transplantation service" means the acquisition (including purchase, lease, donation, or other arrangement) of an existing bone marrow transplantation service.

(b) "Adult," for purposes of these standards, means an individual age 18 or older.

(c) "Allogeneic" means transplantation between genetically nonidentical individuals of the same species.

(d) "Autologous" means transplantation in which the donor and recipient are the same individual.

(e) "Bone marrow transplantation service" means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source.

(f) "Cancer hospital" means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with Section 1886 (d)(1)(B)(v) of the Social Security Act, as amended.

(g) "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.

(h) "Comparative group" means the applications that have been grouped for the same type of project in the same planning area and are being reviewed comparatively in accordance with the CON

rules.

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

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

(k) "Department inventory of bone marrow transplantation services" means the list maintained by the Department of: (i) the bone marrow transplantation services operating pursuant to a valid CON issued under Part 222 or former Part 221; (ii) operating bone marrow transplantation services for which the operation of that service did not require a CON; and (iii) bone marrow transplantation services that are not yet operational but have a valid CON issued under Part 222. The list shall inventory adult and pediatric services separately and shall specify the site at which the bone marrow transplantation service is authorized.

(l) "Existing bone marrow transplantation service," for purposes of Section 3(5) of these standards, means any of the following: (i) a bone marrow transplantation service listed on the Department inventory, (ii) a proposed bone marrow transplantation service under appeal from a final decision of the Department, or (iii) a proposed bone marrow transplantation service that is part of a completed application under Part 222 (other than the application under review) for which a proposed decision has been issued and which is pending final decision.

(m) "Health service area" or "HSA" means the geographic area set forth in Section 9.

(n) "Implementation plan" means a plan that documents how a proposed bone marrow transplantation service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:

(i) each component or activity necessary to begin performing the proposed bone marrow transplantation service including, but not limited to, the development of physical plant requirements, such as an intensive care unit capable of treating immuno-suppressed patients, equipment acquisitions, and recruitment and employment of all physician and support staff;

(ii) the time table for completing each component or activity specified in subsection (i); and

(iii) if the applicant previously has been approved for a bone marrow transplantation service for which either the CON expired or the service did not perform a transplant procedure during any consecutive 12-month period, what changes have or will be made to ensure that the proposed service can be initiated and provided on a regular basis.

(o) "Initiate" or "implement" for purposes of these standards, means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2), if authorized by the Department.

(p) "Initiate a bone marrow transplantation service" means to begin operation of a bone marrow transplantation service at a site that does not provide either adult or pediatric bone marrow transplantation services and is not listed on the Department inventory as of the date an application is submitted to the Department. The term includes an adult service that is proposing to provide a pediatric bone marrow transplantation service, and a pediatric service that is proposing to provide an adult bone marrow transplantation service. The term does not include beginning operation of a bone transplantation service by a cancer hospital which acquires an existing bone marrow transplantation service provided that all of the staff, services, and programs required under section 3(3) are to be provided by the cancer hospital and/or by the hospital from which the bone marrow transplantation service is being acquired.

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

(r) "Licensed site" means either:

(i) in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure or

(ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

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

(t) "Pediatric" means, for purposes of these standards, any patient 20 years of age or less or any patient with congenital conditions or diseases for which bone marrow transplantation is a treatment.

(u) "Planning area" means:
(i) for an adult bone marrow transplantation service, the state of Michigan.
(ii) for a pediatric bone marrow transplantation service, either:
(A) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or
(B) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.
(v) "Qualifying project" means each application in a comparative group that has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the Code and these standards.
(w) "Survival rate" means, for purposes of these standards, the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

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

Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service

Sec. 3. (1) An applicant proposing to initiate a bone marrow transplantation service shall specify in the application whether the proposed service will perform either or both adult and pediatric bone marrow transplant procedures.

(2) An applicant shall specify the licensed hospital site at which the bone marrow transplantation service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the transplants will be offered provides each of the following staff, services, and programs:
(a) operating rooms.
(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.
(c) dialysis.
(d) inpatient-outpatient social work.
(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.
(g) a microbiology and virology laboratory.
(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.
(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.
(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.
(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.
(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.
(m) continuous availability of red cells, platelets, and other blood components.
(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.
(i) anesthesiology.
(ii) cardiology.
(iii) critical care medicine.
(iv) gastroenterology.
(v) general surgery.
(vi) hematology.
(vii) infectious diseases.
(viii) nephrology.
(ix) neurology.
(x) oncology.
(xi) pathology, including blood banking experience.
(xii) pulmonary medicine.
(xiii) radiation oncology.
(xiv) radiology.
(xv) urology.
(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric bone marrow transplant procedures, these specialists shall have specific experience in the care of pediatric patients.
(i) dermatology.
(ii) immunology.
(iii) neurosurgery.
(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed bone marrow transplantation service.

(5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation services in the planning area identified in Section 2(1)(u)(i) does not exceed three (3) adult bone marrow transplantation services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding three (3) in the planning area.
(b) An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) pediatric bone marrow transplantation services in planning area one identified in Section 2(1)(u)(ii)(A) or one (1) pediatric bone marrow transplantation service in planning area two identified in Section 2(1)(u)(ii)(B) and that approval of the proposed application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific pediatric planning area.

(6)(a) An applicant proposing to initiate an adult bone marrow transplantation service that will perform

only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate an adult bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.

(b) An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only allogeneic transplants, or both allogeneic and autologous transplants, shall project that at least 10 allogeneic transplant procedures will be performed in the third 12-months of operation. An applicant proposing to initiate a pediatric bone marrow transplantation service that will perform only autologous procedures shall project that at least 10 autologous transplant procedures will be performed in the third 12-months of operation.

(c) An applicant proposing to initiate both an adult and a pediatric bone marrow transplantation service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

(7) An applicant shall provide megavoltage radiation therapy services, either on-site or physically connected, with a nominal beam energy of at least 6 MEV, including the capability to perform total body irradiation.

(8) An applicant shall demonstrate that the licensed hospital site at which the proposed bone marrow transplantation service is proposed has an institutional review board.

(9) An applicant proposing to initiate a pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the pediatric transplant procedures will be performed has each of the following:

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

(c) membership status in either the Pediatric Oncology Group (POG) or the Children's Cancer Group (CCG).

(d) a pediatric tumor board that meets on a regularly scheduled basis.

(e) family support group services, provided either directly or through written agreements.

(f) a pediatric cancer program with the following staff:

(i) a director who is either a board-certified immunologist who has specific training and experience in bone marrow transplantation or a board-certified pediatric hematologist/oncologist.

(ii) nurses with training and experience in pediatric oncology.

(iii) social workers with training and experience in pediatric oncology.

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric bone marrow transplantation service shall submit, in its application, a written consulting agreement with an existing bone marrow transplantation service, that meets each of the requirements in subsection (b).

(b) The written consulting agreement required by subsection (a) shall specify the term of the agreement and the roles and responsibilities of both the existing and proposed service, including at least the following:

(i) The term of the written consulting agreement is no less than 36 months after the proposed service begins to perform bone marrow transplant procedures.

(ii) One or more representatives of the existing bone marrow transplantation service have been designated as staff responsible for carrying out the roles and responsibilities of the existing service.

(iii) The existing service shall evaluate and make recommendations to the proposed service on policies and procedures, including time tables, for at least each of the following:

(A) nursing services.
(B) infection control.
(C) nutritional support.
(D) staff needs and training.
(E) inpatient and outpatient medical coverage.
(F) transfusion and blood bank policies.
(G) transplant treatment protocols.
(H) hematopoiesis laboratory services and personnel.
(I) data management.
(J) quality assurance program.
(iv) Specify a schedule of site visits by staff of the existing bone marrow transplantation service that, at a minimum, includes:
(A) 6 visits during the first 12-months of operation of the proposed service.
(B) 4 visits during each the second 12-months and third 12-months of operation of the proposed service.
(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:
(A) a review of the number of patients transplanted.
(B) transplant outcomes.
(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.
(D) all deaths occurring within 100 days from transplant.
(E) each of the requirements of subdivision (iii).
(vi) Specify that a written report and minutes of each site visit shall be completed by the existing bone marrow transplantation service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).
(vii) Specify that the existing bone marrow transplantation service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.
(viii) Specify that the existing bone marrow transplantation service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.
(c) For purposes of subsection (10), "existing bone marrow transplantation service" means a service that meets all of the following:
(i) currently is performing and is Foundation for Accreditation of Cell Therapy (FACT) accredited in, the types of transplants (allogeneic or autologous; adult or pediatric) proposed to be performed by the applicant;
(ii) currently is certified as a National Marrow Donor Program; and
(iii) is located in the United States.
(d) An applicant shall document that the existing bone marrow transplantation service meets the requirements of subsection (c).

Section 4. Additional requirements for applications included in comparative reviews

Sec. 4. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards, shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews.

(2)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed service will be located, on the date the application is submitted to the Department, as shown in the following schedule:

Number of BMT Transplant Services (adult or pediatric, as applicable) in HSA	Points Awarded
Two or more services	0
One service	2
No services	4

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will be awarded to each applicant pursuant to this subsection.

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(c) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the bone marrow transplant procedures will be performed and were referred for and received a bone marrow transplant at an existing bone marrow transplantation service, and submits documentation from the existing bone marrow transplantation service(s) of these referrals.

(3) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, when taken together, do not

exceed the need, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the Department in accordance with Rule 325.9123.

(4) No points will be awarded to an applicant under specific subsections of Section 4 if information presented is inconsistent with related information provided in other portions of the CON application.

Section 5. Requirements for approval -- all applicants

Sec. 5. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall provide a signed affidavit stating 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. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 6. Project delivery requirements -- terms of approval for all applicants

Sec. 6. (1) An applicant shall agree that, if approved, the bone marrow transplantation service shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the bone marrow transplantation service that may affect its ability to comply with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable, no later than the date the first bone marrow transplant procedure, allogeneic or autologous, is performed:

(i) An applicant shall establish and maintain, either on-site or through written agreements, all of the following:

(A) 24-hour blood bank support, including pheresis capability, irradiated blood, products suitable for cytomegalovirus-negative transplants, and blood component therapy.

(B) a cytogenetics and/or molecular genetic laboratory.

(C) a processing and cryopreservation laboratory that meets the standards of the Foundation for Accreditation of Cell Therapy (FACT) or an equivalent organization.

(D) for a program that performs allogeneic transplants, a histocompatibility laboratory that has the capability of DNA-based HLA-typing and meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(E) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease (programs performing allogeneic transplants) and other opportunistic infections in immuno-compromised hosts (programs performing allogeneic or autologous transplants).

(F) therapeutic drug monitoring.

(ii) An applicant shall establish and maintain, at the licensed hospital site at which the transplants are performed, both of the following:

(A) a protective environmental bone marrow transplant inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

(B) a specialized intensive care unit capable of treating immuno-suppressed neutropenic patients.

(iii) An applicant shall establish and maintain written policies related to outpatient care for bone marrow transplantation patients, including at least the following:

(A) the ability to evaluate and provide treatment on a 24-hour basis.

(B) nurses experienced in the care of bone marrow transplantation patients.

(C) a designated outpatient area for patients requiring long-duration infusions or the administration of multiple medications or blood product transfusions.

(iv) A bone marrow transplantation service shall establish and maintain a dedicated transplant team that includes at least the following staff:

(A) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. If the bone marrow transplantation service performs allogeneic transplants, the team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(B) one or more attending physicians with specialized training in pediatric and/or adult, as appropriate, bone marrow transplantation. If a service performs allogeneic transplants, at least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic or autologous transplants), cardiology, gastroenterology, infectious diseases with experience in immuno-compromised hosts, nephrology, psychiatry, pulmonary medicine, and radiation oncology with experience in total body irradiation, and an intensivist who is board-certified in critical care.

(D) a transplant team coordinator, who shall be responsible for providing pre-transplant patient evaluation and coordinating treatment and post-transplant follow-up and care.

(E) a nurse to patient ratio necessary to provide care consistent with the severity of a patient's clinical status.

(F) nurses with specialized training in pediatric and/or adult, as appropriate, bone marrow transplantation, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(G) a pharmacist experienced with the use of cytotoxic therapies, use of blood components, the hemodynamic support of the transplant patient, and the management of immuno-suppressed patients.

(H) dietary staff capable of providing dietary consultations regarding a patient's nutritional status, including total parenteral nutrition.

(I) designated social services staff.

(J) designated physical therapy staff.

(K) data management personnel designated to the bone marrow transplantation service.

(L) for an applicant performing pediatric bone marrow transplants, a child-life specialist.

(v) In addition to the dedicated transplant team required in subdivision (iv), an applicant's staff shall include a patient ombudsman, who is familiar with the bone marrow transplantation service, but who is not a member of the transplant team.

(vi) An applicant shall develop and maintain patient management plans and protocols that include the following:

(A) therapeutic and evaluative procedures for the acute and long-term management of a patient.

(B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the service.

(C) long-term management and evaluation, including education of the patient, liaison with the patient's attending physician, and the maintenance of active patient records for at least 5 years.

(D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative

regimen, post-transplantation care, prevention and treatment of graft-versus-host disease (allogeneic transplants), and follow-up care.

(vii) An applicant shall establish and maintain a written quality assurance plan.

(viii) An applicant shall implement a program of education and training for nurses, technicians, service personnel, and other hospital staff.

(ix) An applicant shall participate actively in the education of the general public and the medical community with regard to bone marrow transplantation, and make donation literature available in public areas of the institution.

(x) An applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed bone marrow transplantation service.

(xi) An applicant shall operate, either on-site or under its direct control, a multi-disciplinary selection committee which includes, but is not limited to, a social worker, a mental health professional, and physicians experienced in treating bone marrow transplant patients.

(xii) A pediatric bone marrow transplant service shall maintain membership status in the Children's Oncology Group (COG).

(xiii) For purposes of evaluating subsection (c), except subdivision (xii), the Department shall consider it prima facie evidence as to compliance with the applicable requirements if an applicant documents that the bone marrow transplantation service is accredited by the National Marrow Donor Program (NMDP) or the Foundation for the Accreditation of Cell Therapy (FACT).

(xiv) 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) Compliance with the following terms of approval:

(i) An applicant shall perform the applicable required volumes as follow:

(A) An adult bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If an adult service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 adult transplants in any 36-month consecutive period, with no fewer than 5 allogeneic in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(B) A pediatric bone marrow transplantation service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 10 allogeneic transplants in the third 12-months of operation. If a pediatric service performs only autologous transplants, the service shall perform at least 10 autologous transplants in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

(C) A bone marrow transplantation service that performs both adult and pediatric bone marrow transplants shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

(ii) 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, annual budget and cost information, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; 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. In addition, an applicant shall report at least the following data for each patient:

(A) disease type.

(B) transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous.

(C) source of hematopoietic stem cell, i.e., bone marrow, peripheral circulation, cord blood, etc.
(D) patient age, i.e., adult or pediatric as defined by these standards.
(E) data on 100-day, 6-month, 1-year, 2-year, and 5-year survival rates.
(F) relapse rates at 6-months, 1-year, and 5-years post-transplant.
(G) median follow-up, and patients lost-to-followup.
(H) cause(s) of death, if applicable.
(I) additional summary information, as applicable.

An applicant annually shall report for its bone marrow transplantation service annual and cumulative survival rates by type of transplant performed reported in actual number of transplants by disease category, transplant type, i.e., related allogeneic, unrelated allogeneic, and autologous; source of hematopoietic stem cell; patient age, i.e., adult or pediatric, as defined by these standards; and relapse rates at 100-days, 6-months, one year, and five years post-transplant. For purposes of these standards, procedure-related mortality is defined as death occurring within 100 days from bone marrow transplant.

(iii) The applicant shall maintain an organized institutional transplant registry for recording ongoing information on its patients being evaluated for transplant and on its transplant recipients and shall participate in the national and international registries applicable to the bone marrow transplantation service.

(iv) An applicant, to assure that the bone marrow transplantation service(s) will be utilized by all segments of the Michigan population, shall:

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

(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; and

(C) 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.

(v) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform either allogeneic or autologous procedures, whichever was not performed initially by the applicant.

(vi) An applicant shall notify the Department immediately if the consulting agreement required pursuant to Section 3(10) of these standards is terminated prior to the end of the first 36-months of operation of the bone marrow transplantation service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

(vii) The Department may use the information provided pursuant to Section 3(10) of these standards in evaluating compliance with the requirements of this section.

(2) The agreements and assurances required by this section, as applicable, shall be in the form of a certification authorized by the governing body of the applicant or its authorized agent.

Section 7. Documentation of projections

Sec. 7. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. This specification of projections shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 8. Requirements for approval – acquisition of a bone marrow transplantation service by a cancer hospital

(1) An applicant proposing to acquire an existing bone marrow transplantation service shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with section 3(5) and the department inventory.

(a) The total number of bone marrow transplantation services is not increased in the planning area as the result of the acquisition.

(b) As part of the acquisition of the bone marrow transplantation service, the acquisition or replacement of the cancer hospital, or for any other reasons, the location of the bone marrow transplantation service shall be located at its prior location or in space within the licensed cancer hospital site.

(c) The applicant is a cancer hospital as defined by these standards. The applicant shall, to the satisfaction of the Department, provide verification of PPS-exemption at the time of application, or shall demonstrate compliance with the following to the satisfaction of the Department:

(i) The applicant, or an affiliate of the applicant, operates a comprehensive cancer center recognized by the National Cancer Institute in conjunction with a Michigan university that is designated as a comprehensive cancer center, or the applicant is the Michigan university that is designated as a comprehensive cancer center.

(ii) The applicant commits to provide evidence, satisfactory to the Department, of approval as a PPS-exempt hospital within the time limits specified in subsection (g).

(d) The applicant demonstrates that it meets, directly or through arrangements with the hospital from which it acquires the bone marrow transplantation service, the requirements set forth under section 3(3), (6), (7), and (8), as applicable.

(e) The applicant agrees to either have a written consulting agreement as required by Section 3(10) or obtain a determination by the Department that such an agreement is not required because the existing bone marrow transplantation staff, services, and program substantially will continue to be in place after the acquisition.

(f) The applicant agrees and assures to comply, either directly or through arrangements with the hospital from which it acquires the bone marrow transplantation service, with all applicable project delivery requirements.

(g) If the applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS within 24 months after receiving CON approval under this section, the Department may extend the 24-month deadline to no later than the last session day permitted by the United States Constitution for the NEXT United States Congress then in session AFTER THE EFFECTIVE DATE OF THESE STANDARDS. Extension of the deadline shall require demonstration by the applicant, to the satisfaction of the Department, that there has been progress toward achieving the changes in federal law and regulations that are required to secure the PPS exemption. If the applicant fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or its possible extension, then the CON granted pursuant to this section shall expire automatically and will not be subject to further applications for acquisition. However, prior to the final deadline for the expiration of the CON, the prior holder of the (CON/authorization) to provide the bone marrow transplantation service may apply for acquisition of the service, pursuant to all the provisions of this section, except for subsection (c).

2. Applicants proposing to acquire an existing bone marrow transplantation service under this section shall not be subject to comparative review.

Section 9. Health Service Areas

Sec. 9. Counties assigned to each health service area are as follows:

HSA		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 10. Department Inventory of Bone Marrow Transplantation Services

Sec 10. The Department shall maintain, and provide on request, a listing of the Department Inventory of bone marrow transplantation services.

Section 11. Effect on prior CON Review Standards; comparative reviews

Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Transplantation Services pertaining to bone marrow transplantation services approved by the CON Commission on ~~June 22, 2005~~December 12, 2006 and effective on ~~September 21, 2005~~March 8, 2007.

(2) Projects reviewed under these standards shall be subject to comparative review.

Proton Beam Therapy Update Compliance with CON Resolution

Nick Lyon, Deputy Director

Department of Community Health

6.11.08 CON Commission Meeting

Requirements of the Resolution on Proton Beam Therapy, Approved by the CON Commission on April 30, 2008

- By June 5, 2008, the CEOs of those of the high volume hospital-owned programs identified in Section 10 (1) (b) of the CON MRT Standards who have committed to be in the collaborative shall submit a letter to MDCH for review and analysis to be provided to the Commission. This letter will indicate that the respective governing bodies for the participating hospitals have agreed to (a) participate in the collaborative, and (b) contribute their appropriate share of at least $13 million to be the minimum sponsoring hospitals' share of the program.

- By September 6, 2008, the collaborative is to submit a business plan. That business plan shall include: a proposed financial plan outlining the projected costs and sources of funds for the PBT Collaborative, a proposed governance plan, a proposed time-line for completing the PBT facility, the process and timeline for selecting the PBT equipment manufacturer, and a timely process for identification and purchase/lease of the site.

- Each of the high volume hospital-owned MRT programs (those eligible to be among the minimally required participants in the collaborative because they are above 30,000 MRT ETVs statewide or are among the highest volume programs in at least two health planning areas) are asked to report in writing to the Commission within 10 days before each scheduled Commission meetings with their assessment of progress in developing a collaborative.

Facilities Reporting +30,000 ETVs

Nine facilities report more than 30,000 ETVs (equivalent treatment visits) and are eligible to participate in the collaborative:

- The language in the standards requires participation by five (5) of the nine (9) facilities.
- Six (6) of the nine (9) eligible facilities have submitted their letter of commitment to MDCH.
- More than one (1) Planning Area is represented by the collaborative participants-this meets the requirements of the standards.
- All six (6) facilities that have submitted their written intent to participate have also submitted the required progress report.
- All six (6) facilities have submitted their written intent to contribute their share of the required $13 million “seed” money to the collaborative.

Facility Name Above 30,000 ETVs (Five required to be part of the collaborative)	**Planning Area**	**MRT ETVs** April 30, 2008	**Progress Report and June 5, 2008 Commitment Letter**	**Participation in Collaborative**	**Contribute Share of $13 Million**	**Comments**	
William Beaumont Hosp Royal Oak	1	55,805	Progress Report	N/A		Working on own collaborative.	
University of Michigan Health System	1	54,193	Yes	Exclusive	Yes		
Karmanos Cancer Center	1	38,892	Yes	Exclusive	Yes*	*Specifies dollar amount of $2.2 million.	
St. Joseph Mercy Hosp Ann Arbor	1	33,905	Yes	Agreed to participate in noted collaborative. (See Comment)	Yes	Has been quoted as saying they are in discussion with Beaumont. (Crain's 6/8/08)	
Henry Ford Hospital	1	33,750	Yes	Exclusive	Yes		
Genesys Hurley Cancer Institute	5	31,855	Yes	Exclusive	Yes		
William Beaumont Hosp Troy	1	30,865	Progress Report	N/A		Working on own collaborative.	
West Michigan Cancer Center	3	36,016	No	Undecided		Has stated that they are undecided. (Crain's 6/8/08)	
Great Lakes Cancer Institute–McLaren Campus	5	37,106	Yes	Non Exclusive	Yes	Will participate in either collaborative	

Progress Made By Collaborative

Specific progress made to date:

- Four (4) of the six (6) organizations have agreed to work exclusively with this collaborative for development of a PBT center. One has committed to work with the collaborative, but is still in discussions with Beaumont. One agrees to work in a collaboration but does not commit to any single entity.

- The collaborative has agreed upon and engaged a consultant to develop a viable business plan.

- The collaborative has agreed to work cooperatively on this initiative and to devote the necessary people and financial support to ensure the business plan is submitted by September 6, 2008.

- A collaborative website has been launched to inform the public about Proton Beam Therapy services (protontherapyformichigan.org).

- Meetings have been scheduled over the next several months to ensure that we finalize plans in a timely fashion.

Compliance with CON Resolution

- The group of hospitals led by University of Michigan demonstrates timely progress toward the formation and operation of a successful statewide Collaborative as required by the CON Resolution.
- Letters of participation and financial commitment were received by the Department by the required deadline
- Progress reports by individual hospitals were received as required.
- The Commission has three months from the effective date of the standards (June 20, absent legislative and/or Governor negative action) to determine the adequacy of substantial and timely progress by the Collaborative; thus at September 16 meeting.
- The Department supports a single statewide Proton Beam Therapy Center and encourages both groups to come to an agreement on a single statewide initiative
- Hospitals can only be a member of one collaborative as part of the CON application process (Part of the Standards).

CERTIFICATE OF NEED
Compliance Activity Report to the CON Commission
June 11, 2008

This quarterly report is designed to update the Commission on the Department's activity in monitoring compliance with all Certificates of Need issued as required by Section 22247 of the Public Health Code. This report details activities from January 1 through March 31, 2008.

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 performs follow up checks on approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222 of the Code. For the 2nd quarter of FY 2008, the following actions have occurred:

- 203 follow-up letters mailed (Year to Date: 519)
- 106 projects deemed 100% complete and operational (Year to Date: 284)
- 103 CON approvals expired due to noncompliance with Part 222, not meeting required time frames to implement projects (Year to Date: 123)

Compliance Report to CON Commission
June 11, 2008

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 in accordance with Part 222 of the Code. For the 2nd quarter of FY 2008, the following action has occurred:

- A compliance hearing was held on a freestanding surgical outpatient facility for performing surgical procedures in two (2) operating rooms when the health facility was CON-approved for one (1) operating room. A civil fine has been issued for $15,000 and the health facility has ceased use of the second operating room until CON approval is received.

- A compliance hearing was held on a freestanding computed tomography (CT) scanner service for operating a CT scanner without properly registering the scanner with the MDCH Radiation Safety Section and submitting a Project Implementation Progress Report (PIPR) as required by the terms and conditions of the CON approval. A civil fine of $25,000 was issued and paid along with proper registration of the CT scanner and submission of a PIPR.

- A statewide review was performed against the Nursing Home Bed Inventory to verify CON-approved for new beds are being implemented or beds returned to the inventory pool. Review included all 84 planning areas with approximately 460 nursing homes. The Department sent 12 certified letters requesting updates on approved projects. Six (6) projects were expired, while three (3) submitted required documents. Follow up is still pending on the three (3) remaining approved projects.

Actions below are outside reporting period, but provided for the Commission's information.

- Recently, the Department issued 21 compliance letters to CON-approved facilities with outstanding 2005 and/or 2006 annual surveys. The compliance letter requires immediate submission of any outstanding survey or a civil fine up to $25,000 will be imposed. To date, 11 facilities have submitted delinquent surveys. Enforcement of civil fines will be pursued on the remaining 10 delinquent surveys.

- The Department will soon post the delinquent list for outstanding 2007 surveys. Once the advisory is posted, delinquent facilities will not receive further CON approval until compliant and civil fine enforcement action will soon follow.

CERTIFICATE OF NEED

Quarterly Program Section Activity Report to the CON Commission

October 1, 2007 through March 31, 2008 (FY 2008)

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

Measures

Administrative Rule 325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	137	274
Letters of Intent Processed within 15 days	136	273

Administrative Rule 325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application.

Activity	Most Recent Quarter	Year-to-Date
Applications Received	98	210
Applications Processed within 15 Days	98	210
Applications Incomplete/More Information Needed	69	151

Administrative rules 325.9206 and 325.9207 requires 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	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	44	1	108	1
Substantive Applications	46	0	74	1
Comparative Review Applications	1	0	4	0

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.

Administrative Rule 325.9227 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	Most Recent Quarter	Year-to-Date
Emergency Applications Received	1	2
Decisions Issued within 10 workings Days	0	1

Measures – continued

Administrative Rule 325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	6	7	18	9

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 other than good cause as determined by the Commission.

Activity	Most Recent Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

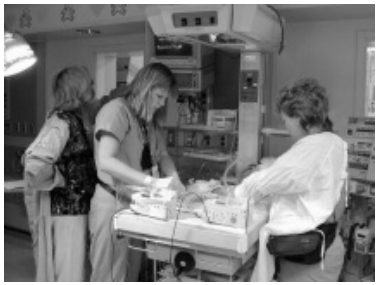
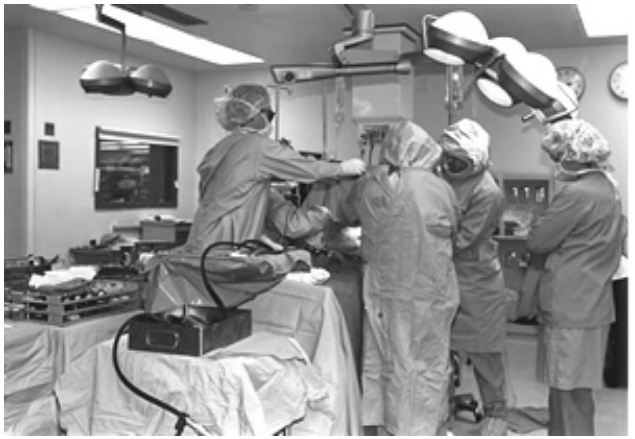
Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	38	71
FOIA Requests Processed on Time	38	71
Number of Applications Viewed Onsite	4	15

FOIA – Freedom of Information Act.

Source: Certificate of Need Program Review Section, Division of Health Facilities and Services, Bureau of Health Systems, Michigan Department of Community Health.

Certificate of Need
Online Application/Management System
CON Commission Update June 2008



Michigan Department
of Community Health

MDCH

Overview of Michigan CON Web Site
http://www.michigan.gov/con

Highlights

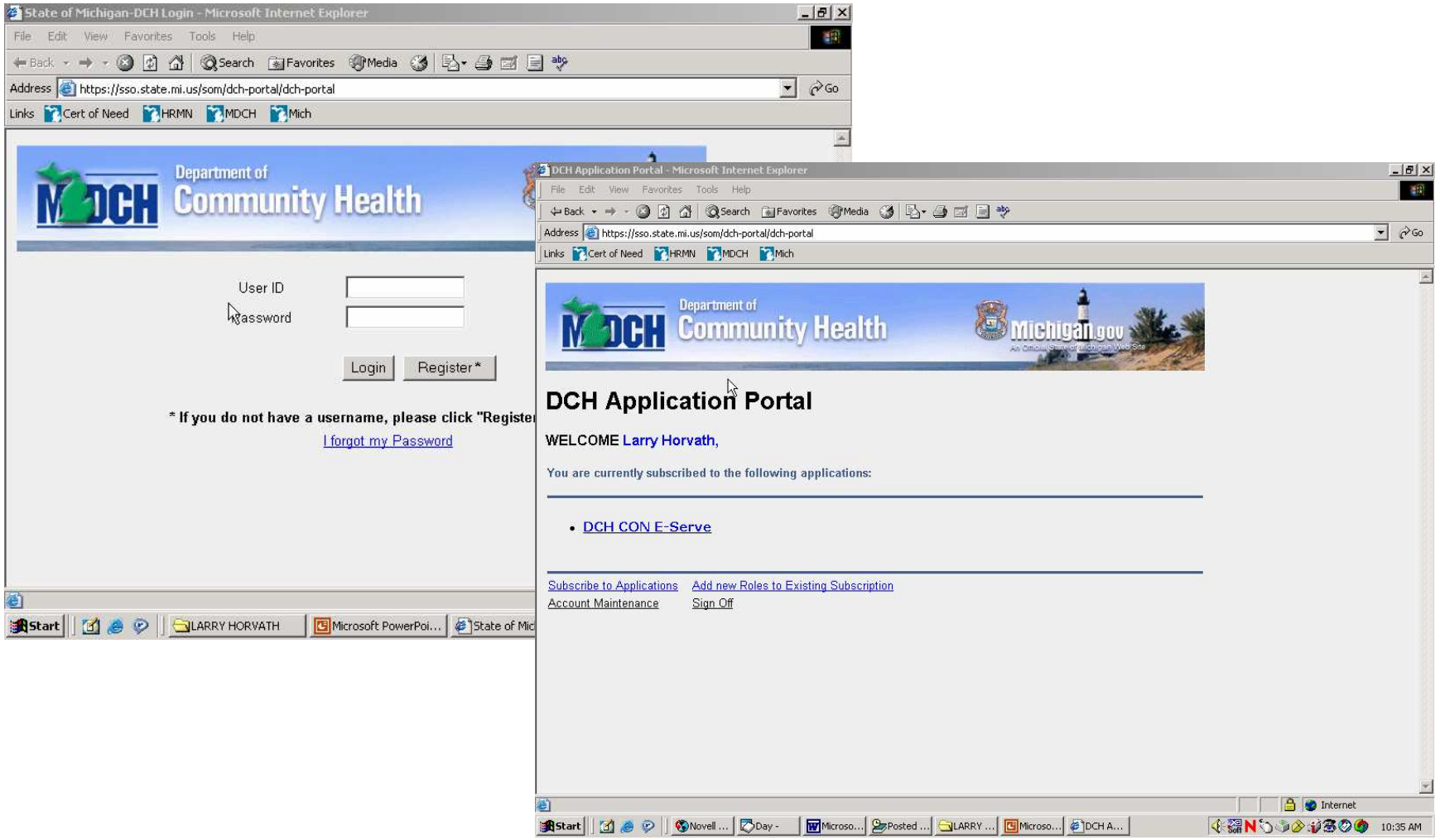
- ✓Advisories
- ✓CON E-Serve
- ✓Listserv
- ✓Forms
- ✓Standards
- ✓Laws
- ✓Rules
- ✓FQA
- ✓Reports
- ✓Contact Info

CON Online Application and Management System Release Dates

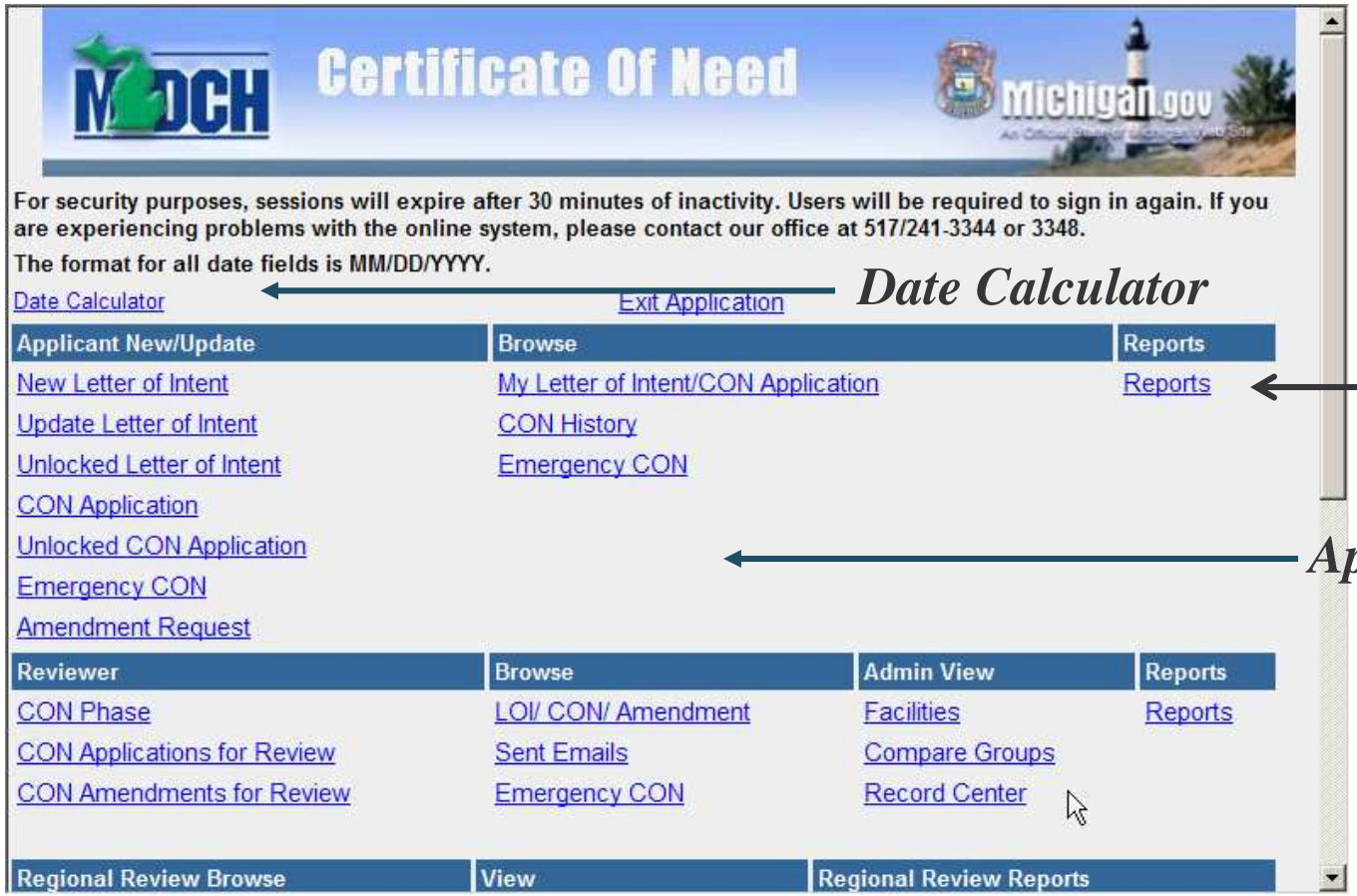
- Letter of Intent module released in January 2006
- Nonsubstantive application, Nonsub (Notice), Amendment and Emergency CON modules released in April 2007
- Substantive application module released in April 2008
- Potential comparative applications are required to be submitted in paper copy format
- Online payment system (EFT) tentatively scheduled for release in summer 2008

MDCH Single Sign-on & CON E-Serve

Web Site: https://sso.state.mi.us



CON E-Serve Main Page Applicant Screen

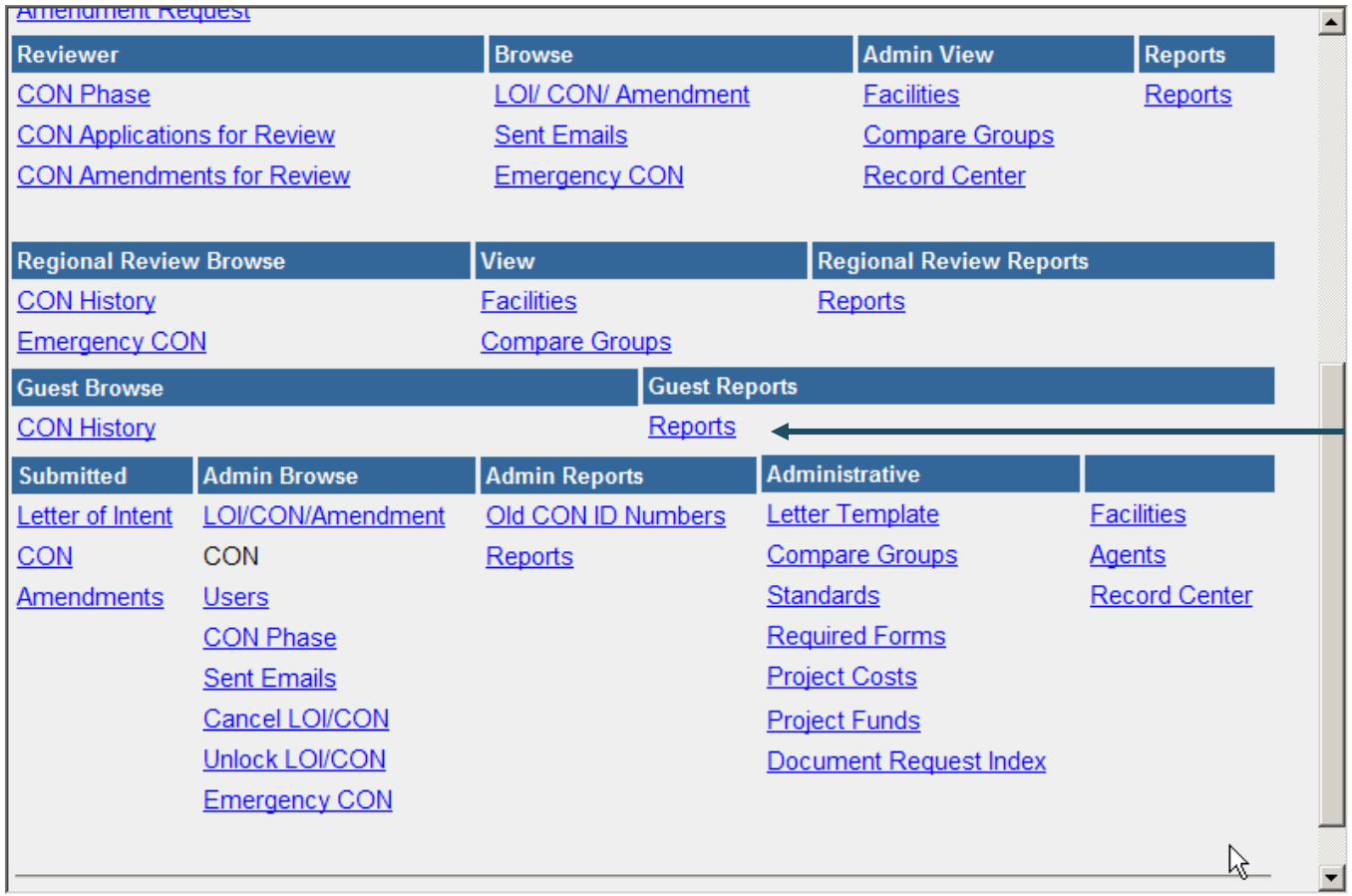


Date Calculator

Reports

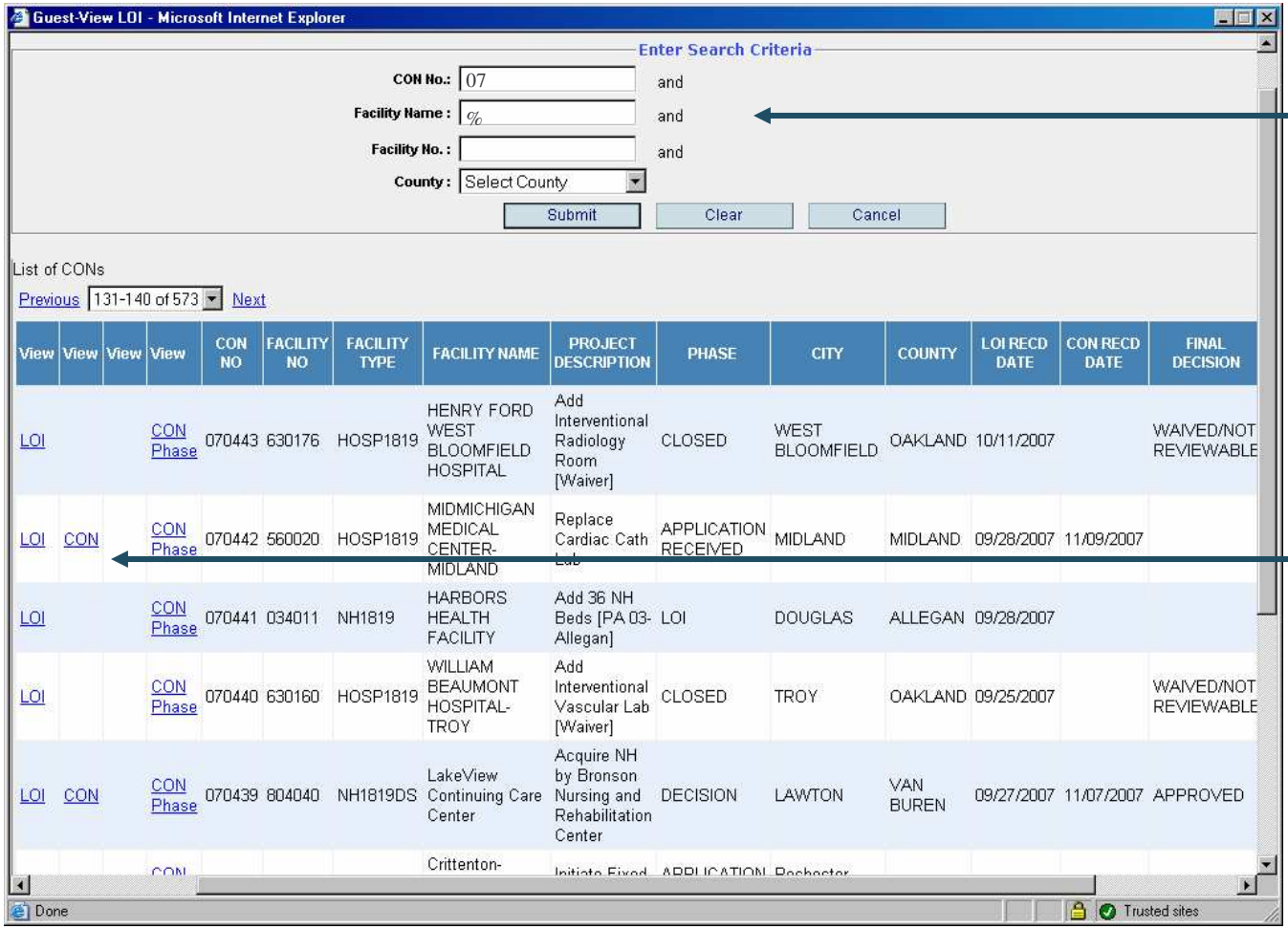
Applicant Screen

CON E-Serve Main Page Guest Screen



Guest Screen

Information Search



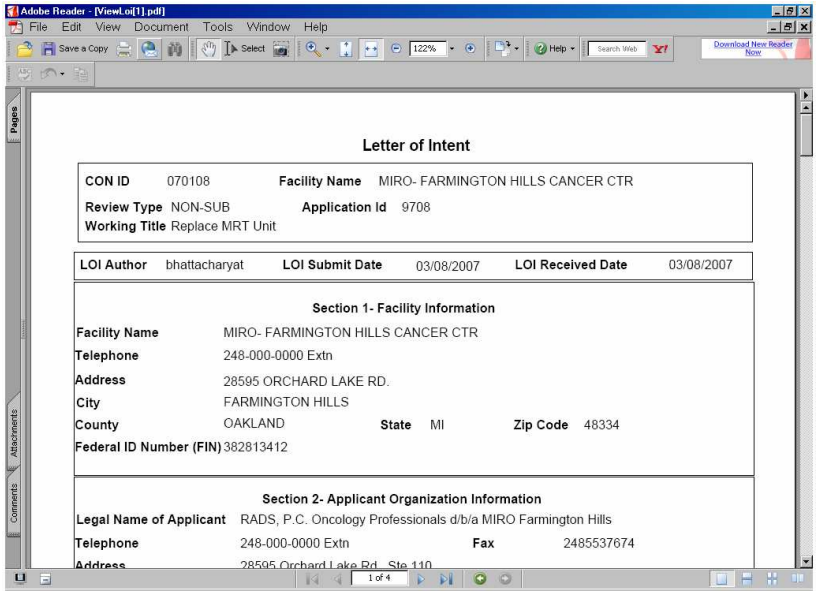
View	View	View	View	CON NO	FACILITY NO	FACILITY TYPE	FACILITY NAME	PROJECT DESCRIPTION	PHASE	CITY	COUNTY	LOI RECD DATE	CON RECD DATE	FINAL DECISION
LOI			CON Phase	070443	630176	HOSP1819	HENRY FORD WEST BLOOMFIELD HOSPITAL	Add Interventional Radiology Room [Waiver]	CLOSED	WEST BLOOMFIELD	OAKLAND	10/11/2007		WAIVED/NOT REVIEWABLE
LOI	CON		CON Phase	070442	560020	HOSP1819	MIDMICHIGAN MEDICAL CENTER-MIDLAND	Replace Cardiac Cath Lab	APPLICATION RECEIVED	MIDLAND	MIDLAND	09/28/2007	11/09/2007	
LOI			CON Phase	070441	034011	NH1819	HARBORS HEALTH FACILITY	Add 36 NH Beds [PA 03-Allegan]	LOI	DOUGLAS	ALLEGAN	09/28/2007		
LOI			CON Phase	070440	630160	HOSP1819	WILLIAM BEAUMONT HOSPITAL-TROY	Add Interventional Vascular Lab [Waiver]	CLOSED	TROY	OAKLAND	09/25/2007		WAIVED/NOT REVIEWABLE
LOI	CON		CON Phase	070439	804040	NH1819DS	LakeView Continuing Care Center	Acquire NH by Bronson Nursing and Rehabilitation Center	DECISION	LAWTON	VAN BUREN	09/27/2007	11/07/2007	APPROVED
							Crittenton-							

Search by multiple fields

CON link appears only if submitted online

Online LOIs, Nonsubstantive, Substantives, Amendments, & Emergency Applications

- Applicants can save work prior to submission
- Online submissions allow for faster processing
- Online forms and reports can be save as PDF, Word, or Excel documents as applicable
- Guests can view real-time submissions in “Read Only” version



New Features & Accomplishments

- Printable/savable PDF reports for all nonsubstantive application forms to be released soon.
- Report generator for applicants and guests. Activity reports for LOIs, applications and final decisions issued.
- Eliminated more than 30 forms and unneeded signature pages when applicable during the design and development of the system. In addition, remaining forms were streamlined when possible.
- First in the nation to have an online application system. In May, Michigan's E-Serve system was demonstrated to representatives from 17 states.

CERTIFICATE OF NEED LEGAL ACTION

(06/04/08)

Case Name	*Date Opened*	*Case Description*	*Status*
Mobile Diagnostic Docket No: 2007-1870 CON CON Application #06-0031	03/14/07	Appeal of denial of CON application # 06-0031 to expand mobile MRI Network No. 79 by adding a second MRI unit.	Motion for Summary Disposition Granted. Appellant's appeal dismissed.
Mobile Diagnostic Ingham County Circuit Docket No: 08-461-AA CON Application #06-0031	04/07/08	Appeal to Circuit Court of Denial of application for CON (Docket No: 2007-1870 CON) by Administrative Law Judge Lisa Gigliotti.	Filed Administrative Record with the Court. Waiting for Hearing date.
Regency on the Lake-Novi, LLC Admin Tribunal Docket No.: 2007-1988 CON	04/02/07	Appeal of Denial of CON application. Comparative Review decision including Maple Drake Real Estate, Maple Manor Rehabilitation Center Status.	Hearing set for 7/23/08
Maple Drake Real Estate, LLC Admin Tribunal Docket No: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Comparative Review proposed decision including Maple Manor Rehabilitation Center and Regency on the Lake.	Hearing set for 7/23/08
Maple Manor Rehabilitation Center Admin Tribunal Docket No.: 2007-2263 CON	05/24/07	Appeal of Comparative Review of CON application. Approval with Regency on the Lake and Maple Drake Real Estate.	Hearing set for 7/23/08.
MediLodge of Milford, LLC (AG#20073000935) Admin Tribunal Docket No.: 2007-3545 CON	07/17/07	Appeal of denial of CON application.	Status Conference held on 5/13/08. Motion to Dismiss due 6/27/08.
MediLodge of Montrose, Inc. (AG#20073002174) Admin Tribunal Docket No.: 2007-4038 CON	08/21/07	Comparative Review - includes Heartland HCC-Briarwood, CON Application No. 07-0008 Heartland HCC-Fostrain, CON Application No.07-0009. The latter two received a proposed approval.	Medilodge withdrew appeal of the Department's decision-case dismissed. Stipulation & Order entered 5/29/08.
Metron of Kalamazoo (2007-3000872-A)	07/13/07	Appeal of Certificate of Need. Appeal of Department's Proposed Decision denying Petitioner its request to acquire an existing nursing home.	Final Order granting the Department's Motion for Summary Disposition entered 5/02/08.

CERTIFICATE OF NEED LEGAL ACTION

(06/04/08)

Case Name	*Date Opened*	*Case Description*	*Status*
Fountain View of Jackson, LLC Admin Tribunal Docket No: 2008-925 CON CON Application No: 07-0089	12/21/07	CON, Comparative Review including Allen Care Center and Ganton Rehab Center. Ganton Rehb Center received a proposed approval and has filed a Motion to Dismiss Allen Care Center's appeal	Proposal for Decision entered 5/29/08, granting the Dept's Motion for Summary Disposition. Waiting final order.
Maple Manor Rehabilitation Center Admin Tribunal Docket No: 2008-17098 CON CON Application No: 08-0018	5/28/08	Appeal of Proposed Decision of Disapproval dated 4/16/08. Proposed project to acquire an 82 bed nursing home and replace 22 beds disapproved.	Waiting for hearing date.
Fountainbleu, LLC Admin Tribunal Docket No: 2008-10920 CON	3/20/08	Appeal of proposed CON decision dated February 22, 2008.	Hearing scheduled for 6/03/08.

s: chd; assign control; special; CON Leg Action; report 6-03-08

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.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2007												2008											
	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	PH		D R	•	•	• —	P		▲									F						
Bone Marrow Transplantation (BMT) Services																		• —	• P	•	• ▲ F	PH		
Computed Tomography (CT) Scanner Services	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —		P	▲ F P	• ▲ F	•	•	•	•	•			
Heart/Lung and Liver Transplantation Services																						PH		
Hospital Beds	•	•	•	•	•	• R				PH			D R	•	•	•	•	•	•	•	• —	• P	•	• ▲ F
Magnetic Resonance Imaging (MRI) Services	P	•	▲F—		P				▲F				•	•	• R	•	•	• —	• P	•	• ▲ F	PH		
Megavoltage Radiation Therapy (MRT) Services/Units										PH		R	D R	•	• — P	• ▲ F	•	•	•	•	• R			
Nursing Home and Hospital Long-term Care Unit Beds	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	•	P •	▲ F • P	• ▲ F								
Pancreas Transplantation Services																						PH		
Psychiatric Beds and Services																						PH		
Surgical Services										PH			D R	•	• — P	• ▲ F								
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R A	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M R

KEY

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

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PH - Public Hearing for initial comments on review standards
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approval June 11, 2008

Updated June 2, 2008

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, Health Policy, Regulation & Professions Administration, CON Policy 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	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	December 27, 2006	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2011
Magnetic Resonance Imaging (MRI) Services	November 13, 2007	2009
Megavoltage Radiation Therapy (MRT) Services/Units	January 30, 2006	2011
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 2, 2008	2010
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	February 25, 2008	2009
Surgical Services	June 5, 2006	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2010

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

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