

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

Thursday, September 10, 2009

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 9:03 a.m.

A. Members Present:

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

B. Members Absent:

None.

C. Department of Attorney General Staff:

Ronald J. Styka
Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Michael Berrios
Tulika Bhattacharya
William Hart
Irma Lopez
Kasi Kelley
Joette Laseur
Nick Lyon
Andrea Moore
Tania Rodriguez
Brenda Rogers

II. Introductions

Chairperson Goldman, gave appreciation announcement to Norma Hagenow, for her outstanding work and dedication while she served as the Vice-Chairperson and Chairperson of the Commission for many years. Commissioner James B. Falahee, Jr., JD. was introduced as a new Commissionmember, as well as Joseph Potchen who will be taking over for Mr. Styka from the Attorney General's office.

III. Review of Agenda

Motion by Commissioner Sandler, seconded by Commissioner Ajlunli, to approve the agenda as presented. Motion Carried.

IV. Declaration of Conflicts of Interest

Chairperson Goldman gave an overview of the conflict of interest. Commissioner Falahee identified a potential conflict. After discussion, it was determined that no conflict existed.

V. Review of Minutes – June 9, 2009

Motion by Commissioner Smith, seconded by Commissioner Young, to approve the minutes of June 9, 2009 as presented. Motion Carried.

VI. Pancreas Transplantation Services

Ms. Rogers gave an overview of the proposed language for Pancreas Transplantation Services. (Attachment A).

Public Comment:

Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment B)
Sean Gehle, St. John's Health System
Dennis McCafferty, Economic Alliance of Michigan

Motion by Commissioner Smith, seconded by Commissioner Keshishian, to approve the proposed language and move forward to the Governor and Joint Legislative Committee (JLC) for the 45-day review period. Motion Carried.

VII. Psychiatric Bed Services

Ms. Rogers gave an overview of the proposed language for Psychiatric Bed Services (Attachment C). Discussion followed.

Motion by Commissioner Smith, seconded by Commissioner Falahee, to approve the proposed language and move forward to the Governor and JLC for the 45-day review period. Motion Carried.

VIII. Magnetic Resonance Imaging (MRI) Services – Workgroup Report & Commission Discussion

Ms. Rogers gave an overview of the proposed language and technical changes for Magnetic Resonance Imaging (MRI) Services. (Attachment D)

Commissioner Sandler provided an overview of MRI simulators and provided joint testimony from Dr. Lawrence and Dr. Movsad. (Attachment E)

Public Comment:

Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment B)
Dennis McCafferty, Economic Alliance of Michigan

Discussion followed.

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to approve the proposed language for MRI simulators and move forward to the Governor and JLC for the 45-day review period. Motion Carried.

Motion by Commissioner Sandler, seconded by Commissioner Deremo, to approve the Department's technical changes and amendments and move forward to the Governor and JLC for the 45-day review period. Motion Carried.

Public Comment:

Alec Allen, Oaklawn Hospital
Dennis McCafferty, Economic Alliance of Michigan

On behalf of the Commission, Chairperson Goldman thanked Ron Styka for his years of service to the Commission and presented him with a plaque.

Discussion followed on the ER exemption for conversion of mobile to fixed. An amendment to Section 12 was shared with the Commission (Attachment F).

Recessed at 10:50 a.m. and reconvened at 11:17 a.m.

Motion by Commissioner Sandler, seconded Commissioner Deremo, to accept the language in Section 3 for the ER exemption for conversion of mobile to fixed and the amendment to Section 12 and move forward to the Governor and JLC for the 45-day review period. Motion Carried.

IX. Magnetic Resonance Imaging (MRI) Services – Workgroup Report & Commission Discussion

Commissioner Sandler provided a summary of the MRI Workgroup report.

Public Comment:

Dennis McCafferty, Economic Alliance of Michigan
Yahya Basha, M.D., Basha Diagnostics
Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment B)
Carrie Lindereth, Edge Partnerships
Lody Zwarensteijn, Alliance for Health
Sean Gehle, Ascension Health
Amy Barkholz, Michigan Health & Hospital Association

Discussion followed.

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to accept the concept and have the Department draft the language for the next meeting, and to obtain payer source data in the tri-county area. Yes – 6, No – 5, Abstention – 0. Motion Carried.

X. Bone Marrow Transplantation (BMT) Services – Standard Advisory Committee (SAC) Status Report

Chairperson VeCasey gave brief overview of the BMTSACs activity.

XI. Heart/Lung, and Liver (HLL) Services – SAC Status Report

Chairperson Ball gave brief overview of the HLLSACs activity.

XII. Standing New Medical Technology Advisory Committee (NEWTAC) - Report

Commissioner Keshishian gave a brief update of the NEWTAC activity.

XIII. Legislative Report

None.

XIV. Compliance Report

Mr. Lyon gave a brief overview of the compliance report. The written report will be provided to the Commissioners. (Attachment G)

XV. Administrative Update

Mr. Hart gave the administrative update.

XVI. CON Program Update

Mr. Horvath gave an overview of the following:

- A. Quarterly Performance Measures (Attachment H)
- B. Web CON Application System Update/Demo
- C. Web CON Annual Survey Update/Demo
- D. MDCH Health Facility Atlas Update
- E. Administrative Rules Update
- F. 2009 CON Seminar – October 27, 2009
- G. NASCIO Award (Attachment I)
- H. American Health Planning Association Chart (Attachment J)

XVII. Legal Activity Report

Mr. Potchen gave an overview of the Legal Activity Report (Attachment K)

XVIII. Future Meeting Dates –

December 9, 2009
January 28, 2010 (Special)
March 25, 2010
June 10, 2010
September 23, 2010
December 15, 2010

XIX. Public Comment

Dennis McCafferty, Economic Alliance of Michigan
James Pomeroy, Select Medical (Attachment L)

Amy Barkholz, Michigan Health & Hospital Association

XX. Review of Commission Work Plan

Ms. Rogers gave an overview of the Work Plan (Attachment M). Discussion followed.

Motion by Commissioner Smith, seconded by Commissioner Cory, to approve the Work Plan as presented and add Hospital Beds regarding the proposal by Select Medical and have the Department look at the issue and bring a report back to the December meeting. Motion Carried.

XXI. Election of Officer – Vice-Chairperson

Motion by Commissioner Young, seconded by Commissioner Keshishian, to nominate and elect Commissioner Smith as Vice-Chairperson to serve the remaining months of former Vice-Chairperson Hagenow's term. Motion Carried.

XXII. Adjournment

Motion by Commissioner Sandler, seconded by Commissioner Ajunli, to adjourn the meeting at 1:23 p.m. Motion Carried.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR PANCREAS 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 pancreas transplantation services.~~ PURSUANT TO PART 222 OF THE CODE.

~~(2) Pancreas transplantation is a covered clinical service for purposes of Part 222 of the Code.~~

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

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

Section 2. Definitions

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

(a) "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.

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

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

~~(d) "Implementation plan" means a plan that documents how a proposed pancreas 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 pancreas transplantation service including but not limited to the development of physical plant requirements such as an intensive care unit capable of treating immune-suppressed patients, equipment acquisition(s), 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 has previously been approved for a pancreas transplantation service where 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.~~

~~(eD) "Initiate" or "implement" for purposes of these standards, means the performance of the first transplant procedure. If the CON rules do not authorize a CON review standard to define the term of the certificate, the term shall be as provided in Rule 325.9403(1) and (2). If the CON rules do authorize a standard to define the term of a certificate, the term shall be 18 months or the extended period established by Rule 325.9403(2), if authorized.~~

~~(fE) "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.~~

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

(hG) "OPO" or "Organ Procurement Organization" means an organ procurement organization as defined by Title 42, Part 486.302.

(iH) "OPTN" or "Organ Procurement and Transplantation Network" means the organization contracted by the federal Department of Health and Human Services to operate the organ procurement and transplantation network.

(jI) "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 -- all applicants

Sec. 3. (1) An applicant proposing to perform a pancreas transplantation service shall demonstrate that it offers all of the following services or programs on site:

- (a) operating rooms;
- (b) anesthesiology;
- (c) microbiology and virology laboratory;
- (d) continuous availability, either on-site or on-call, of diagnostic imaging services including: (i) CT scanning, (ii) magnetic resonance imaging, and (iii) nuclear medicine;
- (e) continuous availability, either on-site or on-call, of a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support; cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology;
- (f) dialysis;
- (g) infectious disease;
- (h) inpatient-outpatient social work;
- (i) inpatient-outpatient psychiatry/psychology;
- (j) clinical research;
- (k) 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;
- (l) other support services, as necessary, such as physical therapy and rehabilitation medicine;
- (m) continuous availability of anatomic and clinical pathology and laboratory services including clinical chemistry, immuno-suppressive drug monitoring, and tissue typing;

- (n) continuous availability of red cells, platelets, and other blood components;
 (o) an established organ donation protocol, with brain death protocol, consistent with applicable Michigan law; and
 (p) a written agreement with Michigan's federally designated organ procurement organization (OPO) to promote organ donation at the applicant hospital(s).

(2) An applicant must provide, ~~at the time the CON application is submitted,~~ an implementation plan for the proposed pancreas transplantation service. IMPLEMENTATION PLAN MEANS A PLAN THAT DOCUMENTS HOW A PROPOSED PANCREAS 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:

(A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE PROPOSED PANCREAS 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 ACQUISITION(S), AND RECRUITMENT AND EMPLOYMENT OF ALL PHYSICIAN AND SUPPORT STAFF;

(B) THE TIME TABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN SUBSECTION (A); AND

(C) IF THE APPLICANT HAS PREVIOUSLY BEEN APPROVED FOR A PANCREAS TRANSPLANTATION SERVICE WHERE 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.

(3) An applicant for a pancreas transplantation service shall project a minimum of 42 pancreas transplantation procedures annually in the second 12 months of operation following the date on which the first pancreas transplant procedure is performed ~~and annually thereafter.~~

(4) An applicant proposing to provide a pancreas transplantation service shall demonstrate that it offers all of the following services or programs:

- (a) continuous availability, either on-site or on-call, of angiography;
- (b) an intensive care unit with 24 hour per day on-site physician coverage;
- (c) an on-site renal transplant service that has performed a minimum of 80 kidney transplants in the 2 most recent 12 month periods for which verifiable data are available; and
- (d) ophthalmology retinal eye service availability, either on site or on call.

(5) An applicant shall provide verification of Medicaid participation ~~at the time the application is submitted to the Department.~~ 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. ~~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 4. Project delivery requirements -- terms of approval for all applicants

Sec. 4. (1) An applicant shall agree that, if approved, the services 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 pancreas 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:

(i) The applicant shall perform A MINIMUM OF 2 PANCREAS TRANSPLANTATION PROCEDURES ANNUALLY IN THE SECOND 12 MONTHS OF OPERATION FOLLOWING THE DATE ON WHICH THE FIRST PANCREAS TRANSPLANT PROCEDURE IS PERFORMED~~the applicable required volumes within the time periods specified in these standards, and annually thereafter.~~

(II) THE APPLICANT SHALL PERFORM A MINIMUM OF 80 KIDNEY TRANSPLANTS AND/OR PANCREAS TRANSPLANTATION PROCEDURES BY THE SECOND 12 MONTHS OF OPERATION FOLLOWING THE DATE ON WHICH THE FIRST PANCREAS TRANSPLANT PROCEDURE IS PERFORMED AND BIENNIALY (EVERY TWO YEARS) THEREAFTER.

(iii) The applicant shall comply with applicable OPTN and Medicare requirements.

~~(iii)~~(V) The applicant shall have 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; and (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 five (5) years.

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

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

(vii) The applicant shall establish and maintain an active, formal multi-disciplinary research program related to the proposed pancreas transplantation service.

(viii) The applicant's education and research program related to pancreas transplantation shall be subject to external peer review.

~~(viii)~~X 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 state and national transplantation registries applicable to the pancreas transplantation service.

(ix) 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, through-put schedules, demographic and diagnostic information, patient survival rates at both 12 and 24 months following the transplant procedure, 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.

(xI) The applicant, to assure that the pancreas transplantation service 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.

(xiI) 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.

(xiiI) 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) An applicant shall agree to establish and maintain all of the following:

- (i) a written agreement with the federally approved organ procurement organization whose designated service area includes the location of the proposed pancreas transplantation service;
- (ii) organ preservation capability;
- (iii) an organized 24-hour transport system for transportation of organs, donors, and blood serum;
- (iv) an organized 24-hour communication service capable of serving the transplant team and others, as appropriate;
- (v) a laboratory with immunosuppression assay results available on the same day, as appropriate;
- (vi) an immunologic monitoring laboratory;
- (vii) a specialized inpatient pancreas transplantation unit or a combined inpatient renal and extrarenal transplantation unit;
- (viii) a medical staff and governing board policy that provides for the selection of candidates for organ transplantation procedures in accordance with the patient selection criteria approved by the Department;
- (ix) an ethics committee or human use committee to review and approve the institution's protocols related to organ transplantation, including protocols involving the selection of donors and recipients;
- (x) a multi-disciplinary transplant recipient evaluation committee;
- (xi) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization, either operated on-site or through written agreement;
- (xii) insulin, C-peptide, glycosylated hemoglobin assays;
- (xiii) glucometer glucose assay availability; and
- (xiv) electromyography.
- (e) An applicant shall agree that the pancreas transplantation service shall be staffed and provided by at least the following:
- (i) a transplant team leader and coordinator;
- (ii) transplant surgeons and physicians experienced with renal transplantation in diabetics;
- (iii) surgeons with demonstrated proficiency in major pancreatic surgery;
- (iv) both adult and pediatric surgeons, as appropriate;
- (v) qualified adult and pediatric, as appropriate, transplant surgeon(s) and transplant physician(s). For purposes of evaluating subsection (v), the Department shall consider it prima facie evidence as to the qualifications of the surgeon(s) and physician(s) if both the kidney and pancreas transplantation programs are approved by and a member in good standing of the OPTN;
- (vi) a pathologist capable of diagnosing pancreatic rejection; and
- (vii) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in conjunction with the transplantation service, trained in the hemodynamic support of transplant patients, and managing immuno-suppressed patients.
- (f) Compliance with the REVISED Uniform Anatomical Gift Law, ~~Act No. 186 of the Public Acts of 1986, being pursuant to MCL~~ Section 333.10101 et seq. of the Michigan Compiled Laws.

(2) An applicant must demonstrate pancreatic graft survival rates at one year and two years after transplantation of no less than the national average survival rate for the most recent year for which data is published by the OPTN.

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

Section 5. Documentation of projections

Sec. 5. 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 6. Effect on prior CON review standards; comparative reviews

Sec. 6. (1) These CON review standards supersede and replace the CON Review Standards for Pancreas Transplantation Services approved by the CON Commission on ~~September 26, 2002~~ MARCH 9, 2004 and effective on ~~December 23, 2002~~ JUNE 4, 2004.

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



Proposed MRI CON Standards continued

- o BCBSM supports the language that exempts MRI units used to simulate megavoltage radiation treatment for cancer. Our clinical group, the BCBSM/BCN collaborative, believes that this is an important component to effective treatment by providing for more accurate treatment planning, thus yielding higher quality services for patients.

To clarify our position, BCBSM/BCN supports final action on the MRI simulation language but does not support the ER or charity care language being moved forward.

Bone Marrow Transplant Standard Advisory Committee-Interim Report

As stated in previous testimony, BCBSM/BCN does not believe that there is any need for any additional BMT programs anywhere in the state, including information from SAC meeting discussions, such as trended data, input of clinician specialists and cost information.

At the last SAC meeting, BCBSM/BCN BMT SAC member Dr. Tom Ruane stated "BCBSM/BCN is not convinced that the improved access that would occur would outweigh the problems caused by decreased volume in the existing centers and we remained opposed." The Economic Alliance for Michigan, an organization to which we have been a longtime member and active participant has also addressed and upheld this concern.

Heart Liver Lung Transplant Standard Advisory Committee-Interim Report

Consistent with prior testimony, BCBSM and BCN believe that there has been no demonstration of need that merits the initiation of additional transplant programs anywhere in the state of Michigan. Thus, we support the recommendation that the current HLLT CON standard be retained with a cap of 3 programs in Michigan.

Conclusion

BCBSM/BCN continues to support the CON program and the ongoing review of the standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, by eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM/BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program to help ensure the delivery of high quality, safe and effective care to patients across the state.

9/9/09

**Blue Cross
Blue Shield**
Of Michigan



Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Commission Meeting
September 10, 2009

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to actively participate and support the Certificate of Need (CON) program, designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

Proposed Pancreas Transplant Standards

Over the past year, BCBSM/BCN professional and clinical staff members have been actively engaged with this issue. There have been meetings with many of the organizations interested in modifying the Pancreas Transplant CON review standards and staff members actively participated in the MDCH Pancreas Transplant Work Group.

BCBSM/BCN supports the proposed language. We believe that this language captures the connection between kidney and pancreas transplants, generating quality-driven programs by linking pancreas transplant programs to kidney transplant programs with high annual volume thresholds. In addition, these proposed standards help to retain the comprehensive role of Gift of Life as a Michigan-based organ procurement program. We urge the Commission to take final action on this standard.

Proposed MRI CON Standards

Beyond the concerns expressed previously regarding the transparency of the work group process in which we actively participated, BCBSM and BCN continue to oppose most proposed exemptions to the standards based on multiple exceptions weakening the standards as a whole and increasing the costs of health care service delivery. BCBSM/BCN's position follows, with one area of support noted:

- BCBSM/BCN does not support the proposed action to that allows replacement of a mobile MRI with a fixed MRI for any hospital emergency room with more than 20,000 visits per year. Based on the input of the BCBSM/BCN clinical collaborative, we feel that there is not public policy rationale for this approach as the majority of MRI services do not need to be completed immediately upon arrival in the emergency department, or there may be no capacity at such facilities to treat the findings of a positive MRI regardless if immediate scanning is indicated.
- BCBSM/BCN does not support replacing mobile MRI units with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their service to Medicaid-covered patients. This item was sent back to the work group with no consensus. There are many questions left to be addressed as to the validity of this proposal from a public policy rationale. This additional capacity would be in direct competition with existing hospital-based not for profit MRI units, including for patients having coverage other than Medicaid.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS

FOR PSYCHIATRIC BEDS AND 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 psychiatric beds and services.~~

~~(2) A psychiatric hospital or unit is a covered health facility for purposes of Part 222 of the Code.~~

~~(3) An increase in licensed psychiatric beds or the physical relocation from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.~~

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

~~(5) The Department shall use Sections 12 and 13, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

~~(6) The Department shall use Section 11 in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws~~

SEC. 1 THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL AND DELIVERY OF PSYCHIATRIC SERVICES UNDER PART 222 OF THE CODE. AN INCREASE IN LICENSED PSYCHIATRIC BEDS OR THE PHYSICAL RELOCATION FROM A LICENSED SITE TO ANOTHER GEOGRAPHIC LOCATION IS A CHANGE IN BED CAPACITY FOR THE PURPOSES OF PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE CODE, A PSYCHIATRIC HOSPITAL OR UNIT IS A COVERED HEALTH FACILITY. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE, BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION 22225(2)(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

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

(a) "Acquisition of a psychiatric hospital or unit" means the issuance of a new license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed psychiatric hospital or unit and which does not involve a change in the number of licensed psychiatric beds at that health facility.

(b) "Adult" means any individual aged 18 years or older.

(c) "Base year" means 1992 or the most recent year for which verifiable data are collected by the Department and are available separately for the population age cohorts of 0 to 17 and 18 and older.

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

- 54 (e) "Child/adolescent" means any individual less than 18 years of age.
- 55 (f) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et
56 seq. of the Michigan Compiled Laws.
- 57 (g) "Community mental health board" or "board" or "CMH" means the board of a county(s)
58 community mental health board as referenced in the provisions of MCL 330.1200 to 330.1246.
- 59 (h) "Comparative group" means the applications which have been grouped for the same type of
60 project in the same planning area and are being reviewed comparatively in accordance with the CON
61 rules.
- 62 (i) "Department" means the Michigan Department of Community Health (MDCH).
- 63 (j) "Department inventory of beds" means the current list maintained by the Department which
64 includes:
- 65 (i) licensed adult and child/adolescent psychiatric beds; and
- 66 (ii) adult and child/adolescent psychiatric beds approved by a valid CON, which are not yet licensed.
67 A separate inventory will be maintained for child/adolescent beds and adult beds.
- 68 (k) "Existing adult inpatient psychiatric beds" or "existing adult beds" means:
- 69 (i) all adult beds in psychiatric hospitals or units licensed by the Department pursuant to the Mental
70 Health Code;
- 71 (ii) all adult beds approved by a valid CON, which are not yet licensed;
- 72 (iii) proposed adult beds under appeal from a final Department decision, or pending a hearing from a
73 proposed decision; and
- 74 (iv) proposed adult beds that are part of a completed application (other than the application or
75 applications in the comparative group under review) which are pending final Department decision.
- 76 (l) "Existing child/adolescent inpatient psychiatric beds" or "existing child/adolescent beds" means:
- 77 (i) all child/adolescent beds in psychiatric hospitals or units licensed by the Department pursuant to
78 the Mental Health Code;
- 79 (ii) all child/adolescent beds approved by a valid CON, which are not yet licensed;
- 80 (iii) proposed child/adolescent beds under appeal from a final Department decision, or pending a
81 hearing from a proposed decision; and
- 82 (iv) proposed child/adolescent beds that are part of a completed application (other than the
83 application or applications in the comparative group under review) which are pending final Department
84 decision.
- 85 (m) "Initiation of service" means the establishment of an inpatient psychiatric unit with a specified
86 number of beds at a site not currently providing psychiatric services.
- 87 (n) "Involuntary commitment status" means a hospital admission effected pursuant to the provisions
88 of MCL 330.1423 to 330.1429.
- 89 (o) "Licensed site" means either:
- 90 (i) in the case of a single site hospital, the location of the facility authorized by license and listed on
91 that licensee's certificate of licensure; or
- 92 (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient
93 unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.
- 94 (p) "Medicaid" means title XIX of the Social Security Act, chapter 531, 49 Stat. 620, 1396r-6
95 and 1396r-8 to 1396v.
- 96 (q) "Mental Health Code" means Act 258 of the Public Acts of 1974, as amended, being Sections
97 330.1001 to 330.2106 of the Michigan Compiled Laws.
- 98 (r) "Mental health professional" means an individual who is trained and experienced in the area of
99 mental illness or developmental disabilities and who is any 1 of the following:
- 100 (i) a physician who is licensed to practice medicine or osteopathic medicine and surgery in Michigan
101 and who has had substantial experience with mentally ill, mentally retarded, or developmentally disabled
102 clients for 1 year immediately preceding his or her involvement with a client under administrative rules
103 promulgated pursuant to the Mental Health Code;
- 104 (ii) a psychologist who is licensed in Michigan pursuant to the provisions of MCL 333.16101 to
105 333.18838;

(iii) a licensed master's social worker licensed in Michigan Pursuant to the provisions of MCL 333.16101 to 333.18838;

(iv) a registered nurse who is licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(v) a licensed professional counsel or licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(vi) a marriage and family therapist licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838;

(vii) a professional person, other than those defined in the administrative rules promulgated pursuant to the Mental Health Code, who is designated by the Director of the Department or a director of a facility operated by the Department in written policies and procedures. This mental health professional shall have a degree in his or her profession and shall be recognized by his or her respective professional association as being trained and experienced in the field of mental health. The term does not include non-clinical staff, such as clerical, fiscal or administrative personnel.

(s) "Mental health service" means the provision of mental health care in a protective environment with mental illness or mental retardation, including, but not limited to, chemotherapy and individual and group therapies pursuant to MCL 330.2001.

(t) "Non-renewal or revocation of license" means the Department did not renew or revoked the psychiatric hospital's or unit's license based on the hospital's or unit's failure to comply with state licensing standards.

(u) "Non-renewal or termination of certification" means the psychiatric hospital's or unit's Medicare and/or Medicaid certification was terminated or not renewed based on the hospital's or unit's failure to comply with Medicare and/or Medicaid participation requirements.

(v) "Offer" means to provide inpatient psychiatric services to patients.

(w) "Physician" means an individual licensed in Michigan to engage in the practice of medicine or osteopathic medicine and surgery pursuant to MCL 333.16101 to 333.18838.

(x) "Planning area" means the geographic boundaries of the groups of counties shown in Section 15.

(y) "Planning year" means 1990 or a year in the future, at least 3 years but no more than 7 years, established by the CON Commission for which inpatient psychiatric bed needs are developed. The planning year shall be a year for which official population projections from the Department of Management and Budget are available.

(z) "Psychiatric hospital" means an inpatient program operated by the Department for the treatment of individuals with serious mental illness or serious emotional disturbance or a psychiatric hospital or psychiatric unit licensed under Section 137, pursuant to MCL 330.1100.

(aa) "Psychiatrist" means 1 or more of the following, pursuant to MCL 330.1100:

(i) a physician who has completed a residency program in psychiatry approved by the Accreditation Council for Graduate Medical Education or The American Osteopathic Association, or who has completed 12 months of psychiatric rotation and is enrolled in an approved residency program;

(ii) a psychiatrist employed by or under contract with the Department or a community health services program on March 28, 1996;

(iii) a physician who devotes a substantial portion of his or her time to the practice of psychiatry and is approved by the Director.

(bb) "Psychiatric unit" means a unit of a general hospital that provides inpatient services for individuals with serious mental illness or serious emotional disturbances pursuant to MCL 330.1100.

(cc) "Psychologist" means an individual licensed to engage in the practice of psychology, who devotes a substantial portion of his or her time to the diagnosis and treatment of individuals with serious mental illness, serious emotional disturbance, or developmental disability, pursuant to MCL 333.16101 to 333.18838.

(dd) "Public patient" means an individual approved for mental health services by a CMH or an individual who is admitted as a patient under Section 423, 429, or 438 of the Mental Health Code, Act No. 258 of the Public Acts of 1974, being Sections 330.1423, 330.1429, and 330.1438 of the Michigan Compiled Laws.

(ee) "Qualifying project" means each application in a comparative group which 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.

(ff) "Registered professional nurse" or "R.N." means an individual licensed in Michigan pursuant to the provisions of MCL 333.16101 to 333.18838.

(gg) "Replacement beds" means beds in a psychiatric hospital or unit which meet all of the following conditions:

(i) an equal or greater number of beds are currently licensed to the applicant at the current licensed site;

(ii) the beds are proposed for replacement in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, or other comparable arrangement); and

(iii) the beds to be replaced will be located in the replacement zone.

(hh) "Replacement zone" means a proposed licensed site which is:

(i) in the same planning area as the existing licensed site; and

(ii) on the same site, on a contiguous site, or on a site within 15 miles of the existing licensed site.

(ii) "Social worker" means an individual registered in Michigan to engage in social work under the provisions of MCL 333.18501.

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

Section 3. Determination of needed inpatient psychiatric bed supply

Sec. 3. (1) Until changed by the Commission in accordance with Section 4(3) and Section 5, the use rate for the base year for the population age 0-17 is set forth in Appendix D.

(2) The number of child/adolescent inpatient psychiatric beds needed in a planning area shall be determined by the following formula:

(a) Determine the population for the planning year for each separate planning area for the population age 0-17.

(b) Multiply the population by the use rate established in Appendix D. The resultant figure is the total patient days.

(c) Divide the total patient days obtained in subsection (b) by 365 (or 366 for leap years) to obtain the projected average daily census (ADC).

(d) Divide the ADC by 0.75.

(e) For each planning area, all psychiatric hospitals or units with an average occupancy of 60% or less for the previous 24 months will have the ADC, for the previous 24 months, multiplied by 1.7. The net decrease from the current licensed beds will give the number to be added to the bed need.

(f) The adjusted bed need for the planning area is the sum of the results of subsections (d) and (e).

(3) The number of needed adult inpatient psychiatric beds shall be determined by multiplying the population aged 18 years and older for the planning year for each planning area by either:

(a) The ratio of adult beds per 10,000 adult population set forth in Appendix C; or

(b) The statewide ratio of adult beds per 10,000 adult population set forth in Appendix C, whichever is lower; and dividing the result by 10,000. If the ratio set forth in Appendix C for a specific planning area is "0", the statewide ratio of adult beds per 10,000 adult population shall be used to determine the number of needed adult inpatient psychiatric beds.

(c) For each planning area, an addition to the bed need will be made for low occupancy facilities. All psychiatric hospitals or units with an average occupancy of 60% or less for the previous 24 months will have the ADC, for the previous 24 months, multiplied by 1.5. The net decrease from the current licensed beds will give the number to be added to the bed need.

(d) The adjusted bed need for the planning area is the sum of the results of subsections (b) and (c).

Section 4. Bed need for inpatient psychiatric beds

Sec. 4. (1) For purposes of these standards, until otherwise changed by the Commission, the bed need numbers determined pursuant to Section 3, incorporated as part of these standards as Appendices A and B, as applicable, shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Department shall apply the bed need methodologies in Section 3 on a biennial basis.

(3) The Commission shall designate the planning year, and, for child/adolescent beds, the base year, which shall be utilized in applying the bed need methodologies pursuant to subsection (2).

(4) The effective date of the bed need numbers shall be established by the Commission.

(5) New bed need numbers established by subsections (2) and (3) shall supercede the bed need numbers shown in Appendices A and B and shall be included as amended appendices to these standards.

(6) Modifications made by the Commission pursuant to this Section shall not require Standard Advisory Committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 5. Modification of the child/adolescent use rate by changing the base year

Sec. 5. (1) The Commission may modify the base year based on data obtained from the Department and presented to the Commission. The Department shall calculate the use rate for the population age 0-17 and biennially present the revised use rate based on the most recent base year information available biennially to the CON Commission.

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

(3) Modifications made by the Commission pursuant to subsection (1) shall not require Standard Advisory Committee action, a public hearing, or submittal of the standard to the Legislature and the Governor in order to become effective.

Section 6. Requirements for approval to initiate service

Sec. 6. An applicant proposing the initiation of an adult or child/adolescent psychiatric service shall demonstrate or provide the following:

(1) The number of beds proposed in the CON application cannot result in the number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area exceeding the bed need set forth in Appendix A or B, as applicable. However, an applicant may request and be approved for up to a maximum of 10 beds if, when the total number of existing adult beds or existing child/adolescent beds is subtracted from the bed need for the planning area set forth in Appendix A or B, the difference is equal to or more than 1 or less than 10.

(2) A written recommendation, from the Department or the CMH that serves the county in which the proposed beds or service will be located, which shall include an agreement to enter into a contract to meet the needs of the public patient. At a minimum, the letter of agreement shall specify the number of

beds to be allocated to the public patient and the applicant's intention to serve patients with an involuntary commitment status.

(3) The number of beds proposed in the CON application to be allocated for use by public patients shall not be less than 50% of the beds proposed in the CON application. Applications proposed in direct response to a Department plan pursuant to subsection (5) shall allocate not less than 80% of the beds proposed in the CON application.

(4) The minimum number of beds in a psychiatric unit shall be at least 10 beds. If a psychiatric unit has or proposes to operate both adult and child/adolescent beds, each unit shall have a minimum of 10 beds. The Department may approve an application for a unit of less than 10 beds, if the applicant demonstrates to the satisfaction of the Department, that travel time to existing units would significantly limit access to care.

(5) An applicant shall not be required to be in compliance with subsection (1) if the applicant demonstrates that the application meets both of the following:

(a) The Director of the Department determines that an exception to subsection (1) should be made and certifies in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital; and

(b) The proposed beds will be located in the area currently served by the public institution that will be closed, as determined by the Department.

Section 7. Requirements for approval to increase beds

Sec. 7 An applicant proposing an increase in the number of adult or child/adolescent beds shall demonstrate or provide the following:

(1) The number of beds proposed in the CON application will not result in the number of existing adult or child/adolescent psychiatric beds, as applicable, in the planning area exceeding the bed need set forth in Appendix A or B, as applicable. However, an applicant may request and be approved for up to a maximum of 10 beds if, when the total number of existing adult beds or existing child/adolescent beds is subtracted from the bed need for the planning area set forth in Appendix A or B, the difference is equal to or more than 1 or less than 10.

(2) The average occupancy rate for the applicant's facility, where the proposed beds are to be located, was at least 70% for adult or child/adolescent beds, as applicable, during the most recent, consecutive 24 month period, as of the date of the submission of the application, for which verifiable data are available to the Department.

(3) Subsections (1) and (2) shall not apply if the ~~applicant meets the following~~ **ARE MET:**

(A) THE NUMBER OF EXISTING ADULT OR CHILD/ADOLESCENT PSYCHIATRIC BEDS IN THE PLANNING AREA IS EQUAL TO OR EXCEEDS THE BED NEED SET FORTH IN APPENDIX A OR B, AS APPLICABLE;

(aB) the beds are being added at the existing licensed site;

(bC) the average occupancy rate for the applicant's facility was at least 75% for facilities with 19 beds or less and 80% for facilities with 20 beds or more, as applicable, during the most recent, consecutive 24 month period, as of the date of the submission of the application, for which verifiable data are available to the Department;

(eD) the number of beds being added shall not exceed the results of the following formula: the facility's average daily census for the most recent, consecutive 24 month period, as of the date of the submission of the application, for which verifiable data are available to the Department multiplied by 1.5 for adult beds and 1.7 for child/adolescent beds.

(4) Proof of current contract or documentation of contract renewal, if current contract is under negotiation, with at least one CMH or its designee that serves the planning area in which the proposed beds or service will be located.

(5) Previously made commitments, if any, to the Department or CMH to serve public patients have been fulfilled.

(6) The number of beds proposed in the CON application to be allocated for use by public patients shall not be less than 50% of the beds proposed in the CON application. Applications proposed in direct response to a Department plan pursuant to subsection (9) shall allocate not less than 80% of the beds proposed in the CON application.

(7) The minimum number of beds in a psychiatric unit shall be at least 10 beds. If a psychiatric unit has or proposes to operate both adult and child/adolescent beds, then each unit shall have a minimum of 10 beds. The Department may approve an application for a unit of less than 10 beds, if the applicant demonstrates, to the satisfaction of the Department, that travel time to existing units would significantly impair access to care.

(8) Subsection (2) shall not apply if the Director of the Department has certified in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital.

(9) An applicant shall not be required to be in compliance with subsection (1) if the applicant demonstrates that the application meets both of the following:

(a) The Director of the Department determines that an exception to subsection (1) should be made and certifies in writing that the proposed project is a direct response to a Department plan for reducing the use of public institutions for acute mental health care through the closure of a state-owned psychiatric hospital; and

(b) The proposed beds will be located in the area currently served by the public institution that will be closed as determined by the Department.

Section 8. Requirements for approval for replacement beds

Sec. 8. An applicant proposing replacement beds shall not be required to be in compliance with the needed bed supply set forth in Appendix A or B, as applicable, if the applicant demonstrates all of the following:

(1) The project proposes to replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently located.

(2) The proposed licensed site is in the replacement zone.

~~(3) The applicant meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.~~

(43) Not less than 50% of the beds proposed to be replaced shall be allocated for use by public patients.

(54) Previously made commitments, if any, to the Department or CMH to serve public patients have been fulfilled.

(65) Proof of current contract or documentation of contract renewal, if current contract is under negotiation, with the CMH or its designee that serves the planning area in which the proposed beds or service will be located.

Section 9. Requirements for approval for acquisition of a psychiatric hospital or unit

Sec. 9. An applicant proposing to acquire a psychiatric hospital or unit shall not be required to be in compliance with the needed bed supply set forth in Appendix A or B, as applicable, for the planning area in which the psychiatric hospital or unit subject to the proposed acquisition is located, if the applicant demonstrates that all of the following are met:

(1) The acquisition will not result in a change in the number of licensed beds or beds designated for a child/adolescent specialized psychiatric program.

(2) The licensed site does not change as a result of the acquisition.

Section 10. Additional requirements for applications included in comparative review

Sec. 10. (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 review.

(2) 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 (3) 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.

(3)(a) A qualifying project application will be awarded 5 points if, within six months of beginning operation and annually thereafter, 100% of the licensed psychiatric beds (both existing and proposed) at the facility will be Medicaid certified.

(b) A qualifying project will have 4 points deducted if, on or after November 26, 1995, the records maintained by the Department document that the applicant was required to enter into a contract with either the Department or a CMH to serve the public patient and did not do so.

(c) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records maintained by the Department document that the applicant entered into a contract with MDCH or CMH but never admitted any public patients referred pursuant to that contract.

(d) A qualifying project will have 5 points deducted if, on or after November 26, 1995, the records maintained by the Department document that an applicant agreed to serve patients with an involuntary commitment status but has not admitted any patients referred with an involuntary commitment status.

(e) A qualifying project will be awarded 3 points if the applicant presents, in its application, a plan, acceptable to the Department, for the treatment of patients requiring long-term treatment. For purposes of this subsection, long-term treatment is defined to mean an inpatient length of stay in excess of 45 days.

(f) A qualifying project will be awarded 3 points if the applicant currently provides a partial hospitalization psychiatric program, outpatient psychiatric services, or psychiatric aftercare services, or

the applicant includes any of these services as part of their proposed project, as demonstrated by site plans and service contracts.

(g) A qualifying project will have 4 points deducted if the Department has issued, within three years prior to the date on which the CON application was deemed submitted, a temporary permit or provisional license due to a pattern of licensure deficiencies at any psychiatric hospital or unit owned or operated by the applicant in this state.

(h) A qualifying project will have points awarded based on the percentage of the hospital's indigent volume as set forth in the following table.

<u>Hospital Indigent Volume</u>	<u>Points Awarded</u>
0 - <6%	1
6 - <11%	2
11 - <16%	3
16 - <21%	4
21 - <26%	5
26 - <31%	6
31 - <36%	7
36 - <41%	8
41 - <46%	9
46% +	10

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 Department pursuant to Chapter VIII of the Medical Assistance Program 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.

(i) A qualifying project will have points deducted based on the applicant's record of compliance with applicable safety and operating standards for any psychiatric hospital or unit owned and/or operated by the applicant in this state. Points shall be deducted in accordance with the following schedule if, on or after November 26, 1995, the Department records document any non-renewal or revocation of license for cause or non-renewal or termination of certification for cause of any psychiatric hospital or unit owned or operated by the applicant in this state.

<u>Psychiatric Hospital/Unit Compliance Action</u>	<u>Points Deducted</u>
Non-renewal or revocation of license	4
Non-renewal or termination of:	
Certification - Medicare	4
Certification - Medicaid	4

(4) ~~The minimum number of points will be awarded to an applicant under the individual subsections of this Section for conflicting information presented in this Section and related information provided in other Sections of the CON application.~~ **SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT AWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE**

LOWER POINT VALUE THAT COULD BE AWARDED FROM THE CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED.

Section 11. Requirements for approval for all applicants

Sec. 11. (1) 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.

(2) THE APPLICANT CERTIFIES ALL OUTSTANDING DEBT OBLIGATIONS OWED TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL MONETARY PENALTIES (CMP) HAVE BEEN PAID IN FULL.

(3) THE APPLICANT CERTIFIES THAT THE HEALTH FACILITY FOR THE PROPOSED PROJECT HAS NOT BEEN CITED FOR A STATE OR FEDERAL CODE DEFICIENCY WITHIN THE 12 MONTHS PRIOR TO THE SUBMISSION OF THE APPLICATION. IF A CODE DEFICIENCY HAS BEEN ISSUED, THEN THE APPLICANT SHALL CERTIFY THAT A PLAN OF CORRECTION FOR CITED STATE OR FEDERAL CODE DEFICIENCIES AT THE HEALTH FACILITY HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT OR AS APPLICABLE, THE CENTERS FOR MEDICARE AND MEDICAID SERVICES. IF CODE DEFICIENCIES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT OR THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THAT ARE THE BASIS FOR THE DENIAL, SUSPENSION, OR REVOCATION OF AN APPLICANT'S HEALTH FACILITY LICENSE, POSES AN IMMEDIATE JEOPARDY TO THE HEALTH AND SAFETY OF PATIENT, OR MEETS A FEDERAL CONDITIONAL DEFICIENCY LEVEL, THE PROPOSED PROJECT CANNOT BE APPROVED WITHOUT APPROVAL FROM THE BUREAU OF HEALTH SYSTEMS.

Section 12. Project delivery requirements - terms of approval for all applicants

Sec. 12. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable operating standards in the Mental Health Code or the administrative rules promulgated there under.
- (c) Compliance with the following applicable quality assurance standards:
 - (i) The average occupancy rate for all licensed beds at the psychiatric hospital or unit shall be at least 60 percent (%) for adult beds and 40 percent (%) for child/adolescent beds for the second 12 months of operation, and annually thereafter. After the second 12 months of operation, if the average occupancy rate is below 60% for adult beds or 40% for child/adolescent beds, the number of beds shall be reduced to achieve a minimum of 60% average annual occupancy for adult beds or 40% annual average occupancy for child/adolescent beds for the revised licensed bed complement. However, the psychiatric hospital or unit shall not be reduced to less than 10 beds.

(ii) The proposed licensed psychiatric beds shall be operated in a manner that is appropriate for a population with the ethnic, socioeconomic, and demographic characteristics including the developmental stage of the population to be served.

(iii) The applicant shall establish procedures to care for patients who are disruptive, combative, or suicidal and for those awaiting commitment hearings, and the applicant shall establish a procedure for obtaining physician certification necessary to seek an order for involuntary treatment for those persons that, in the judgment of the professional staff, meet the Mental Health Code criteria for involuntary treatment.

(iv) The applicant shall develop a standard procedure for determining, at the time the patient first presents himself or herself for admission or within 24 hours after admission, whether an alternative to inpatient psychiatric treatment is appropriate.

(v) The inpatient psychiatric hospital or unit shall provide clinical, administrative, and support services that will be at a level sufficient to accommodate patient needs and volume, and will be provided seven days a week to assure continuity of services and the capacity to deal with emergency admissions.

(vi) 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, and demographic, diagnostic, morbidity and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each 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.

(vii) The applicant shall provide the Department with a notice stating the date the beds or services are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(viii) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(A) Not deny acute inpatient mental health services to any individual based on ability to pay, source of payment, age, race, handicap, national origin, religion, gender, sexual orientation or commitment status;

(B) Provide acute inpatient mental health services to any individual based on clinical indications of need for the services;

(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.

(ix) An applicant required to enter into a contract with a CMH(s) or the Department pursuant to these standards shall have in place, at the time the approved beds or services become operational, a signed contract to serve the public patient. The contract must address a single entry and exit system including discharge planning for each public patient. The contract shall specify that at least 50% or 80% of the approved beds, as required by the applicable sections of these standards, shall be allocated to the public patient, and shall specify the hospital's or unit's willingness to admit patients with an involuntary commitment status. The contract need not be funded.

(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.

(2) Compliance with this Section shall be determined by the Department based on a report submitted by the applicant and/or other information available to the Department.

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

Section 13. Project delivery requirements - additional terms of approval for child/adolescent service

Sec. 13. (1) In addition to the provisions of Section 12, an applicant for a child/adolescent service shall agree to operate the program in compliance with the following terms of CON approval, as applicable:

(a) There shall be at least the following child and adolescent mental health professionals employed, either directly or by contract, by the hospital or unit, each of whom must have been involved in the delivery of child/adolescent mental health services for at least 2 years within the most recent 5 years:

- (i) a child/adolescent psychiatrist;
- (ii) a child psychologist;
- (iii) a psychiatric nurse;
- (iv) a psychiatric social worker;
- (v) an occupational therapist or recreational therapist; and

(b) There shall be a recipient rights officer employed by the hospital or the program.

(c) The applicant shall identify a staff member(s) whose assigned responsibilities include discharge planning and liaison activities with the home school district(s).

(d) There shall be the following minimum staff employed either on a full time basis or on a consulting basis:

- (i) a pediatrician;
- (ii) a child neurologist;
- (iii) a neuropsychologist;
- (iv) a speech and language therapist;
- (v) an audiologist; and
- (vi) a dietitian.

(e) A child/adolescent service shall have the capability to determine that each inpatient admission is the appropriate treatment alternative consistent with Section 498e of the Mental Health Code, being Section 330.1498e of the Michigan Compiled Laws.

(f) The child/adolescent service shall develop and maintain a coordinated relationship with the home school district of any patient to ensure that all public education requirements are met.

(g) The applicant shall demonstrate that the child/adolescent service is integrated within the continuum of mental health services available in its planning area by establishing a formal agreement with the CMH(s) serving the planning area in which the child/adolescent specialized psychiatric program is located. The agreement shall address admission and discharge planning issues which include, at a minimum, specific procedures for referrals for appropriate community services and for the exchange of information with the CMH(s), the probate court(s), the home school district, the Michigan Department of Human Services, the parent(s) or legal guardian(s) and/or the patient's attending physician.

(2) Compliance with this Section shall be determined by the Department based on a report submitted by the program and/or other information available to the Department.

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

Section 14. Department inventory of beds

Sec. 14. The Department shall maintain, and provide on request, a listing of the Department Inventory of Beds for each adult and child/adolescent planning area.

Section 15. Planning areas

Sec. 15. The planning areas for inpatient psychiatric beds are the geographic boundaries of the groups of counties as follows.

Planning Areas

Counties

- | | |
|---|--|
| 1 | Livingston, Macomb, Monroe, Oakland, St. Clair, Washtenaw, Wayne |
| 2 | Clinton, Eaton, Hillsdale, Ingham, Jackson, Lenawee |

629	3	Barry, Berrien, Branch, Calhoun, Cass, Kalamazoo, St. Joseph, Van
630		Buren
631		
632	4	Allegan, Ionia, Kent, Lake, Mason, Montcalm, Muskegon, Newaygo,
633		Oceana, Ottawa
634		
635	5	Genesee, Lapeer, Shiawassee
636		
637	6	Arenac, Bay, Clare, Gladwin, Gratiot, Huron, Iosco, Isabella, Midland,
638		Mecosta, Ogemaw, Osceola, Oscoda, Saginaw, Sanilac, Tuscola
639		
640	7	Alcona, Alpena, Antrim, Benzie, Charlevoix, Cheboygan, Crawford,
641		Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee,
642		Montmorency, Otsego, Presque Isle, Roscommon, Wexford
643		
644	8	Alger, Baraga, Chippewa, Delta, Dickinson, Gogebic, Houghton, Iron,
645		Keweenaw, Luce, Mackinac, Marquette, Menominee, Ontonagon,
646		Schoolcraft
647		

Section 16. Effect on prior CON review standards; comparative reviews

Sec. 16. (1) These CON review standards supercede and replace the CON Review Standards for Psychiatric Beds and Services, approved by the CON Commission on ~~June 22, 2005~~ DECEMBER 11, 2007 and effective on ~~October 17, 2005~~ FEBRUARY 25, 2008.

(2) Projects involving replacement beds or an increase in beds, approved pursuant to Section 7(3), are reviewed under these standards and shall not be subject to comparative review.

(3) Projects involving initiation of services or an increase in beds, approved pursuant to Section 7(1), are reviewed under these standards and shall be subject to comparative review.

APPENDIX A

**CON REVIEW STANDARDS
FOR CHILD/ADOLESCENT PSYCHIATRIC BEDS**

The bed need numbers, for purposes of these standards until otherwise changed by the Commission, are as follows:

Planning Area	Bed Need
1	109 <u>113</u>
2	12
3	20 <u>22</u>
4	40 <u>26</u>
5	20 <u>11</u>
6	17 <u>14</u>
7	8 <u>7</u>
8	5
TOTAL	234 <u>210</u>

APPENDIX B**CON REVIEW STANDARDS
FOR ADULT PSYCHIATRIC BEDS**

The bed need numbers, for purposes of these standards until otherwise changed by the Commission, are as follows:

PLANNING AREA	BED NEED
1	1011 <u>967</u>
2	170 <u>179</u>
3	186
4	282 <u>283</u>
5	172 <u>153</u>
6	101 <u>96</u>
7	51 <u>52</u>
8	37 <u>38</u>
TOTAL	2010 <u>1,954</u>

APPENDIX C

**RATIO OF ADULT INPATIENT PSYCHIATRIC
BEDS PER 10,000 ADULT POPULATION**

THE RATIO PER 10,000 ADULT POPULATION, FOR PURPOSES OF THESE STANDARDS, UNTIL
OTHERWISE CHANGED BY THE COMMISSION, IS AS FOLLOWS:

PLANNING AREA	ADULT BEDS PER 10,000 ADULT POPULATION
1	2.9524 <u>2.8516</u>
2	2.3372 <u>2.3906</u>
3	2.4239 <u>2.3950</u>
4	2.4423 <u>2.4095</u>
5	2.9853 <u>3.2442</u>
6	1.3419 <u>1.3483</u>
7	1.2070 <u>1.1977</u>
8	1.4938 <u>1.4781</u>
STATE	2.5342 <u>2.4903</u>

APPENDIX D

CON REVIEW STANDARDS
FOR CHILD/ADOLESCENT INPATIENT PSYCHIATRIC BEDS

The use rate per 1000 population age 0-17, for purposes of these standards, until otherwise changed by the Commission, is ~~18.53~~ 20.8898.

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, 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 13, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.~~

SEC. 1 THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL OF THE INITIATION, EXPANSION, REPLACEMENT, RELOCATION, OR ACQUISITION OF MRI SERVICES AND THE DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE CODE, MRI IS A COVERED CLINICAL SERVICE. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE, BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION 22225(2)(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

Section 2. Definitions

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

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

(b) "Actual MRI adjusted procedures," for purposes of sections 16 and 17, means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 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~~MRI SERVICE UTILIZATION List," as of the date an application is deemed complete by the Department.

(c) "Available MRI adjusted procedures," ~~for purposes of Section 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 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 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 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 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"~~ INSTITUTIONAL review board" OR "IRB" means an institutional review board as defined by Public Law 93-348 that is regulated by Title 45 CFR 46.
- (w) "Intra-operative magnetic resonance imaging" or "IMRI" means the integrated use of MRI technology during surgical and interventional procedures within a licensed operative environment.
- (x) "Licensed hospital site" means 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~~ HOSPITAL 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.~~
- (y) "Magnetic resonance IMAGING" or "MRI" means the analysis of the interaction that occurs between radio frequency energy, atomic nuclei, and strong magnetic fields to produce cross sectional images similar to those displayed by computed tomography (CT) but without the use of ionizing radiation.
- (z) ~~"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 14.
- (aa) ~~"Magnetic resonance imaging database" or~~ "MRI database" means the database, maintained by the Department pursuant to Section 13 of these standards, that collects information about each MRI visit at MRI services located in Michigan.
- (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- IRB~~. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section 9(1).
- (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.
- (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. THE TERM DOES NOT INCLUDE MRI SIMULATORS USED SOLEY FOR TREATMENT PLANNING PURPOSES IN CONJUNCTION WITH AN MRT UNIT.
- (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.
- (ff) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.
- (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.
- (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.
- (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.

(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.

(kk) "Pediatric patient," ~~for purposes of these standards, except for Section 10,~~ means a patient who is 12 years of age or less, **EXCEPT FOR SECTION 9.**

(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 76(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 14(2)(d), the health service area in which all the proposed mobile host sites will be located.

(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.

(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.

(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.

(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.

(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.

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

(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.

(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.

(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).

(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.

(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.

(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.

(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 14.

(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. AN APPLICANT PROPOSING TO INITIATE AN MRI SERVICE OR A HOST SITE SHALL DEMONSTRATE THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

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

(2) AN APPLICANT PROPOSING TO INITIATE A FIXED MRI SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1):

(A) THE APPLICANT IS CURRENTLY AN EXISTING HOST SITE.

(B) THE APPLICANT HAS RECEIVED IN AGGREGATE, ONE OF THE FOLLOWING:

(I) AT LEAST 6,000 MRI ADJUSTED PROCEDURES, OR,

(II) AT LEAST 4,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF THE FOLLOWING:

(A) IS LOCATED IN A COUNTY THAT HAS NO FIXED MRI MACHINES THAT ARE PENDING, APPROVED BY THE DEPARTMENT, OR OPERATIONAL AT THE TIME THE APPLICATION IS DEEMED SUBMITTED.

(B) THE NEAREST FIXED MRI MACHINE IS LOCATED MORE THAN 15 RADIUS MILES FROM THE APPLICATION SITE.

(III) AT LEAST 3,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF THE FOLLOWING:

(A) THE PROPOSED SITE IS A HOSPITAL LICENSED UNDER PART 215 OF THE CODE.

(B) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AT LEAST 20,000 VISITS WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.

(C) ALL OF THE MRI ADJUSTED PROCEDURES FROM THE MOBILE MRI SERVICE REFERENCED IN (B) SHALL BE UTILIZED EVEN IF THE AGGREGATED DATA EXCEEDS THE MINIMUM REQUIREMENTS.

(D) THE APPLICANT SHALL INSTALL THE FIXED MRI UNIT AT THE SAME SITE AS THE EXISTING HOST SITE OR WITHIN THE RELOCATION ZONE. **IF APPLYING PURSUANT TO SECTION 3(2)(B)(III), THE APPLICANT SHALL INSTALL THE FIXED MRI UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.**

(E) THE APPLICANT SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE AND ITS UNIT BECOMES OPERATIONAL.

(23)(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,~~ **AND THE APPLICANT SHALL MEET THE FOLLOWING: per proposed unit result from application of the methodology in Section 16 of these standards.**

(A) IDENTIFY THE PROPOSED ROUTE SCHEDULE AND PROCEDURES FOR HANDLING EMERGENCY SITUATIONS.

(B) SUBMIT COPIES OF ALL PROPOSED CONTRACTS FOR THE PROPOSED HOST SITE RELATED TO THE MOBILE MRI SERVICE.

(C) IDENTIFY A MINIMUM OF TWO (2) HOST SITES FOR THE PROPOSED SERVICE.

~~(b4) The AN applicant, whether the central service coordinator or the host site, PROPOSING TO INITIATE A HOST SITE ON A NEW OR EXISTING MOBILE MRI SERVICE SHALL must demonstrate THE FOLLOWING, AS APPLICABLE: 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 16 of these standards, for each proposed host site that~~

(A) 600 AVAILABLE MRI ADJUSTED PROCEDURES, FROM WITHIN THE SAME PLANNING AREA AS THE PROPOSED SERVICE/UNIT, FOR A PROPOSED HOST SITE THAT IS NOT LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY, OR

(B) 400 AVAILABLE MRI ADJUSTED PROCEDURES FROM WITHIN THE SAME PLANNING AREA FOR A PROPOSED HOST SITE THAT IS LOCATED IN A RURAL OR MICROPOLITAN STATISTICAL AREA COUNTY, AND

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

~~(ii)~~ **(C) THE PROPOSED HOST SITE** has not received any mobile MRI service within the most recent 12-month period as of the date an application is submitted to the Department.

~~(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 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 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 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: AN APPLICANT PROPOSING TO ADD OR CHANGE SERVICE ON AN EXISTING MOBILE MRI SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (4) AND SHALL MEET EACH OF THE FOLLOWING:~~

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

~~(B) SUBMIT COPIES OF ALL PROPOSED CONTRACTS FOR THE PROPOSED HOST SITE RELATED TO THE MOBILE MRI SERVICE.~~

~~(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 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.~~

~~(6) THE APPLICANT SHALL DEMONSTRATE THAT THE AVAILABLE MRI ADJUSTED PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED AVAILABLE MRI ADJUSTED PROCEDURES LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.~~

SECTION 4. REQUIREMENTS TO REPLACE AN EXISTING MRI UNIT.

SEC 4 AN APPLICANT PROPOSING TO REPLACE AN EXISTING MRI UNIT SHALL DEMONSTRATE THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(1) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTED PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

(A) EACH EXISTING MOBILE MRI UNIT ON THE NETWORK HAS PERFORMED AT LEAST AN AVERAGE OF 5,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.

(B) EACH EXISTING FIXED MRI UNIT AT THE CURRENT SITE HAS PERFORMED AT LEAST AN AVERAGE OF 6,000 MRI ADJUSTED PROCEDURES PER MRI UNIT.

(C) EACH EXISTING DEDICATED PEDIATRIC MRI UNIT AT THE CURRENT SITE HAS PERFORMED AT LEAST AN AVERAGE OF 3,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.

(2) EQUIPMENT THAT IS REPLACED SHALL BE REMOVED FROM SERVICE AND DISPOSED OF OR RENDERED CONSIDERABLY INOPERABLE ON OR BEFORE THE DATE THAT THE REPLACEMENT EQUIPMENT BECOMES OPERATIONAL.

(3) THE REPLACEMENT UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS THE REQUIREMENTS OF THE RELOCATION SECTION HAVE BEEN MET.

(4) 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.

Section 45. 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 14 and as documented in accordance with Section 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 14 and as documented in accordance with Section 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 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).~~

SEC 5. AN APPLICANT PROPOSING TO EXPAND AN EXISTING MRI SERVICE SHALL DEMONSTRATE THE FOLLOWING:

(1) AN APPLICANT SHALL DEMONSTRATE THAT THE APPLICABLE MRI ADJUSTABLE PROCEDURES ARE FROM THE MOST RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE OF AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT:

(A) EACH EXISTING MRI UNIT ON THE NETWORK HAS PERFORMED AT LEAST AN AVERAGE OF 9,000 MRI ADJUSTED PROCEDURES PER MRI UNIT.

(B) EACH EXISTING FIXED MRI UNIT AT THE CURRENT SITE HAS PERFORMED AT LEAST AN AVERAGE OF 11,000 MRI ADJUSTED PROCEDURES PER MRI UNIT.

(C) EACH EXISTING DEDICATED PEDIATRIC MRI UNIT AT THE CURRENT SITE HAS PERFORMED AT LEAST AN AVERAGE OF 3,500 MRI ADJUSTED PROCEDURES PER MRI UNIT.

(2) THE ADDITIONAL FIXED UNIT SHALL BE LOCATED AT THE SAME SITE UNLESS THE REQUIREMENTS OF THE RELOCATION SECTION HAVE BEEN MET.

Section 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 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 76. Requirements for approval of an applicant proposing to relocate an existing FIXED MRI service and/or MRI unit(s)

Sec 76. (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.~~

(eC) 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 RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.

~~(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 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 APPLICANT CURRENTLY OPERATES THE MRI SERVICE FROM WHICH THE UNIT WILL BE RELOCATED.

~~(aB) 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.~~

(bC) 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.~~

~~(eD) 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 RECENTLY PUBLISHED MRI SERVICE UTILIZATION LIST AS OF THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT.~~

~~— (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 13 of these standards.~~

~~(gE) 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 87. Requirements ~~for approval of an applicant proposing~~ to acquire an existing MRI service or an existing MRI unit(s)

SEC 7. (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 13 of these standards.~~

~~(dA) 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 (dA), 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 ~~76~~(2), unless the applicant demonstrates that the project is in compliance with the requirements of THE INITIATION OR EXPANSION 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 THE REPLACEMENT SECTION 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 13 of these standards.~~

Section 98. Requirements for approval of an applicant proposing an MRI unit to be used exclusively for research TO ESTABLISH A DEDICATED RESEARCH MRI UNIT

Sec. ~~98. (1)~~ An applicant proposing an MRI unit to be used exclusively for research shall demonstrate ~~each of~~ the following:

~~(a1)~~ SUBMIT COPIES OF DOCUMENTATION DEMONSTRATING THAT ~~The~~ 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.

~~(b2)~~ SUBMIT COPIES OF DOCUMENTATION DEMONSTRATING THAT ~~The~~ THE MRI unit shall operate under a protocol approved by the applicant's ~~institutional review board~~ IRB.

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

~~(23)~~ An applicant meeting the requirements of ~~subsection (1)~~ THIS SECTION shall be exempt from meeting the requirements ~~and terms of sections 3, 4, 5, 6, 7, 8, 13 [with the exception of 13(1)(d)(iii)], 15, and 16 of these standards~~ TO INITIATE AND REPLACE.

Section 109. Requirements for approval of an applicant proposing to establish A dedicated pediatric MRI UNIT

Sec. ~~109.~~ (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 4410. Pilot program requirements for approval – applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 4410. 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 or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room.
- (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this section unless the patient meets one of the following criteria:
 - (a) the patient has been admitted to an inpatient unit; or
 - (b) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
- (7) The approved IMRI unit will not be subject to MRI volume requirements.
- (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need or to satisfy MRI CON review standards requirements.

~~(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.~~

(409) The provisions of Section 44-10 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 1211. Requirements for ~~approval~~—all applicants

Sec. 1211. 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 1312. Project delivery requirements – terms of approval

Sec. 1312. (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 IRB policies relating to non-FDA approved pulse sequences or investigational procedures.~~
~~(N) Staff inservice regarding subdivisions (A) through (M).~~
~~(ivII) 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.~~
~~(viIII) 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.~~
~~(BA) 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.~~
~~(CB) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.~~
~~(DC) 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)V 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.~~

(BA) 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.

(CB) 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.

(DC) 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)V 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.~~

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

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

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

~~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), 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).

(eD)(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.

(#E) 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 **APPROVED** under Section 9(1) shall agree that the services provided by the MRI unit ~~approved pursuant to Section 9(1) shall be IS~~ 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 IRB~~ 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 4413. MRI procedure adjustments

Sec. 4413. (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 4514. Documentation of actual utilization

Sec. 4514. 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 MRI SERVICE UTILIZATION 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 4615. The Department may elect to verify the data through on-site review of appropriate records.

Section 4615. Methodology for computing the number of available MRI adjusted procedures

Sec. 4615. (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 4413.

(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 98(1) and dedicated pediatric MRI approved pursuant to Section 40-9 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(42)(eC), 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 45(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(42).

Section 4716. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. 4716. (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 THAT REQUIRES DOCTOR COMMITMENTS 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 SIGNED AND DATED 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 ~~4615~~, 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, INDIRECT OWNERSHIP INCLUDES OWNERSHIP IN AN ENTITY THAT HAS OWNERSHIP INTEREST IN THE APPLICANT ENTITY. ~~except that this~~ THIS requirement

shall not apply if the applicant entity is a group practice of which the committing doctor is a member.
GROUP PRACTICE MEANS A GROUP PRACTICE AS DEFINED PURSUANT TO THE PROVISIONS OF 42 U.S.C. 1395NN (H)(4), COMMONLY KNOWN AS STARK II, AND THE CODE OF FEDERAL REGULATIONS, 42 CFR, PART 411, PUBLISHED IN THE FEDERAL REGISTER ON AUGUST 14, 1995, OR IT'S REPLACEMENT.

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

(4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new or additional MRI unit, pursuant to Section 3 ~~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).

(A) THE APPLICANT WILL HAVE 30 DAYS TO SUBMIT REPLACEMENT OF DOCTOR COMMITMENTS AS IDENTIFIED BY THE DEPARTMENT IN THIS SECTION.

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

(a) 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 ~~4817~~. Lists of MRI adjusted procedures published by the Department

Sec. ~~4817~~. (1) ~~At a minimum, on~~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~~ RESEARCH, OR DEDICATED PEDIATRIC.

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

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section ~~4615~~ (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 ~~4615~~ (1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section ~~4615~~ (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 ~~43(1)(d)(iii)~~ 12, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section ~~43(1)(d)(iii)~~ 12, 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 ~~49~~18. Effect on prior CON Review Standards; Comparative reviews

Sec. ~~49~~18. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on ~~September 18, 2007~~ SEPTEMBER 16, 2008 and effective ~~November 13, 2007~~ NOVEMBER 13, 2008.

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

Section 20. Health Service Areas

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

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

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

July 31, 2009

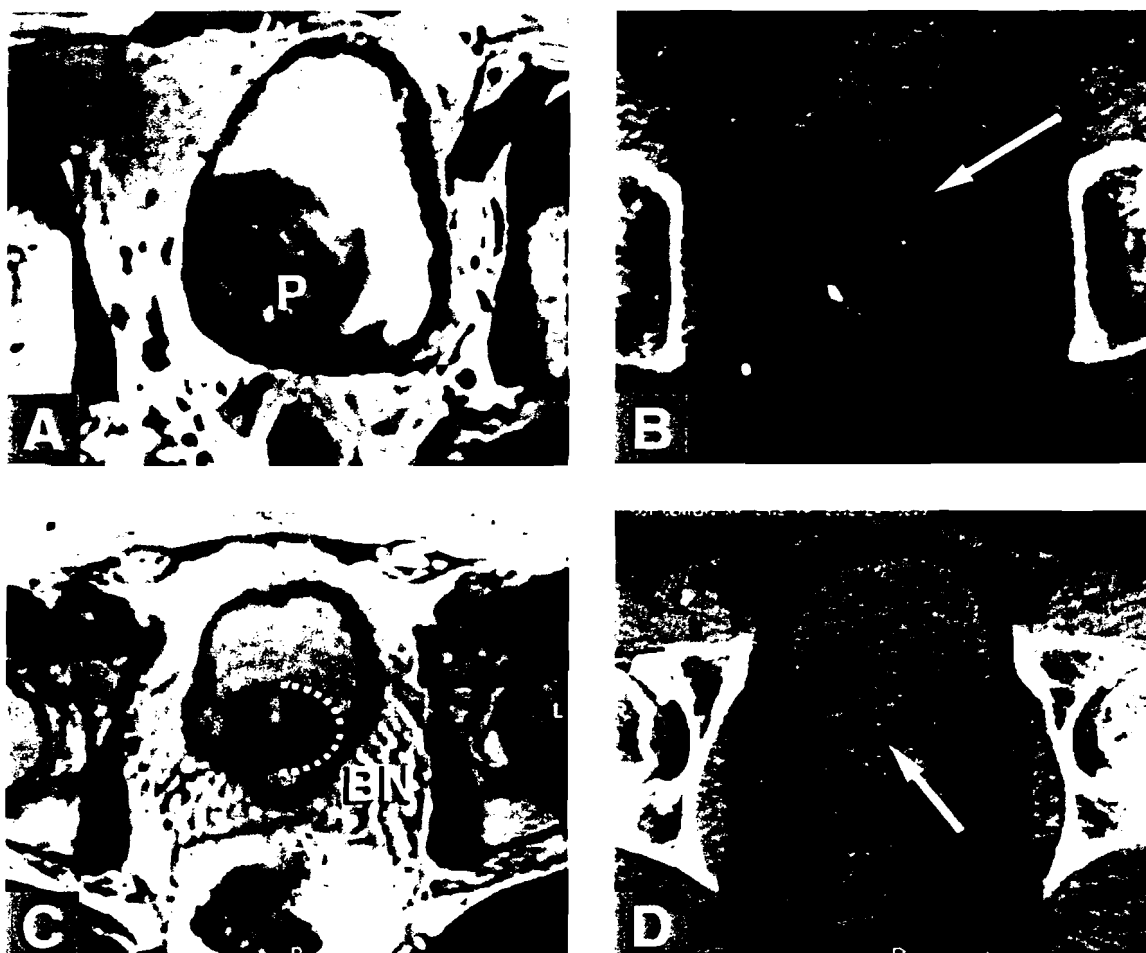
To: MRI Workgroup

Re: MRI used for MRT Simulation

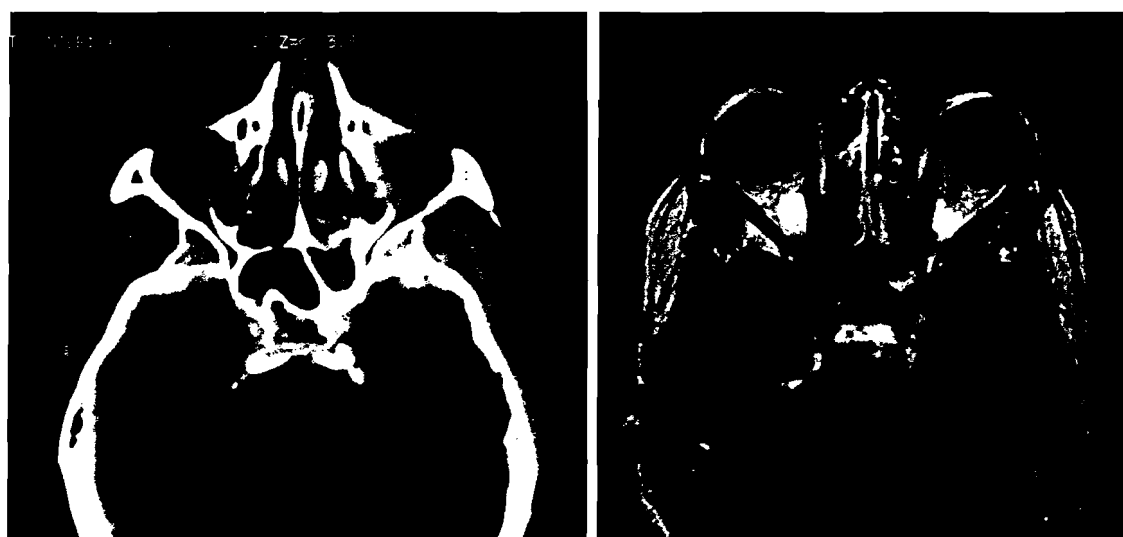
The following is a joint statement from:

Dr. T. Lawrence, Chairman, Radiation/Oncology, Univ. of Michigan Health System
Dr. B. Movsas, Chairman, Radiation/Oncology, Henry Ford Health System

"We support the exclusion of MRI simulators (used for radiation treatment planning purpose in conjunction with an MRT unit) from the CON standards for MRI units. MRI simulation is emerging as a useful tool for radiation treatment planning that has advantages over the more traditional method of CT simulation. First, compared to CT, MRI imaging provides more detailed and clearer images of the target and surrounding normal structures in certain anatomic locations, such as the brain, spine, prostate and soft tissues. As target delineation is essential for accurate radiation treatments, MRI simulation can help achieve more precise treatment planning for certain disease sites. Moreover, unlike CT simulation, MRI simulation does not involve additional radiation exposure to the cancer patient. The CON standards for CT units already contains an exception for CT simulators. We recommend that the same exclusion be created for MRI units to be used for MRT simulation. As radiation treatments become more precise, the ability to integrate the optimal imaging modality for treatment planning becomes more important."



MRI images (left: A,C) show the location of the tumor within the prostate, detail that is essentially invisible on corresponding CT images (right: B,D).



Nasopharyngeal cancer which involves the left cavernous sinus (green arrows). This involvement is clearly seen on MR but not on the corresponding CT. Images are obtained through the same axial plane at the level of the cavernous sinus (note similar shape of the sphenoid sinus, indicated with red arrows).

open heart programs in MICHIGAN



COUNTY	POPULATION	OPEN HEART PROGRAMS	OPEN HEART SURGERIES*
Bay	107,495	1	355
Berrien	159,481	1	184
Emmet	33,535	1	267
Genesee	428,790	2	460
Grand Traverse	86,071	1	634
Ingham	277,528	2	336
Jackson	160,180	1	105
Kalamazoo	245,912	2	482
Kent	605,213	1	1,025
Macomb	830,663	3	287
Marquette	65,492	1	242
Midland	129,494	1	191
Muskegon	174,344	1	286
Oakland	1,202,174	5	361
Saginaw	200,745	2	841
St. Clair	168,894	1	181
Washtenaw	347,376	2	761
Wayne	1,949,929	5	414

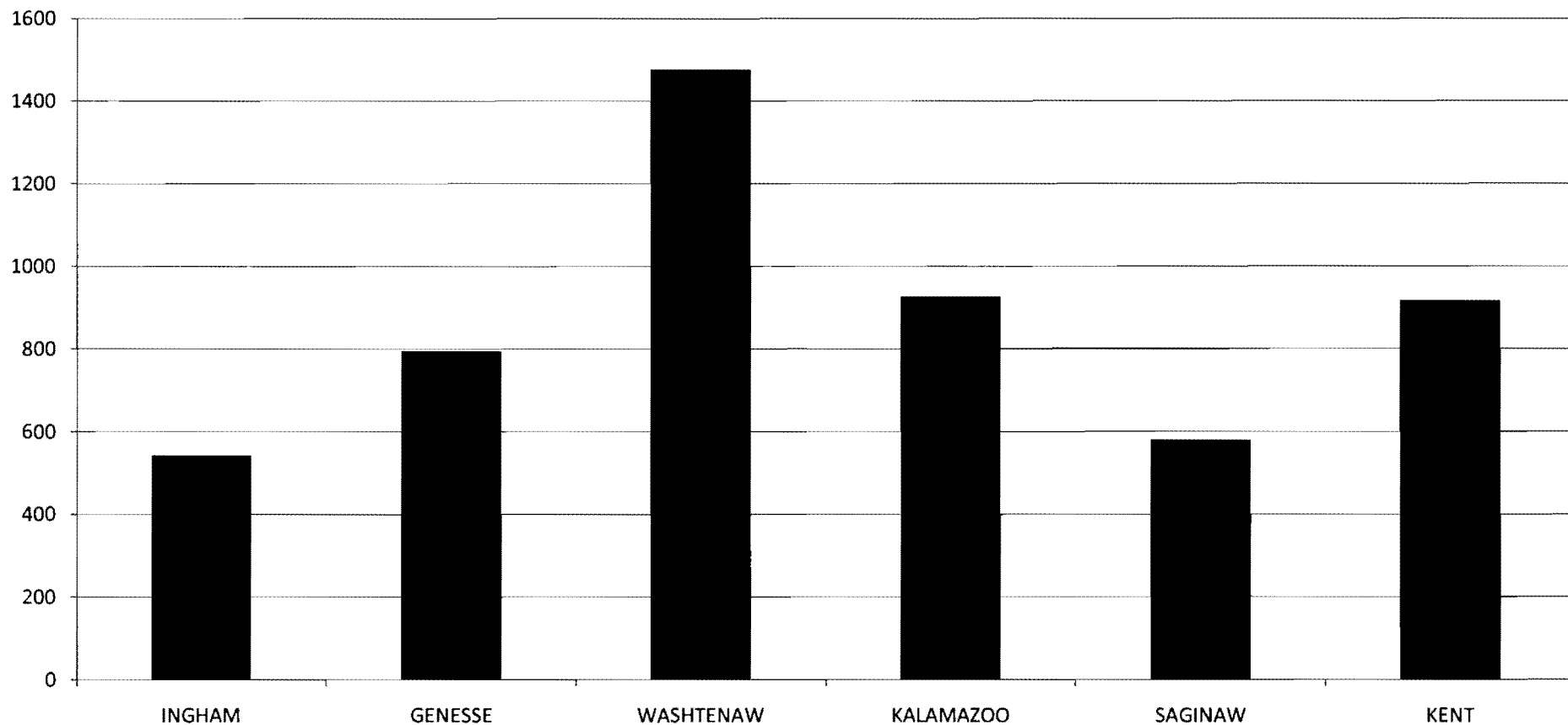


* Average annual open heart surgeries 2005 - 2008

Source: U.S. Census Bureau, Population Division (July 2008)

Source of Heart Surgeries Data: Michigan Department of Community Health

2008 Open Heart Cases



County	Hospital(s)	Total open heart cases	Number of cardiologists	Average cases per cardiologist
INGHAM	Ingham Regional Medical Center Edward W. Sparrow Hospital	542	25	22
GENESSE	McLaren Regional Medical Center Genesys Regional Medical Center	795	22	36
WASHTENAW	University of Michigan St. Joseph Mercy Hospital	1476	65	23
KALAMAZOO	Bronson Medical Center Borgess Medical Center	926	30	31
SAGINAW	St. Mary's Medical Center Covenant Medical Center	580	18	32

CERTIFICATE OF NEED
Quarterly Compliance Activity Report to the CON Commission
 April 1, 2009 through June 30, 2009 (FY 2009)

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.

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 CONs to determine if proposed projects have been implemented in accordance with Part 222 of the Code. For the reporting quarter, the following actions have occurred:

Activity	Recent Quarter	Year-to-Date
Letters mailed to verify progress approved projects	398	1,134
Projects deemed 100% complete and operational	132	371
CON approvals expired due to noncompliance with Part 222	38	127

Of note, the Department has initiated action to expire the approved CONs for three proposed PBT services for noncompliance with submission of the required enforceable contract in a timely manner.

Compliance: In accordance with MCL 333.22247, the Department has initiated several statewide compliance checks.

Recent statewide checks have focused on delinquent surveys, mobile MRI networks, open heart surgical programs, and primary PCI programs without onsite cardiac surgical backup. Some of these reviews/investigations are still ongoing, and additional statewide checks on other services will be initiated throughout the remainder of the year.

As part of these checks, the Department has issued or plans to issue civil fines on four (4) mobile providers for noncompliance with volume and host site requirements, and on five (5) facilities for delinquent 2008 surveys.

As for open heart surgical services and primary PCI programs, these reviews/investigations are still ongoing and a report will be forthcoming to the Commission at the December meeting.

CERTIFICATE OF NEED
Quarterly Program Section Activity Report to the CON Commission
 April 1, 2009 through June 30, 2009 (FY 2009)

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

Measures

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

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	88	N/A	260	N/A
Letters of Intent Processed within 15 days	87	99%	251	97%
Letters of Intent Processed Online	86	98%	259	99%

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

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	64	N/A	182	N/A
Applications Processed within 15 Days	64	100%	181	99%
Applications Incomplete/More Information Needed	41	64%	119	65%
Applications Filed Online*	52	90%	143	92%
Application Fees Received Online*	5	9%	11	7%

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

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

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	34	100%	113	100%
Substantive Applications	15	100%	81	99%
Comparative Review Applications	0	N/A	15	88%

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

Measures – continued

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

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Emergency Applications Received	0	N/A	1	N/A
Decisions Issued within 10 workings Days	0	N/A	1	100%

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

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	21	100%	43	98%

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

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

Other Measures

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	23	N/A	70	N/A
FOIA Requests Processed on Time	23	100%	70	100%
Number of Applications Viewed Onsite	4	N/A	12	N/A

FOIA – Freedom of Information Act.



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NEWS ROOM | Press Releases

For immediate release: August 12, 2009

Contact: [Shawn Karrick](#)

Outstanding Achievement in State IT: NASCIO Announces Finalists for 2009 Recognition Awards

(Lexington, KY) – The National Association of State Chief Information Officers (NASCIO) has selected 30 state IT initiatives in 10 categories as finalists for the **2009 Recognition Awards for Outstanding Achievement in the Field of Information Technology in State Government**. This year's high quality of nominations shows that states continue to innovate and achieve great results, despite the difficult economic climate.

“State information technology best practices should be promoted and shared,” said Deputy Director of Information Technology, State of Oklahoma and NASCIO Awards Committee Co-Chair, Joe Fleckinger. “The Recognition Award program provides a showcase of innovative initiatives from across the nation and encourages state governments to continue to focus on efficiency, excellence and quality service to citizens.”

Celebrating its 21st consecutive year, the Recognition Awards Program features categories reflecting the wide range of IT projects currently under development within state government. Emphasis was placed on recognizing programs that exemplify best practices, support the public policy goals of state leaders, represent an innovative use of existing and new technology, assist government officials to efficiently execute their duties, provide cost-effective service to citizens and are transferable to other agencies or units of government.

“NASCIO’s Recognition Award program highlights leadership, innovation and collaboration,” stated Greg Wass, Chief Information Officer, State of Illinois and NASCIO Awards Committee Co-Chair. “Learning from the successes of our colleagues around the country, we can all reap the benefit of efficient business practices, quality information management, and sound technology policy.”

Thirty exemplary initiatives were chosen as finalists from 117 submissions by 31 states. NASCIO’s Awards committee, comprised of judges from NASCIO’s state and corporate members, selected the 2009 award finalists. Full submissions from all nominations are posted on NASCIO’s website at www.nascio.org/awards.

One initiative in each category will be honored as the award recipient during the State Dinner and Award Presentation at NASCIO’s Annual Conference on October 26 in Austin, Texas.

The following is a list of award finalists organized by category:

Business Continuity & Disaster Recovery

State of Illinois – Illinois National Electronic Disease Surveillance System (I-NEDSS)
 State of Tennessee - Enterprise Storage, Backup/Recovery, and Tape Virtualization
 State of Utah - Business Continuity and Disaster Recovery Across Government Boundaries

Cross Boundary Collaboration & Partnerships

State of Michigan - Government, Business and Academia collaboration to increase supply of graduating technology professionals, and promote economic growth
 Commonwealth of Virginia - University IT Internship Partnership
 State of Washington - Enhanced Driver License/Identification Card Project

Data, Information & Knowledge Management

State of New York - NYS Enhanced Drivers License - A Smart Way to Travel
 State of Texas - Revenue and Sales Reporting (RASR) Business Intelligence Platform
 Commonwealth of Virginia - Virginia Performs: Virginia's Performance Leadership and Accountability System

Digital Government: G to B

State of Michigan - Certificate of Need (CON) e-Serv
 State of Nebraska - Court Document E-filing
 State of Utah - On the Spot Renewal System and Highway Patrol Safety Inspections

Digital Government: G to C

State of Minnesota - Minnesota Unemployment Insurance Technology Initiative Project
 State of North Carolina - Integrated Voice Recognition System for Unemployment Insurance Initial and Continued Claims
 Commonwealth of Virginia - Virginia.gov Portal Widgets

Digital Government: G to G

State of California - DCSS - California Child Support Automated System

State of Michigan - Michigan Standard Desktop Environment

State of North Carolina - Probation Officer's Dashboard

Enterprise IT Management Initiatives

Commonwealth of Pennsylvania - IT Shared Services

State of Texas - Business Process Improvements Project at the Texas Comptroller of Public Accounts

State of West Virginia - West Virginia IT Consolidation Program

ICT Innovations

State of North Carolina - Wearable Inspection Grading Information Network System

State of South Dakota - Research, Education & Economic Development Network

State of Washington - Statewide Electronic Collision & Ticket Online Records (SECTOR)

Information Security & Privacy

State of Maine - CERTS

State of Michigan - Secure Wireless LAN

Commonwealth of Pennsylvania - Commonwealth Application Certification & Accreditation (CA)2

IT Project & Portfolio Management

State of California - How to transform from a Project Management Office to a Performance Management Office on a shoestring budget

State of Oklahoma - Information Technology and Telecommunications Application

Commonwealth of Virginia - Virginia Technology Portfolio 2.0

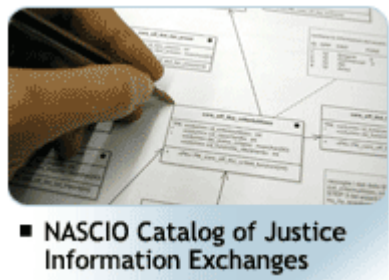
State government projects and initiatives from the member states, territories, and the District of Columbia were eligible to be nominated for these prestigious annual awards. Criteria for selection included a description of the business problem and solution, significance of the project to the improvement of the operation of government, and the benefits of the project.

NASCIO is the premier network and resource for state CIOs and a leading advocate for technology policy at all levels of government. NASCIO represents state chief information officers and information technology executives from the states, territories, and the District of Columbia. The primary state government members are senior officials who have executive level and statewide responsibility for information technology leadership. State officials who are involved in agency level information technology management may participate as state members. Representatives from other public sector and non-profit organizations may also participate as associate members. Private sector firms may join as corporate members and participate in the Corporate Leadership Council. For more information about NASCIO visit www.nascio.org.

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Contact Dianne Adams, NASCIO Programs and Education Coordinator at (859) 514-9167 or dadams@AMRms.com, or Shawn Karrick, NASCIO Membership and Communications Coordinator at (859) 514-9156 or skarrick@AMRms.com for more information.

AMR Management Services provides NASCIO's executive staff. For more information about AMR visit www.AMRms.com.



AMERICAN HEALTH PLANNING ASSOCIATION

RANK	STATE	# CON APPS
1	Michigan	337
2	New York	293
3	Kentucky	162
4	Connecticut	122
5	Illinois	103
6	Tennessee	79
7	Missouri	69
8	Virginia	68
9	Alabama	60
10	South Carolina	59
11	West Virginia	52
12	Mississippi	40
13	Arkansas	39
14	Ohio	36
15	Maryland	28
16	Florida	19
17	Iowa	14
18	Vermont	13
19	New Hampshire	9
20	Maine	9
21	Rhode Island	4
22	Delaware	4
23	Oregon	3
24	Wisconsin	0
25	Nevada	0
26	Nebraska	0
27	Montana	0
28	Louisiana	0
29	Washington	NR
30	Oklahoma	NR
31	North Carolina	NR
32	New Jersey	NR
33	Massachusetts	NR
34	Hawaii	NR
35	Georgia	NR
36	District of Columbia	NR
37	Alaska	NR
38	Wyoming	NA
39	Utah	NA
40	Texas	NA
41	South Dakota	NA
42	Pennsylvania	NA
43	North Dakota	NA
44	New Mexico	NA
45	Minnesota	NA
46	Kansas	NA
47	Indiana	NA
48	Idaho	NA
49	Colorado	NA
50	California	NA
51	Arizona	NA

NR - CON state but data not reported

NA - Non-CON state

CERTIFICATE OF NEED LEGAL ACTION

(8/27/09)

<i>Case Name</i>	<i>Date Opened</i>	<i>Case Description</i>	<i>Status</i>
Brighton Senior Care & Rehab Center Heartland Healthcare Center Livingston II Livingston Health Campus Livingston Care Center, LLC Medilodge of Howell, Inc. Admin Tribunal Docket No.: 2009-5815, 5819, 6457, 6458 CON	12/30/08	Comparative review of 1) Brighton Senior Care & Rehab Center, 2) Heartland Healthcare Center Livingston II, 3) Livingston Care Center, LLC, 4) Medilodge of Howell, Inc.	On August 12, 2009, the parties appeared before the ALJ to argue three motions: (1) Heartland's Motion to Dismiss Livingston Care Center and Medilodge due to their failure to comply with R 503 when they filed their appeal; (2) Medilodge's Motion to Determine the Scope of the Hearing; and (3) MDCH's Motion for Summary Disposition. After approximately three hours of argument, ALJ Gigliotti took the motions under advisement. While we are waiting for a decision, the ALJ agreed to hold off briefing in the two other comparative review appeals for the Oakland county and Macomb county planning areas.

CERTIFICATE OF NEED LEGAL ACTION

(8/27/09)

<i>Case Name</i>	<i>Date Opened</i>	<i>Case Description</i>	<i>Status</i>
<i>Macomb County – Comparative Review</i> Includes: FountainBleu-Shelby Township CON #08-0223 Utica Health Campus - CON #08-0187	4/30/09	Comparative Review of nursing home beds: 1) FountainBleu-Shelby Township CON #08-0223 2) Utica Health Campus – CON #08-0187 3) Windmere Park Nursing Center - CON #08-0218; 4) MediLodge of Richmond - CON #08-0176 5) MediLodge of Sterling Heights, Inc. - CON #08-0177 5) MediLodge of Washington - CON #08-0178 7) Heartland Health Care Center Macomb 1 - CON #08-0201	Briefing on hold pending decision regarding Livingston CON planning area.
<i>Oakland County-Comparative Review</i>	4/30/09	Comparative review of nursing home beds. Manor of Farmington Hills - CON #08-0032 Bloomfield Orchard Villa - CON #08-0036 Woodward at Bloomfield Hills Health Center - CON #07-0572 Waltonwood at Main - Phase 2 - CON #08-0027 Waltonwood at Twelve Oaks - Phase 3 - CON #08-0026 McAuley Center - CON #08-0010	Briefing on hold pending decision regarding Livingston CON planning area.
<i>Medilodge of Howell (CON)</i> Macomb Cty Circuit Ct Docket No: 08-4125 CZ AG#20083027936	9/22/08	Medilodge of Howell seeks an injunction to prohibit Defendant from proceeding with a comparative, competitive review of applications to add additional nursing home beds in Livingston County, unless and until Medilodge of Howell is included in that review.	The Court entered an order granting the relief requested. MDCH complied with the order. Plaintiff has withdrawn its complaint in this matter. This matter will now be closed.

CERTIFICATE OF NEED LEGAL ACTION

(8/27/09)

<i>Case Name</i>	<i>Date Opened</i>	<i>Case Description</i>	<i>Status</i>
<i>Medilodge of Richmond (CON)</i> Macomb Cty Circuit Ct Docket No: 08-4123 CZ	9/22/08	Medilodge of Richmond seeks an injunction to prohibit Defendant from proceeding with a comparative, competitive review of applications to add additional nursing home beds in Livingston County, unless and until Medilodge of Richmond is included in that review.	The Court entered an order granting the relief requested. MDCH complied with the order. Plaintiff has withdrawn its complaint in this matter. This matter will now be closed.
<i>Medilodge of Sterling Heights (CON)</i> Macomb Cty Circuit Ct No:	9/22/08	Medilodge of Sterling Heights seeks an injunction to prohibit Defendant from proceeding with a comparative, competitive review of applications to add additional nursing home beds in Livingston County, unless and until Medilodge of Sterling Heights is included in that review.	The Court entered an order granting the relief requested. MDCH complied with the order. Plaintiff has withdrawn its complaint in this matter. This matter will now be closed.
<i>Medilodge of Washington (CON)</i> Macomb Cty Circuit Ct No:	9/22/08	Medilodge of Washington seeks an injunction to prohibit Defendant from proceeding with a comparative, competitive review of applications to add additional nursing home beds in Livingston County, unless and until Medilodge of Washington is included in that review.	The Court entered an order granting the relief requested. MDCH complied with the order. Plaintiff has withdrawn its complaint in this matter. This matter will now be closed.
<i>Ottawa County-Comparative Review</i> Includes: Waterford Rehab Park Place	04/27/09	Comparative review of nursing home beds.	The parties have adjourned the hearing and are awaiting a new date.

CERTIFICATE OF NEED LEGAL ACTION
(8/27/09)

<i>Case Name</i>	<i>Date Opened</i>	<i>Case Description</i>	<i>Status</i>
<i>Woodcare X (Caretel) v MDCH</i> Genesee County Cir Docket No.: 08-89784 CZ	10/13/08	Complaint for Mandamus	Court of appeals denied application and motion for stay. Parties have stipulated to an order of dismissal which was submitted to the Court on 8/27/09.
<i>Woodcare X (Caretel) v MDCH</i> Court of Claims Docket No.: 08-132-MK	12/03/08	Filed for damages and specific performance of a settlement agreement reached 20 years ago.	Trial scheduled to start 9/1/09. We are seeking a 90-day adjournment based on federal action.
<i>Woodcare X (Caretel) v MDCH</i>	5/04/09	Filed Application for Leave to Appeal	See above.
<i>MDCH v Woodcare X (Caretel) and CMS</i> U.S. District Court (Western)	08/27/09	Filed Complaint for Declaratory & Injunctive Relief	Defendant's answer is due in 60 days.

s: chd; assign control; special; CON Leg Action; report 8/27/09

Proposed Modifications to Hospital Bed Standards for Rehabilitation Hospital Provision:

Section 2. Definitions

(w) "~~Long-term (acute) care~~ PPS EXEMPT hospital" means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt LONG-TERM (ACUTE) CARE hospital OR INPATIENT REHABILITATION FACILITY in accordance with 42 CFR Part 412.

Section 6. Requirements for approval -- new beds in a hospital

(2) An applicant proposing to begin operation as a new ~~long-term (acute) care~~ PPS EXEMPT hospital or alcohol and substance abuse hospital within an existing licensed, host hospital shall demonstrate that it meets all of the requirements of this subsection:

(a) If the ~~long-term (acute) care~~ PPS EXEMPT hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as a ~~long-term (acute) care~~ hospital within 12 months after beginning operation, then it may apply for a six-month extension in accordance with R325.9403 of the CON rules. If the applicant fails to meet the Title XVIII requirements for PPS exemption as a ~~long-term (acute) care~~ hospital within the 12 or 18-month period, then the CON granted pursuant to this section shall expire automatically.

(b) The patient care space and other space to establish the new hospital is being obtained through a lease arrangement and renewal of a lease between the applicant and the host hospital. The initial, renewed, or any subsequent lease shall specify at least all of the following:

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital or any subsequent application to add additional beds.

(ii) That the proposed new beds shall be for use in space currently licensed as part of the host hospital.

(iii) That upon non-renewal and/or termination of the lease, upon termination of the license issued under Part 215 of the act to the applicant for the new hospital, or upon noncompliance with the project delivery requirements or any other applicable requirements of these standards, the beds licensed as part of the new hospital must be disposed of by one of the following means:

(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the ~~long-term (acute) care~~ PPS EXEMPT hospital. In the event that the host hospital applies for a CON to acquire the ~~long-term (acute) care~~ PPS EXEMPT hospital [including the beds leased by the host hospital to the ~~long-term (acute) care~~ PPS EXEMPT hospital] within six months following the termination of the lease with the ~~long-term (acute) care~~ PPS EXEMPT hospital, it shall not be required to be in compliance with the hospital bed supply set forth in Appendix C if the host hospital proposes to add the beds of the long-term (acute) care hospital to the host hospital's medical/surgical licensed capacity and the application meets all other applicable project delivery requirements. The beds must be used for general medical/surgical purposes. Such an application shall not be subject to comparative review and shall be processed under the procedures for non-substantive review (as this will not be considered an increase in the number of beds originally licensed to the applicant at the host hospital);

(B) Delicensure of the hospital beds; or

(C) Acquisition by another entity that obtains a CON to acquire the new hospital in its entirety and that entity must meet and shall stipulate to the requirements specified in Section 6(2).

(c) The applicant or the current licensee of the new hospital shall not apply, initially or subsequently, for CON approval to initiate any other CON covered clinical services; provided, however, that this section is not intended, and shall not be construed in a manner which would prevent the licensee from contracting and/or billing for medically necessary covered clinical services required by its patients under arrangements with its host hospital or any other CON approved provider of covered clinical services.

(d) The new licensed hospital shall remain within the host hospital.

(e) The new hospital shall be assigned to the same subarea as the host hospital.

(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(3) of these standards.

(g) The lease will not result in an increase in the number of licensed hospital beds in the subarea.

(h) Applications proposing a new hospital under this subsection shall not be subject to comparative review.

Amendment to Section 12. Project delivery requirements – terms of approval

Sec. 12(1)(d)(i) to be modified as follows:

(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,~~ **AND A TOTAL OF 3,000 MRI ADJUSTED PROCEDURES FOR A FIXED MRI UNIT APPROVED UNDER SECTION 3(2)(B)(III).** 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.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2008												2009											
	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		F	
Bone Marrow Transplantation (BMT) Services						•—	•P	•	•▲ F	PH•	•	•	•R	•	•R	•	•	■	■	■	■	■	■	•—
Computed Tomography (CT) Scanner Services																					PH			
Heart/Lung and Liver Transplantation Services										PH•	•	•	•R	•	•	■	■	■	■	■	■	■	•	•—
Magnetic Resonance Imaging (MRI) Services	•	•	•R	•	•	•—	•P	•	•▲ F	PH•	•	•	•R	•	•	•	•	•—	•P	•	•▲ F R	•	•	•
Neonatal Intensive Care Services/Beds (NICU)																					PH			
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups																					PH			
Pancreas Transplantation Services										PH•	•	•	•R	•	•	•	•	•—	•P	•	•▲ F			
Psychiatric Beds and Services										PH•	•	•	•R	•	•	•	•	•—	•P	•	•▲ F			
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units																					PH			
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M
Commission & Department Responsibilities			M			M			M			M R			M			M			M			M
Administrative Rules													•	•	• R			• R			• R D			
<div><div><div>KEY</div><div><div>—</div><div>-</div><div>Receipt of proposed standards/documents, proposed Commission action</div></div><div><div>*</div><div>-</div><div>Commission meeting</div></div><div><div>■</div><div>-</div><div>Staff work/Standard advisory committee meetings</div></div><div><div>▲</div><div>-</div><div>Consider Public/Legislative comment</div></div><div><div>**</div><div>-</div><div>Current in-process standard advisory committee or Informal Workgroup</div></div><div><div>•</div><div>-</div><div>Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work</div></div></div><div><div>A</div><div>-</div><div>Commission Action</div></div><div><div>C</div><div>-</div><div>Consider proposed action to delete service from list of covered clinical services requiring CON approval</div></div><div><div>D</div><div>-</div><div>Discussion</div></div><div><div>F</div><div>-</div><div>Final Commission action, Transmittal to Governor/Legislature for 45-day review period</div></div><div><div>M</div><div>-</div><div>Monitor service or new technology for changes</div></div><div><div>P</div><div>-</div><div>Commission public hearing/Legislative comment period</div></div><div><div>PH</div><div>-</div><div>Public Hearing for initial comments on review standards</div></div><div><div>R</div><div>-</div><div>Receipt of report</div></div><div><div>S</div><div>-</div><div>Solicit nominations for standard advisory committee or standing committee membership</div></div></div>																								

For Approval September 10, 2009

Updated August 13, 2009

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	November 13, 2008	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2011
Magnetic Resonance Imaging (MRI) Services	November 13, 2008	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	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 20, 2008	2010
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	June 4, 2004	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	February 25, 2008	2012
Surgical Services	June 20, 2008	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.