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

Tuesday, March 13, 2007

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

## APPROVED MINUTES

### I. Call To Order

Vice-Chairperson Goldman called the meeting to order at 9:11 a.m.

A. Members Present:

Norma Hagenow, Chairperson (Arrived @ 9:50 a.m.)
Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO
Roger G. Andrzejewski (Left @ 12:32 p.m.)
Dorothy E. Deremo
Marc Keshishian, MD
Adam Miller
Michael A. Sandler, MD
Michael W. Young, DO (Arrived @ 9:40 a.m.)

B. Members Absent:

Bradley N. Cory
Kathie VanderPloeg-Hoekstra

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Umbrin Ateequi
Jan Christensen
William Hart
John Hubinger
Joette Laseur
Irma Lopez
Dave McLaury
Andrea Moore
Stan Nash
Taleitha Pytlowanyj
Brenda Rogers

## II. Review of Agenda

Motion by Commissioner Ajluni, seconded by Commissioner Sandler, to approve the agenda with the amendment at Section XII to add Membership under subsection B and move Committee Update to the new subsection C. Motion Carried.

## III. Declaration of Conflicts of Interest

No conflicts were stated at this time.

## IV. Review of Minutes – December 12, 2007

Motion by Commissioner Andrzejewski, seconded by Commissioner Miller, to approve the minutes as presented. Motion Carried.

## V. Public Comment for Action Items (i.e., VI)

Magnetic Resonance Imaging (MRI)

Jim Foresman, Miller, Canfield, Paddock and Stone

Nursing Home (NH) and Hospital Long-Term Care Unit Beds (HLTC)

Sean Youngren, Rainbow Rehabilitation

Multiple Services

Larry Horwitz, Economic Alliance for Michigan

## VI. MRI Services – Placement Location after Converting from Mobile to Fixed [Section 3(4)(e)]

A. Commission Discussion

Ms. Rogers provided an oral overview of the technical and proposed changes made to the MRI Standards. Discussion followed.

B. Commission Proposed Action

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to support the draft language and the technical changes made to the MRI Standards and move forward to Public Hearing (Attachment A). Motion Carried.

## VII. Psychiatric Beds and Services Workgroup – Report

A. Review Recommendations

Commissioner Deremo provided a brief overview of the recommendations made by the Workgroup (Attachment B). Ms. Moore spoke briefly regarding the Department's recommendations. Discussion followed.

B. Commission Action

Motion by Commissioner Deremo, seconded by Commissioner Miller, to give the Department an additional 3 months and to have a report to present to the Commission at the June 13 Meeting. Motion Carried.

## VIII. NH-HLTC Unit Beds – Distribution of Remaining Special Pool Beds – MDCH Report

A. Commission Discussion

Ms. Moore spoke briefly in regards to the Department's recommendations (Attachment C). Discussion followed.

B. Commission Action

Motion by Commissioner Goldman, seconded by Commissioner Sandler, to correct the number of beds set-aside for future allocation from 22 to 26 and that the beds be distributed as follows: 16 HNSNC and 10 Alzheimer's. Further, to defer review of the Special Population Groups with the full review of the standards of the NH-HLTC Unit Beds. Motion Carried.

## IX. Air Ambulance (AA) Services, Computed Tomography (CT) Scanner Services, Neonatal Intensive Care Unit (NICU) Services/Beds, NH-HLTC Unit Beds, and Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units – Follow-up from January 9, 2007 Public Hearing

A. Commission Discussion

Mr. Christensen provided a brief overview of the foundational question related to the standards review process and whether the covered clinical service should continue to be subject of CON regulation (Attachment D). Further, he commented on the letter to the CON Commissioners from Senator George.

Ms. Rogers also provided a brief overview of the process for reviewing the standards. In addition, she reviewed of each of the services addressed at the Public Hearing and stated the Department's recommendations. Discussion followed.

Public Comment

Larry Horwitz, Economic Alliance for Michigan

B. Commission Action

AA Services

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to accept the Department's recommendation (Attachment E) and for the Department to pull together a workgroup and bring its recommendation back to the Commission at its June 2007 meeting. Motion Carried.

CT Scanner Services

Motion by Commissioner Sandler, seconded by Commissioner Deremo, to accept the Department's recommendation (Attachment F) for a Standard Advisory Committee (SAC) to be formed to look at the items covered in the Department's recommendations and any additional items brought to the Chairperson's attention within a reasonable time. Motion Carried.

NICU Services/Beds

Motion by Commissioner Ajluni, seconded by Commissioner Keshishian, to accept the recommendations of the Department (Attachment G) with Proposed Action by the Commission at its June meeting. Motion Carried.

NH and HLTC Unit Beds

Motion by Commissioner Deremo, seconded by Commissioner Keshishian, to accept the recommendations of the Department (Attachment H) and to include spinal cord injury and brain injury when reviewing the special population groups. Motion Carried.

UESWL Services/Units

Motion by Commissioner Goldman, seconded by Commissioner Deremo, that the Department review the necessity of continuing regulation on Lithotripsy and report back to the Commission at the June Commission meeting. If it is found that it should continue to be regulated, the necessary technical changes will be drafted for proposed action at the September Commission meeting. Motion Carried.

**X. Cardiac Catheterization (CC) Services SAC and Open Heart Surgery (OHS) Services SAC – Update**

Ms. Rogers provided a brief update on the two SACs. Ms. Carol Joseph, Chairperson of the CCSAC, stated that she would not recommend adding additional items to the SAC's charge. Discussion followed.

Lunch Break from 11:35 a.m. to 12:27 p.m.

**XI. Hospital Beds Fact-Finding - Update**

Mr. Christensen provided a brief update (Attachment I) of the Workgroups progress. Discussion followed.

Motion by Commissioner Goldman, seconded by Commissioner Miller, to accept the HB Fact-Finding report with the amendment of no change from 2 miles to 5 miles for the replacement zone and have the Department present a detailed report at the June 13th meeting. Motion Carried. Commissioner Sandler and Ajluni abstained.

**XII. New Medical Technology**

A. FDA Pre-Market Approval (PMA) Report

Ms. Rogers provided a brief overview of the PMAs. She stated that there was nothing new to report at this time.

B. Membership

Chairperson Hagenow stated that there needed to be 3 additional members added to the New Medical Technology Committee in certain categories. She stated that they have already received the nominations of Ms. Lisa Nagle as a Purchasing Organization Representative and Mr. Don VeCasey as a Health Care Consumer Organization Representative. Further, she stated that Manuel Valdivieso, MD (Karmanos Cancer Institute) and Roland Palmer (Alliance for Health) would be changed to the Health Care Provider Organization Representative category. Another member would also need to be added to the Health Care Consumer Organization Representative category. Discussion followed.

C. New Medical Technology (NEWTAC) Standing Committee Update

Commissioner Keshishian stated that the first meeting will be May 14th from 1:00 p.m. to 4:00 p.m.

Motion by Commissioner Keshishian, seconded by Commissioner Young, that the New Medical Technology Committee will evaluate the new technology to determine whether or not it should be under the guidance of CON. Motion Carried.

**XIII. Legislative Report**

Mr. Christensen stated that the only item to report at this time is the Senator George letter. Discussion followed. The Department will set up a meeting for the Commission Chairperson and Vice-Chairperson to meet with Senator George and the Department.

**XIV. Compliance Report**

Mr. Christensen gave an overview of the Department's compliance activities. Discussion followed.

**XV. Administrative Update**

Mr. Hart provided a brief administrative update. Discussion followed.

**XVI. CON Program Update**

A. Quarterly Performance Measures

Mr. Horvath provided a brief update. Discussion followed.

B. 2006 Annual Activity Report

Mr. Horvath provided a brief update. Discussion followed.

C. On-line Application System – Update

Mr. Horvath provided a brief presentation of the website. He showed the updates made to the CON website and how to use the site. Discussion followed.

**XVII. Future Meeting Dates**

June 13, 2007
September 18, 2007
December 11, 2007

**XVIII. Public Comment**

Robert Meeker, Spectrum Health
Anne Mitchell, United Medical Systems

**XIX. Review of Commission Work Plan.**

Ms. Rogers gave an overview of the draft Work Plan. She stated that there is a Public Hearing scheduled for the MRI Services on May 10th. Commissioner Deremo suggested meeting techniques to progress the work of the Workgroups and SACs. Discussion followed.

Motion by Commissioner Keshishian, seconded by Commissioner Sandler, to delegate responsibility to the Chairperson, Vice-Chairperson and the Department to draft charge language for the CT and NH/HLTC SACs and to start the nomination process and have the Chairperson and Vice-Chairperson seat the SACs. Motion Carried.

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to accept the Work Plan and time line. Motion Carried.

Public Comment

Barbara Jackson, Economic Alliance for Michigan

## XX. Election of Officers

Motion by Commissioner Deremo, seconded by Commissioner Andrzejewski, to nominate Commissioner Hagenow and Commissioner Goldman as the Chairperson and Vice-Chairperson, respectively. Motion Carried.

Motion by Commissioner Sandler, seconded by Commissioner Young, to close the nominations and elect Commissioner Hagenow and Commissioner Goldman as the Chairperson and Vice-Chairperson, respectively. Motion Carried.

## XXI. Adjournment

Public Comment

Anne Mitchell, United Medical Systems

Motion by Commissioner Deremo, seconded by Commissioner Miller, to adjourn the meeting at 1:58 p.m. Motion Carried.

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH**

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

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

## Section 1. Applicability

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

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

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

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

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

## Section 2. Definitions

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

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

(b) "Actual MRI adjusted procedures," for purposes of sections 15 and 16, means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 13, performed on an existing MRI unit, or if an MRI service has two or more MRI units at the same site, the average number of MRI adjusted procedures performed on each unit, for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department.

(c) "Available MRI adjusted procedures," for purposes of Section 15, means the number of MRI adjusted procedures performed by an existing MRI service in excess of 8,000 per fixed MRI unit and 7,000 per mobile MRI unit. For either a fixed or mobile MRI service, the number of MRI units used to compute available MRI adjusted procedures shall include both existing and approved but not yet operational MRI units. In determining the number of available MRI adjusted procedures, the Department shall use data for the 12-month period reported on the most recently published list of available MRI adjusted procedures as of the date an application is deemed complete by the Department.

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

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

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

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s). It shall be a legal entity authorized to do business in the State of Michigan.

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

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

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

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

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

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

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

(l) "Existing magnetic resonance imaging unit" or "existing MRI unit" means a CON-approved and operational MRI unit used to provide MRI services.

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

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

(o) "Group practice," for purposes of Section 16(3)(b), means a group practice as defined pursuant to the provisions of 42 U.S.C. 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411, published in the Federal Register on August 14, 1995, or its replacement.

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

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

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

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

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

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

(u) "Inpatient," for purposes of Section 13 of these standards, means an MRI visit involving an individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI service.

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

(w) "Licensed hospital site" means a health facility licensed under Part 215 of the Code. In the case of a single site hospital, it is ~~either (i)~~ 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 the licensee's certificate of licensure.

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

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

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

(aa) "Magnetic resonance imaging procedure" or "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections 3, 4, 5, 6, 7, 8 or 10 of these standards which is either a single, billable diagnostic magnetic resonance procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an institutional review board. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. The term does not include a procedure conducted by an MRI unit approved pursuant to Section 9(1).

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

(cc) "Magnetic resonance imaging unit" or "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans.

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

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

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

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

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

(ii) "Ownership interest, direct or indirect," for purposes of these standards, means a direct ownership relationship between a doctor and an applicant entity or an ownership relationship between a doctor and an entity that has an ownership relationship with an applicant entity.

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

(kk) "Planning area," for purposes of these standards, means

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

75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area county. For purposes of Section 7(3) of these standards, the planning area shall be measured from the original site at which the MRI service was first initiated.

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

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

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

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

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

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

(pp) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or replacement of, the magnet resulting in an applicant operating the same number and type (fixed or mobile) of MRI units before and after project completion or (ii) an equipment change other than a change in the magnet that involves a capital expenditure of $750,000 or more in any consecutive 24-month period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or unit, and it does not include a host site that proposes to receive mobile MRI services from a different central service coordinator if the requirements of Section 3(5)(a)-(e), as applicable, have been met.

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

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

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

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

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

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

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

(uu) "Site," for purposes of these standards, means

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

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

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

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

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

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

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

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

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

**Section 3. Requirements for approval of applicants proposing to initiate an MRI service or mobile MRI host site**

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

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

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

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

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

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

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

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

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

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

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

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

(b) The applicant is currently a host site being served by one or more mobile MRI units.
(c) The applicant has received, in aggregate, the following:
(i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available or
(ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, and the applicant meets all of the following:
(A) is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted;
(B) the nearest fixed MRI machine is located more than 15 radius miles from the application site;
(C) the applicant is a nonprofit licensed hospital site;
(D) the applicant certifies in its CON application, by providing a governing body resolution, that the board of trustees of the facility has performed a due diligence investigation and has determined that the fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access within the community hospital setting.

(d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent 12-month period, referenced in (c) above, by each mobile MRI service/units from which any of the MRI adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000 adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from network 18 do not need to be used to meet the 6,000 minimum.]
(e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site OR AT THE APPLICANT'S LICENSED HOSPITAL SITE AS DEFINED IN THESE STANDARDS.

(5) Initiation of a mobile MRI host site does not include the provision of mobile MRI services at a host site if the applicant, whether the host site or the central service coordinator, demonstrates or provides each of the following, as applicable:
(a) The host site has received mobile MRI services from an existing mobile MRI unit within the most recent 12-month period as of the date an application is submitted to the Department.
(b) The addition of a host site to a mobile MRI unit will not increase the number of MRI units operated by the central service coordinator or by any other person.
(c) Notification to the Department of the addition of a host site prior to the provision of MRI services by that mobile MRI unit in accordance with (d).
(d) A signed certification, on a form provided by the Department, whereby each host site for each mobile MRI unit has agreed and assured that it will provide MRI services in accordance with the terms for approval set forth in Section 12 of these standards, as applicable. The central service coordinator also shall identify all current host sites, on this form, that are served by the mobile route as of the date of the signed certification or are committed in writing to be served by the mobile route.
(e) The central service coordinator requires, as a condition of any contract with a host site, compliance with the requirements of these standards by that host site, and the central service coordinator assures compliance, by that host site, as a condition of the CON issued to the central service coordinator.

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

Sec. 4. (1) An applicant proposing to expand an existing fixed MRI service shall demonstrate that its existing fixed MRI units (excluding MRI units approved pursuant to Section 10) have performed at least an average of 11,000 adjusted procedures for each fixed unit based on the application of the methodology in Section 13 and as documented in accordance with Section 14 of these standards.
(a) The additional unit shall be located at the same site unless the requirements of Section 7(2) have been met.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sec 7. (1) An applicant proposing to relocate an existing fixed MRI service and its unit(s) shall demonstrate that the proposed project meets all of the following:

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

(b) The proposed new site of the existing MRI service and its unit(s) to be relocated is in the relocation zone.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The project will not change the number of MRI units at the site of the MRI service being acquired unless the applicant demonstrates that the project is in compliance with the requirements of Section 3 or 4, as applicable.

(b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of Section 5 have been met.

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

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

(e) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except the first application approved pursuant to subsection (d), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section 12(1)(d)(i) of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

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

(a) The project will not change the number of MRI units at the site of the MRI service being acquired, subject to the applicable requirements under Section 7(2), unless the applicant demonstrate**s** that the project is in compliance with the requirements of Section 3 or 4, as applicable.

(b) The project will not result in the replacement of an MRI unit at the MRI service to be acquired unless the applicant demonstrates that the requirements of Section 5 have been met.

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

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

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

(a) The applicant operates a diagnostic radiology residency program approved by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or an equivalent organization.

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

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

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

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

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

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

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

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

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

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

(i) pediatric bone marrow transplant program
(ii) established pediatric sedation program
(iii) pediatric open heart program

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

**Section 11. Requirements for approval -- all applicants**

Sec. 11. An applicant shall provide verification of Medicaid participation ~~at the time the application is submitted to the Department~~. An applicant that is ~~initiating a new service or is~~ a new provider not currently enrolled in Medicaid shall ~~provide a signed affidavit stating~~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 12. Project delivery requirements--terms of approval**

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

(a) Compliance with these standards.

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

(c) Compliance with the following quality assurance standards:

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

(A) Signal-to-noise ratio.

(B) Spatial resolution.

(C) Slice thickness, location, and separation.

(D) Spatial linearity.

(E) Field homogeneity and drift.

(F) System calibration and stability.

(G) Cryogen level and boiloff rate.

(H) Radio frequency power monitor.

(I) Hard copy image quality.

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

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

(A) All surface coils.

(B) Positioning devices.

(C) Physiologic triggering/monitoring equipment.

(D) Patient communication devices.

(E) Scan table position indicator and drives.

(F) Data network including storage and retrieval.

(G) Emergency rundown/shutdown units.

(H) Hard copy devices.

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

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

(A) Access to the MRI service.

(B) Access to the MRI scan room.

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

(D) Adverse bioeffects, including

(1) acoustic hazard.

(2) radio frequency burn hazard.

(3) specific absorption rates.

(4) peripheral nerve stimulation.

(5) pregnancy.

(6) magnet quench hazard.

(E) Sedation.

(F) Contrast administration.

(G) Treatment of adverse reactions to contrast.

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

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

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

(K) Mechanism for consultation regarding difficult cases.

(L) Pulse sequence protocols for specific indications.

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

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

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

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

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

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

(1) developing criteria for procedure performance.

(2) developing protocols for procedure performance.

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

(4) transmitting requested data to the Department.

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

(6) taking and interpretation of scans.

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

(8) identifying and correcting MRI image quality deficiencies.

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

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

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

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

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

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

(4) facilitating the repair of acute system malfunctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ix) In addition to all other applicable terms of approval, each mobile MRI unit shall have an

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

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

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

(i) MRI units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site. In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 9(1).

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

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

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

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

(iii)The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to annual budget and cost information, operating schedules, throughout schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. However, the Department shall allow an applicant up to an additional 60 days to submit the required data if reasonable efforts are made by an applicant to provide the required data. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 9(1) or Section 10 shall be reported separately.

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

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

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

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

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

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

(3) The agreements and assurances required by this section shall be in the form of a certification ~~authorized~~ AGREED TO by the ~~owner or governing body of the~~ applicant OR ITS AUTHORIZED AGENT.

(4) An applicant approved to initiate a fixed MRI service pursuant to Section 3(4) of these standards shall cease operation as a host site and not become a host site for at least 12 months from the date the fixed service and its unit becomes operational.

**Section 13. MRI procedure adjustments**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second,

third, etc.) at the same site.

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

**Section 14. Documentation of actual utilization**

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

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

Sec. 15. (1) The number of available MRI adjusted procedures required pursuant to Section 3 or 4(2) of these standards shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed complete by the Department, shall be used:

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

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 9(1) and dedicated pediatric MRI approved pursuant to Section 10 shall be excluded.

(ii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures, from the host site routes utilized to meet the requirements of Section 3(4)(d), shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

(iii) For purposes of computing actual MRI adjusted procedures, the MRI adjusted procedures utilized to meet the requirements of Section 4(1) shall be reduced by 8,000 and shall be excluded beginning at the time the application is submitted and for three years from the date the fixed MRI unit becomes operational.

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

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

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

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

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

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

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

(iv) Using the data produced in iii above, sum the number of available adjusted procedures in

descending order until the summation equals at least 75 percent of the total available adjusted procedures. This summation shall include the minimum number of doctors necessary to reach the 75 percent level.

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

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

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

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

(2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON applications received in which applicants apply for fixed MRI services pursuant to Section 3(4).

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

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

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment, on a form provided by the Department in response to the applicant’s letter of intent or at the applicant's discretion, on a more current form subsequently provided by the Department, for each doctor committing available MRI adjusted procedures to that application for a new or additional MRI unit pursuant to Section 3 or Section 4(2), respectively.

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

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

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

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

(3) The Department shall consider a data commitment, on a form provided by the Department in response to the applicant’s letter of intent or at the applicant's discretion, on a more current form subsequently provided by the Department, submitted by the applicant in support of its application, that meets the requirements of each of the following, as applicable:

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

(b) A committing doctor certifies that he or she does not have an ownership interest, either direct or indirect, in the applicant entity, except that this requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a member.

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

(4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support approval of an application for a new or additional MRI unit, pursuant to Section 3 or 4(2), respectively, for which a final decision to approve has been issued by the Director of the Department until either of the following occurs:

(i) The approved CON is withdrawn or expires.

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

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3 or 4(2), respectively, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

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

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

(5) The Department shall not consider a data commitment from a committing doctor for available MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data commitment, on a form provided by Department, for more than one (1) application for which a final decision has not been issued by the Department. If the Department determines that a doctor has submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or additional mobile MRI unit pursuant to Section 3 or 4(2), respectively, the Department shall,

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

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

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

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

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

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

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

**Section 17. Lists of MRI adjusted procedures published by the Department**

Sec. 17. (1) At a minimum, on or before May 1 and November 1 of each year, the Department shall publish the following lists:

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

(i) The number of actual MRI adjusted procedures;

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

(iii) The number of MRI units, including whether each unit is a clinical unit or an MRI unit used exclusively for research.

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

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 15(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section 15(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section 15(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

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

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

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

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section 12(1)(d)(iii), the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 12(1)(d)(iii), and no data will be shown for that service on either list.

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

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

Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on ~~June 22, 2005~~DECEMBER 12, 2006 and effective ~~October 17, 2005~~MARCH 8, 2007.

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

**Section 19. Health Service Areas**

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

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

**APPENDIX A**

## CON REVIEW STANDARDS FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

**Psychiatric Beds and Services Workgroup 2006**
Report to the Certificate of Need Commission

March 13, 2007

The Psychiatric Beds and Services Workgroup was established at the March 21, 2006 Certificate of Need (CON) Commission Meeting. The Commission assigned the Workgroup to follow up on the public comments received regarding these Standards at the Public Hearing on January 31, 2006. Below is an overview of the public comments.

Public Commends Overview

- Received three (3) recommendations to review the Bed Need Methodology for possible modifications.
- Received four (4) recommendations to review the Planning Areas for possible modifications.
- Received three (3) recommendations for the addition of individual facility high occupancy language.
- Received four (4) recommendations for review of the Replacement Zone for possible modifications.
- Received one (1) recommendation for the addition of Relocation definition and language.
- Received one (1) recommendation for removal of Section 6(2)(f).
- Received one (1) recommendation for review of the Michigan Mental Health Commission Final Report for potential inclusion.

In addition, the CON Program Section requested several technical changes and review of the occupancy rates for possible adjustment. The public comments received and the CON Program Section requests comprised the list of discussion items for the Workgroup.

The Workgroup evaluated each discussion item and offered several different modification options. Concepts were then applied to actual facility data to ensure the proposed modifications did not have any unintended or adverse effects. Due to overlapping issues, the Workgroup found it necessary to make recommendations in a package format titled the Renewing Licensed Concept. A summary of the components of the Renewing License Concept, as recommended by the Workgroup, is listed below.

Renewing License Concept Components

- Bed Need Methodology would be maintained to determine need for initiation of service.
- Adult Planning Areas would be modified to the HSA boundaries.
- Renewing License Concept. A pilot program which allows adjustment of the number of licensed beds at a facility in proportion to their average daily census for the previous two (2) years, at the time of the biennial license renewal. This would eliminate the necessity for high occupancy language. Expansion of service would only be allowed through the renewing license concept. Until the establishment of the Renewing License Concept pilot, the occupancy rates would be 66% for adult beds and 58% child/adolescent beds. (NOTE: These occupancy percentages are lower than what is required in acute care hospitals due to the unique nature of psychiatric care and the significant seasonality of volume that requires more flexibility in bed availability.)
- Replacement Zone would be modified to allow replacement within 15 miles of the existing site within the same planning area.
- Minimum number of beds in a psychiatric unit would be 10 beds. This would allow Critical Access Hospitals to initiate a unit.
- Section 6 (2)(f) would be modified to a maximum of 10 beds.
- Technical changes and updates of the Department.

Draft changes to the standards were prepared during the Workgroup process. The Department continues to evaluate the most effective and efficient manner to implement the Workgroup's concept, including evaluating modifications to the statute, rules and/or standards.

The overall informal Workgroup meeting model was evaluated by participants and comments offered were very positive. The Workgroup noted that the inclusion of all interested parties was very helpful and that round-table questioning allowed all participants the time to speak. In addition, having meeting materials provided prior to the meeting helped the Workgroup stay focused and on task.

Respectfully submitted,

Dorothy E. Deremo, CON Commission Liaison
Psychiatric Beds and Services Workgroup

# Comments to Michigan Certificate of Need Commission
## March 13, 2007

## Regarding CON Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds

My name is Sean Youngren and I am the Administrative Director of Rainbow Rehabilitation Centers, a provider of transitional rehabilitation and long-term residential programs for adults, children and adolescents with brain or spinal cord injuries. Rainbow Rehabilitation is based in Ypsilanti, Michigan, where it operates the Ypsilanti Treatment Center. Rainbow Rehabilitation also operates a second outpatient rehabilitation facility in Farmington and a NeuroRehab Campus Treatment Facility in Farmington Hills that serves adult brain and spinal cord injury populations. In addition to these Treatment Centers, Rainbow Rehabilitation provides an extensive network of homes and apartments for individuals recovering from a brain injury and for adults learning to live with a spinal cord injury. Rainbow Rehabilitation has been a quality provider of therapeutic rehabilitation services for individuals with brain and spinal cord injuries for over 24 years.

Rainbow Rehabilitation urges the CON Commission to appoint a Standard Advisory Committee or SAC to review the current CON Standards for Nursing Home and Hospital Long-Term Care Unit Beds. Although these CON Standards may have benefited from periodic revisions over the past few years, to our knowledge a thorough review of these regulations has not occurred for a number of years. In our judgment, the current CON Standards do not adequately accommodate the need for specialized long-term care settings for non-elderly, working-age adults and adolescents. Post-hospital placement of these individuals can be challenging as traditional nursing home facilities, even those with skilled rehabilitation programs, do not necessarily offer the types of rehabilitative, behavioral or occupational programs that are optimal for rehabilitation of younger adults with traumatic brain or spinal cord injuries. Additionally, many traditional nursing homes simply do not offer a physical environment or culture that is appropriate for working age adults and adolescents with these medical conditions.

By adding a small number of long-term care beds to its continuum of care, Rainbow Rehabilitation could significantly improve its ability to meet the special needs of patients with traumatic brain and spinal cord injuries. These patients would receive the benefits of specialized

rehabilitation programs appropriate for their age and condition beginning with discharge from an acute-care hospital to the skilled nursing setting. Long-term care beds within the Rainbow system would facilitate the gentle transition of many patients from dependence to independence.

Public comments at the January 9, 2007 public hearing on these CON Standards from several hospitals confirm our understanding that placement of younger patients with traumatic brain and spinal cord injuries within the current long-term care spectrum can be challenging. Michigan residents would benefit from more specialization within the long-term care arena and more placement options for non-elderly patients in need of skilled rehabilitation services. Creating more specialized and cost-effective environments for younger adults with traumatic brain and spinal cord injuries would be completely consistent with the statutory goals of the CON program, namely, cost, quality and access.

In addition to supporting the appointment of a SAC to review these Standards, Rainbow Rehabilitation requests the Commission to consider allocating some or all of the existing 22 State-wide special population beds that are currently unallocated to individuals with traumatic brain and spinal cord injuries in non-traditional nursing home environments. Alternatively, in lieu of allocation of these 22 special population beds, we request that the Commission charge the SAC with reviewing the current special population pools and the need for a State-wide pool to meet the unique needs of individuals with brain and spinal cord injuries.

We believe the Standards could, and should, be updated to better reflect the goals of the CON program including cost, quality and access for younger residents of this State who need specialized rehabilitative services in a skilled nursing environment.

We appreciate this opportunity to address the Commission on this important issue. We respectfully request that these Standards be added to the Commission's work plan and that a Standard Advisory Committee be appointed to review these Standards as soon as possible.

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## PROPOSED GUIDING PRINCIPLES FOR DETERMINING WHETHER A CLINICAL SERVICE SHOULD REQUIRE CON REVIEW

Pursuant to the Certificate of Need (CON) law, the Certificate of Need Commission may revise (add, delete, or modify) the list of clinical services that require a CON. The CON Commission may consider the following guiding principles in making a decision to revise the list of covered clinical services:

1. The clinical service has low capital costs.
   For purposes of this document, low capital costs are defined to mean the capital costs associated with developing and offering a service, including but not limited to buildings, equipment, etc., are less than the covered capital expenditure threshold (currently $2,130,040).

2. The clinical service has low operating costs.

3. The capital and operating costs associated with providing the service have decreased significantly during the __3__ most recent years.

4. At the time a clinical service was included on the list, the service was a new technology that was primarily provided by tertiary care centers and was not available widely in the community, and has since become an accepted standard of care provided in community settings.

5. Other organizations or mechanisms monitor the provision of the clinical service.
   For example, the service is licensed or certified by a state agency, or a voluntary accreditation program operated by a recognized private organization exists.

6. The current CON review standards do not establish a methodology that quantifies how the need for the clinical service shall be demonstrated.

7. The requirement to obtain a CON negatively affects geographic access to a clinical service that is considered a standard of care (no. 4) or a less costly alternative to other services.

8. The quality of a clinical service has not been linked, in scientific studies, to the volume of care provided.

9. Reimbursement policies, alone or in conjunction with quality assurance mechanisms, limit unnecessary or inappropriate utilization of the clinical service.

**MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review**
**Presented to CON Commission March, 13, 2007**

| **AIR AMBULANCE SERVICES**<br>(Please refer to 2.26.07 MDCH staff analysis for additional detail - attached) | | | |
|---|---|---|---|
| All Identified Issues | Issue Recommended for Review? | Recommended Course of Action | Other/Comments |
| 1. Modify definition of "Patient Transport" | Possible | Refer to potential workgroup | Two modifications were presented |
| 2. Clarify definition of "Primary " and "Secondary" service areas | Yes | Refer to potential workgroup | |
| 3. Expand definition of "Air Medical Personnel" | No | None | Not within the scope of CON as personnel requirements for operation of an Air Ambulance are in statute; MCL 333.20921(3)(c) |
| 4. Review volume requirements for expansion | Yes | Refer to potential workgroup | |
| 5. Permit expansion to a half-time (12 hour) air ambulance | Possibly | Refer to potential workgroup | |
| 6. Review volume requirements for replacement of equipment | Yes | Review to potential workgroup | |
| 7. Make technical (section 5) program implementation changes and revise language to provide uniformity in all CON standards | Yes | Review draft language developed by MDCH staff and take action at completion of workgroup | |
| 8. Collect Data | Yes | MDCH will send out a survey | This will be reported back to the Commission |
| **Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft necessary technical language changes (#7) for appropriate Commission review and public comment. The Department additionally suggests that the Commission ask the Department to pull together a workgroup for the purpose of making recommendations for items 1, 2, 4, & 6 and to bring these back to the Commission at its June 2007 meeting.** | | | |

Michigan Department of Community Health
**MEMORANDUM**
Lansing, MI

DATE: February 26, 2007

TO: Irma Lopez

FROM: Andrea Moore

RE: 2007 Review of Air Ambulance Standards

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Pursuant to MCL 333.22215 (1)(m) the Certificate of Need (CON) Commission is to "..review, and if necessary, revise each set of Certificate of Need standards at least every 3 years." In accordance with the established review schedule on the Commission Workplan, the Air Ambulance Standards are scheduled for review in calendar year 2007.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Air Ambulance Standards on January 9, 2007, with written testimony being received for an additional 7 days after the hearing. Testimony was received from five (5) facilities and is summarized as follows:

1. Economic Alliance of Michigan
   - Review the requirements for expansion of service.

2. Midwest Medflight
   - The current Standards are effective and should not be modified.

3. St. Mary's Healthcare
   - Review volume requirement for expansion of service.
   - Review the definition of patient transport. Recommends that single helicopter services be allowed to count missed runs when already on a patient transport and during downtime for maintenance.
   - Review the definitions primary service area and secondary service area.

4. Spectrum Health
   - Review the definition of air medical personnel. Recommends allowing a Michigan licensed paramedic or a physician trained in emergency medicine.
   - Review volume requirements for expansion of service.
   - Review volume requirements for replacement of equipment.
   - Establish expansion of service to a 12-hour Air Ambulance.
   - Review requirements for approval and project delivery requirements for duplications.

5. University of Michigan
   - Review volume requirements for expansion of service.
   - Review volume requirements for replacement of equipment.
   - Technical verbiage change/clarification in Section 5.

Definition of Air Medical Personnel

The Department received a request to expand the definition of air medical personnel to allow a physician trained in emergency medicine as an approved air medical personnel. Currently, the standards require that the air ambulance be staffed by two (2) personnel, one of which must be a paramedic licensed in the State of Michigan. The request would allow an air ambulance service to either have a physician trained in emergency medicine or a paramedic licensed in the State of Michigan. The personnel requirements for operation of an advanced life support vehicle, which includes an Air Ambulance, are statutorily held in MCL 333.20921(3)(c) as detailed below:

> 333.20921 (3) Except as provided in subsection (4), an ambulance operation shall not operate, attend, or permit an ambulance to be operated while transporting a patient unless the ambulance is, at a minimum, staffed as follows:
>
> (a) If designated as providing basic life support, with at least 1 emergency medical technician and 1 medical first responder.
>
> (b) If designated as providing limited advanced life support, with at least 1 emergency medical technician specialist and 1 emergency medical technician.
>
> (c) **If designated as providing advanced life support, with at least 1 paramedic** and 1 emergency medical technician.

It is recommended that the standards continue to comply with the statutory definition.

Definition of Patient Transport

The Department received a request to modify the definition of patient transport when it specifically involves an air ambulance service which only operates a single air ambulance. The request is to allow a single air ambulance service to count all potential patient transports that would be missed because the air ambulance was either already transporting a patient or out of service due to maintenance. These potential patient transports would be added to the actual patient transport volume of the single air ambulance service. It is recommended that this concept not be reviewed.

A separate issue regarding patient transport involves the definition in Section 2 (1)(ee). Currently, the definition is that a patient transport is defined as the transport of a patient either via a pre-hospital transport or an inter-facility transport, and specifically states that the use of an air ambulance that does not involve the transport of a patient shall not be counted. Interestingly, in Section 2(1)(d) of the standards, additional air ambulance service activities are defined as being any of the following: advanced life support

intercepts, search/rescue, emergency transport of drugs, organs, medical supplies or equipment and personnel. While these services are acknowledged in the air ambulance standards, they are not counted in the definition of patient transport in Section 2(1)(ee). A review of these definitions is recommended for potential language modification and the inclusion of additional activities in the definition of a patient transport.

Definition of Primary and Secondary Service Areas

The Department received a request to review and clarify the definitions of primary and secondary service areas. The definitions in Section 2 (1)(gg) and (mm) are broad in nature. A review of these definitions for additional clarification is recommended.

Expansion of Service

The Department received four (4) requests to review the volume requirements for expansion of service. Currently, an air ambulance service is required to project 275 patient transports for initiation of service and maintain 275 patient transports per year for maintenance of service. Nonetheless, to expand the service to a second air ambulance, the service is required to have had 600 patient transports and a projection of an additional 200 patient transports to be approved for the second air ambulance, thus a total of 800 patient transports. There seems to be an inconsistency in the progression of the patient transport numbers from initiation of service, expansion of service and replacement of equipment. A review of this language is recommended.

Additionally, the Department received a request that an air ambulance service be allowed to expand to a half-time/12-hour air ambulance. Similar concepts to this have been proposed in other CON standards and the Department was unable to support the recommendation due to the regulatory difficulties and compliance issues it would cause. It is recommended to not review this concept.

Replacement of Equipment

The Department received two (2) requests to review the volume requirements for replacement of equipment. Currently, an air ambulance service with two (2) air ambulance must have had 1,200 patient transports and a projection of an additional 200 patients, thus a total of 1,400 patient transports to replace equipment. There seems to be an inconsistency in the progression of the patient transport numbers from initiation of service, expansion of service and replacement of equipment. It is recommended that this concept be reviewed.

Technical Changes and Updates

The Department received a request for a technical correction/clarification in Section 5. I agree with the necessity of this clarification and the Department has identified several additional technical changes that need to be made to the Standards. In addition, the Department is systematically modifying all standards to achieve uniformity, as well as in preparation for the launch of the on-line application system.

Collection of Air Ambulance Services Data

Until this year, the Department has not collected transport data from the air ambulance services. The Department is finalizing an air ambulance service survey and would expect to have relevant data in the near future.

Recommendations

It is recommended no action be taken on the definition of air medical personnel and expansion of service to a 12-hour air ambulance. In addition, it is recommended that a Workgroup be formed to review the following areas:

- Definition of Patient Transport in Section 2 (1)(ee) for possible modification and inclusion of activities identified in Section 2 (1)(d).
- Definitions Primary and Secondary Service Areas in Section 2 (1)(gg) and (mm) for additional definition and clarification.
- Requirements of Expansion of Service in Section 4, with regards to the volume requirements.
- Requirements of Replacement of Service in Section 5, with regards to the volume requirements.

It is recommended to modify the standards upon receipt of the Workgroup recommendations and include the departmental technical changes and updates.

**MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review**
**Presented to CON Commission March, 13, 2007**

| **COMPUTED TOMOGRAPHY (CT) SCANNER SERVICES**<br>(Please refer to 2.15.07 MDCH staff analysis for additional detail – attached) | | | |
|---|---|---|---|
| All Identified Issues | Issues Recommended as Requiring Review | Recommended Course of Action to Review Issues | Other/Comments |
| 1. Review volume commitment numbers (actual, projected & thresholds) | Yes | Potentially refer for SAC discussion | |
| 2. Review relocation & replacement criteria and definitions | Yes | Potentially refer for SAC discussion | |
| 3. Review commitment procedures; make them similar to MRI & PET | Yes | Potentially refer for SAC discussion | |
| 4. Review criteria and processes for addressing emerging specialty use scanners (e.g., dental, "mini", portable, hybrid) | Yes | Potentially refer for SAC discussion | |
| 5. Review pediatric criteria and need for specific weighting | Yes | Potentially refer for SAC discussion | |
| 6. Review use of commitments from other states | Yes | Potentially refer for SAC discussion | |
| 7. Review CT scanner use in simulation MRT | Yes | Potentially refer for SAC discussion | |
| 8. Technical changes in language to be uniform with other CON standards | Yes | Review draft language developed by MDCH staff and take action at completion of SAC | |
| **Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft technical changes (#8) for appropriate Commission review and public comment. Additionally, the Department recommends that the Commission consider appointing a SAC to bring back recommendations for items 1 through 7 and to ask the SAC to present its final recommendations at the December 2007 meeting. The Department is prepared to assist the Chair and Vice-Chair in drafting a charge to the SAC that is based upon the Commission's determination and decision of the items that are to be included.** | | | |

Michigan Department of Community Health
**MEMORANDUM**
Lansing, MI

DATE: February 15, 2007

TO: Irma Lopez

FROM: Matt Jordan

RE: Summary of Public Hearing Comments on Computed Tomography (CT) Standards

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Note
The information below is only a summary. Please review the Public Hearing folder for a complete transcript of the oral comments and copies of documents provided in written format.

Oral Testimony Summary
Two individuals testified for two facilities/organizations.

Bob Meeker, Spectrum Health: Relocation language of CT scanners should be modified/changed to be more in line with other CON services, such as MRI. This would permit the relocation of individual units as well as the entire CT service, whereas the current CT standards only permit the relocation of the entire service; additional adjustment of standards to allow an underperforming unit to be relocated when operating below the volume threshold; consideration of a dollar amount to distinguish between an upgrade (non-CON action) and a replacement (CON action); consideration of adding a weight to procedures done on special needs and/or pediatric patients; the need for lower volume numbers and requirements for specialty use CT scanners and mini-CT scanners, but while still recognizing a need for some level of regulation on those types of CT scanners.

Steven Szelag, University of Michigan Health System: CT scanner technology is continuing to evolve; the new technology allows for enhanced ways to diagnose disease; while the applications of specialty CT scanners and mini CT scanners is broad, regulation may still be necessary to promote efficient and proper health care and to avoid a rush of machines to the state; special requirements are needed for volumes and use of specialty CT scanners and mini CT scanners; recommends a workgroup or Standard Advisory Committee.

Written Testimony Summary

Four individuals provided written testimony, representing four facilities/organizations.

Caroline Ruddell, Michigan Dental Association: Dental CT scanners should be exempt from CON regulations and the CON Commission should take action to change the current regulations; CON regulations are hindering Michigan citizens' access to the current technology; dental CT scanners have a much lower cost than full body CT scanners and are cheaper than other unregulated pieces of equipment; dental CT scanners replace currently unregulated equipment such as a panoramic x-ray.

Ghabi Kaspo, DDS: Dental CT scanners should be exempt from CON regulations; current regulations on dental CT scanners is hindering access to this important technology; regulating dental CT scanners decreases the quality of care for Michigan residents and forces unnecessary procedures and expenses; CON has never regulated dentistry before and by forcing regulations upon dentists, it is creating delays to access of this important technology.

Ronald Lints, DDS: Dental CT scanners should be exempt from CON regulations; dental CT scanners are significantly different than full body CT scanners, particularly relating to the cost of the equipment; CON does not regulate any other piece of equipment that is as inexpensive as dental CT scanners; Con has never before entered into the realm of dentistry; dental CT scanners are an enhancement upon current products like panoramic x-ray, and not an evolution or use out of a full body CT scanner, which distinguishes it from other specialty CT scanners.

Theodore Freeland, DDS: Dental CT scanners should be exempt from CON regulations; CON has never before regulated dentistry; dental CT scanners are very different from medical CT scanners, particularly in cost of the equipment; dental CT scanners are nearly interchangeable with panoramic x-ray and cephalometric machines, which CON does not currently regulate; dental CT scanning is not replacing other CON covered equipment, but rather replacing currently uncovered equipment.

Email Testimony Summary

Five individuals provided electronic mail testimony, representing five facilities/organizations:

Barbara Jackson, Economic Alliance for Michigan: The current CT Standards language is very imprecise; the modality is continuing to evolve and possibly bringing increased cost and applications; the CT physician commitment process should be strengthened and brought in line with similar provisions in the standards for MRI and PET; volume commitment should be based upon actual utilization, not projected future utilization; supports a deliberate process for specialty use CT scanners, recognizing that different requirements are needed for volume, cost, and quality; CT Standards need to address the use of hybrid machines such as a PET/CT scanner.

Predrag Sukovic, Xoran Technologies: Michigan should carve out an exception in the CT Standards for low radiation dose specialty CT scanners; consider exempting specialty CT scanners from CON regulation, either based upon cost, use, or low radiation output levels; specialty CT scanners such as the MiniCAT provide great benefit to the patient and point of care delivery; low dose radiation machines would benefit Michigan residents in safety and cost, and would free full body CT scanners to do the advanced scanning they were designed for originally.

Stanley Skarli, DeVos Children's Hospital: supports the creation of alternative volume numbers for portable CT scanners; portable CT scanners provide better technology and lower cost for the patient; portable CT scanners reduce risk and cost associated with moving a patient to receive a CT scan; lower volume numbers would allow xenon CT scanning to be done at a lower cost.

Robert Meeker, Spectrum Health: CT Standards have served the state well, but particular provisions need to be reviewed and updated; those areas include clarification of the requirements for relocation, revised definition of replacement, specific acknowledgement of the imaging requirements for pediatric patients, and allowance for new CT technology; relocation of a specific CT scanner versus relocation of an entire service.

Mike Abney, Neurologica: recommends alternative CT equivalents for point of care CT scanners such as bedside scanners; the CereTom scanner is important to Michigan and provides imaging access to recent stroke and TBI patients; the CereTom protects the patient's health by avoiding frequent moves from the ICU to a traditional CT scanner; promoting an annual volume level of around 2000 CT equivalents; or alternatively, an adjustment in the conversion factors for a point of care CT scanner; CereTom scanner is significantly less than traditional CT scanners.

<u>Policy issues to be addressed</u>

Based upon the various testimonies provided, as well as the goals being promoted by MDCH, the CON Policy Section should decide whether to continue with the current CT Standards or to modify the CT Standards. If modifying is chosen, the CON Policy Section should then decide whether a workgroup or a Standard Advisory Committee (SAC) would handle the public discussion and proposed modification. The testimony above indicates that the CT Standards contain a wide breadth of issues to potentially be reviewed, including but not limited to the following: actual commitments, projected commitments, volume threshold, full body CT scanners, specialty and mini CT scanners, dental CT scanners, pediatric patients, and relocation of a CT scanner or a service. Additionally, the CON Program Section has indicated that there are numerous operational and application issues with the current CT Standards that the Section would like to propose to change.

**MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review**
**Presented to CON Commission March, 13, 2007**

| **NEONATAL INTENSIVE CARE SERVICES/BEDS (NICU)** (Please refer to 2.23.07 MDCH staff analysis for additional detail - attached) | | | |
|---|---|---|---|
| All Identified Issues | Issue Recommended for Review? | Recommended Course of Action to Review Issues | Other/Comments |
| 1. Review and recalculate bed need methodology | No | None at this time | The bed need methodology has been calculated three times in the last four years using 2005 data which remains the most current data |
| 2. Modify the project delivery requirements to specify that providers be trained in neonatal/pediatrics | Yes | Review draft language developed by the department to require pediatric specialties | |
| 3. Remove five (5) bed cap contained in expansion of service in Section 6(2) | Not at this time | Review utilization data | Data shows minimal utilization of this provision along with low occupancy rates. If data over the next few years supports a change, this can be a part of subsequent review of the standards |
| 4. Make technical changes and updates that provide uniformity in all CON standards | Yes | Review draft language developed by MDCH staff | |
| **Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft necessary technical changes to the standards for appropriate Commission review and public comment. The Department suggests no specific SAC or workgroup activity for the technical changes.** | | | |

Michigan Department of Community Health
**MEMORANDUM**
Lansing, MI

DATE: February 23, 2007

TO: Irma Lopez

FROM: Andrea Moore

RE: 2007 Review of Neonatal Intensive Care Services/Beds Standards

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Pursuant to MCL 333.22215 (1)(m) the Certificate of Need (CON) Commission is to "..review, and if necessary, revise each set of Certificate of Need standards at least every 3 years." In accordance with the established review schedule on the Commission Workplan, Neonatal Intensive Care Services/Beds Standards are scheduled for review in calendar year 2007.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the NICU Standards on January 9, 2007, with written testimony being received for an additional 7 days after the hearing. Testimony was received from one (1) organization and is summarized as follows:

Spectrum Health

- Review the bed need methodology, due to the increase in the birth rates of premature infants and length of time since the methodology has been established and reviewed.
- Recommends that project delivery requirement in Section 11 (1)(c)(ix) and (x) require pediatric specialties, as apposed to the current general specialties.
- Recommends removing the five (5) bed cap from the expansion of service language in Section 6 (2), which allows a facility to expand beyond the bed need inventory for facilities with a high rate of transferred patients to the facility.

Bed Need Methodology

On June 9, 1995, the current bed need methodology was established utilizing the formula of 4.5 beds per 1,000 live births, taking into consideration the very low birth weight (VLBW) adjustment factor. Prior to 1995, the bed need methodology was 4.5 beds per 1,000 live births. While the methodology has been in place for 11 years, it is comparable to other states; a summary of the states reviewed is as follows:

| State | Current Methodology |
|---|---|
| Mississippi | 4 beds per 1,000 live births in each perinatal planning area. (1- Intensive Care Bed and 3-Intermediate Care Beds)<br>• Minimum unit size is 15 beds. |
| Tennessee | 8 beds per 1,000 live births in each neonatal service area.<br>• Minimum unit size is 15 beds. |
| Virginia | 4 beds per 1,000 live births in each perinatal service area.<br>• Minimum unit size is 15 beds.<br>• Required maintain occupancy level of 85%. |
| West Virginia | 4 beds per 1,000 live births in each perinatal service area.<br>• Level II NICU beds only at facilities with 1,100 deliveries per year. |

The bed need methodology has been calculated three (3) times in the last four (4) years, most recently on December 15, 2006, utilizing 2005 data. The 2005 data is the most current data available to the Department. While the testimony from Spectrum Health suggested that the VLBW numbers have increased, upon review of the data, the VLBW numbers have stayed relatively the same and the total live births have decreased slightly over the four (4) year period. The birth rates and resulting bed need are as follows:

| H.S.A. | 2002 Data | | | 2004 Data | | | 2005 Data | | |
|---|---|---|---|---|---|---|---|---|---|
| | Live Births | VLBW Births | Resulting Bed Need | Live Births | VLBW Births | Resulting Bed Need | Live Births | VLBW Births | Resulting Bed Need |
| 1 | 64,626 | 1,165 | 329 | 64,362 | 1,199 | 329 | 62,450 | 1,228 | 333 |
| 2 | 9,116 | 116 | 33 | 9,312 | 142 | 39 | 9,083 | 117 | 32 |
| 3 | 9,992 | 131 | 37 | 10,499 | 135 | 38 | 10,471 | 160 | 44 |
| 4 | 19,759 | 289 | 82 | 20,277 | 306 | 84 | 20,112 | 281 | 77 |
| 5 | 8,200 | 149 | 42 | 8,161 | 145 | 40 | 7,714 | 111 | 31 |
| 6 | 8,083 | 124 | 35 | 8,072 | 107 | 30 | 7,918 | 126 | 35 |
| 7 | 4,970 | 39 | 11 | 5,059 | 50 | 14 | 4,950 | 40 | 11 |
| 8 | 2,709 | 23 | 7 | 2,830 | 25 | 7 | 2,758 | 22 | 6 |
| ***TOTAL*** | 127,455 | 2,036 | 576 | 128,572 | 2,109 | 581 | 125,456 | 2,085 | 569 |

While the methodology has been in place for 11 years, it is comparable to other CON States; the methodology has been calculated utilizing the must up-to-date data; it is recommended that no revisions be made to the bed need methodology.

Project Delivery Requirements

The project delivery requirements in Section 11 (1)(c)(ix) and (x) require the provision for on-site physician consultation services and provisions for highly specialized services. The current language is very broad and does not specify that the provider of the services be trained in neonatal/pediatrics. It is recommended that an additional clarification regarding training in neonatal/pediatrics would be beneficial and appropriate to the Standards.

Technical Changes and Updates

The Department is systematically modifying all Standards to achieve uniformity, as well as in preparation for the launch of the on-line application system. In addition, there are several technical changes that need to be made to these Standards to remove old terminology and clarify current language.

Expansion of Service

The expansion of service language, established June 9, 1995, in Section 6 (2) allows a facilities with a high rate of transferred patients to expand beyond the bed need inventory with a maximum of five (5) beds. After reviewing the facility activity for the previous five (5) years, the Department found that this language only been utilized by a few facilities. Additionally, the 2005 occupancy rates for NICU facilities were reviewed, see table below.

The 2005 occupancy rates are as follows:

| H.S.A. | FACILITY NAME | CITY | FACILITY NUMBER | LICENSED BEDS | PATIENT DAYS 2005 | OCCUPANCY RATE |
|---|---|---|---|---|---|---|
| 1 | St. Joseph Mercy Hospital Ann Arbor | Ann Arbor | 81-0030 | 15 | 2,396 | 43.76 |
| 1 | North Oakland Medical Center | Pontiac | 63-0110 | 18 | 2,633 | 40.08 |
| 1 | St. Joseph Mercy Oakland | Pontiac | 63-0140 | 15 | 3,893 | 71.11 |
| 1 | Port Huron Hospital | Port Huron | 74-0020 | 4 | 488 | 33.42 |
| 1 | University of Michigan Health System | Ann Arbor | 81-0060 | 40 | 12,560 | 86.03 |
| 1 | Oakwood Hospital | Dearborn | 82-0120 | 30 | 9,531 | 87.04 |
| 1 | William Beaumont Hospital | Royal Oak | 63-0030 | 33 | 12,090 | 100.37 |
| 1 | Providence Hospital & Medical Center | Southfield | 63-0130 | 15 | 3,434 | 62.72 |
| 1 | St. John Hospital & Medical Center | Detroit | 83-0420 | 35 | 10,975 | 85.91 |
| 1 | Children's Hospital of Michigan | Detroit | 83-0080 | 42 | 6,924 | 45.17 |
| 1 | St. John Detroit Riverview Hospital | Detroit | 83-0034 | 15 | 2,543 | 46.45 |
| 1 | Henry Ford Hospital | Detroit | 83-0190 | 35 | 7,354 | 57.57 |
| 2 | Edward W. Sparrow Hospital | Lansing | 33-0060 | 30 | 9,786 | 89.37 |
| 3 | Bronson Methodist Hospital | Kalamazoo | 39-0020 | 45 | 13,834 | 84.23 |
| 4 | Spectrum Health Hosp (Butterworth) | Gr. Rapids | 41-0040 | 67 | 20,040 | 81.95 |
| 4 | St. Mary's Medical Center | Gr. Rapids | 41-0080 | 15 | 5,218 | 95.31 |
| 5 | Hurley Medical Center | Flint | 25-0040 | 44 | 12,776 | 79.55 |
| 7 | Munson Medical Center | Traverse | 28-0010 | 12 | 4,406 | 100.59 |
| 7 | Northern Michigan Hospital | Petoskey | 24-0030 | 12 | 874 | 19.95 |
| 8 | Marquette General Hospital | Marquette | 52-0050 | 10 | 3,034 | 83.12 |

* Sinai-Grace Hospital (83-0450), Hutzel Women's Hospital (83-0240) and Covenant Medical Center (73-0061) have been excluded from the above table due to missing or incomplete data.

It is recommended that the five (5) bed cap should be maintained given the minimal utilization of this provision and the occupancy rates.

Recommendations

In response to the Public Hearing testimony, the following is recommended:

- Maintain the current bed need methodology.
- Modify the project delivery requirements in Section 11(1)(c)(ix) and (x) to require pediatric specialties.
- Maintain the current expansion language in Section 6(2) to allow up to five (5) beds per facility utilizing the current formula.

Drafted changes to the Standards in accordance to the recommendations above, including the departmental technical changes and updates are attached. The Department could ask that the Commission review draft language for possible proposed action.

**MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review**
**Presented to CON Commission March, 13, 2007**

**NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS, ADDENDUM FOR SPECIAL POPULATIONS GROUPS, AND ADDENDUM FOR NEW DESIGN MODEL PILOT**
(Please refer to 3.05.07 MDCH staff analysis for additional detail - attached)

| All Identified Issues | Issue Recommended for Review? | Recommended Course of Action to Review Issues | Other/Comments |
|---|---|---|---|
| 1. Include quality measures for initiation, acquisition and expansion | Yes | Potentially refer for SAC discussion | |
| 2. Review CON standards to ensure consistency with state LTC policy and regulations to the extent that they may be within the scope of CON authority | Yes | Potentially refer for SAC discussion | Specific activities that are the responsibility of other entities may fall outside the scope of a SAC. However, the SAC should have an awareness of the direction in which state policy is moving |
| 3. Review definitions and methodologies contained in the standards and potentially examine other options | Yes | Potentially refer for SAC discussion | |
| 4. Review the applicability of and need for designation of special population group beds | Yes | Potentially refer for SAC discussion | |
| 5. Review pilot status of New Design Model Project (FIDS) | Yes | Potentially refer for SAC discussion | |
| 6. Review need for high occupancy language similar to other CON standards | Yes | Potentially refer for SAC discussion | |
| 7. Review definition of replacement zone | No | None at this time | This issue is currently addressed by statute |
| 8. Consider mandating dual certification | No | No specific activity at this time | MCL 333.22215(1) currently prohibits this mandate |
| 9. Consider standards | No | No specific activity at | This issue would |

**MDCH Synopsis of Comments for CON Standards Scheduled for 2007 Review**
**Presented to CON Commission March, 13, 2007**

| | | | |
|---|---|---|---|
| that require service without regard to ability to pay | | this time | require legislative action |
| 10.Review of project delivery requirements; specifically regarding onsite geriatric services | Yes | Review draft language developed by the department to address geriatric services | |
| 11. Technical changes proposed by the department to ensure uniformity with other CON standards | Yes | Review draft language developed by MDCH staff | |
| **Recommendation: The Department suggests that the Commission assign responsibility to Department staff to draft technical changes (# 10 and #11). The Department further suggests that the Commission consider appointing a SAC to bring back recommendations for items #1 through # 6 and to provide its final recommendations at the December 2007 meeting. The Department is prepared to assist the Chair and Vice-Chair in drafting a charge to the SAC that is based upon the Commission's determination and decision of the items that are to be included.** | | | |

Michigan Department of Community Health
**MEMORANDUM**
Lansing, MI

DATE: March 5, 2007

TO: Irma Lopez

FROM: Andrea Moore

RE: 2007 Review of Nursing Home and Hospital Long-Term-Care Unit Beds Standards

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Pursuant to MCL 333.22215 (1)(m), the Certificate of Need (CON) Commission is to "..review, and if necessary, revise each set of Certificate of Need (CON) standards at least every 3 years." In accordance with the established review schedule on the Commission Workplan, the Nursing Home and Hospital Long-Term-Care Unit Beds Standards are scheduled for review in calendar year 2007.

Public Hearing Testimony
The Department held a Public Hearing to receive testimony regarding the Standards on January 9, 2007, with written testimony being received for an additional 7 days after the hearing. Testimony was received from 12 organizations and is summarized as follows:

1. ADAPT Michigan
   - Requesting a Standard Advisory Committee (SAC) comprised of a consumer majority.
   - Recommends modifying definitions and methodology to encompass all current types of Long-Term-Care (LTC) options.
   - Review 2005 Governor's Medicaid LTC Task Force Report for additional recommendations.
   - Establish quality measures to ensure Nursing Home operators are in compliance with all regulatory standards prior to issuance of an additional CON.

2. AARP Michigan
   - Requesting a SAC comprised of a consumer majority with diverse geographic, generational and cultural representation.
   - Recommends definitions and methodologies that encompass all current types of LTC options.
   - Review 2005 Governor's Medicaid LTC Task Force Report for additional recommendations.
   - Establish quality measures to ensure Nursing Home operators are in compliance with all regulatory standards prior to issuance of an additional CON.

3. Alzheimer's Association
   - Recommends Standards that encompass all current types of LTC options.
   - Review 2005 Governor's Medicaid LTC Task Force Report for additional recommendations.
   - Requesting a SAC comprised of a consumer majority.

4. Area Agencies on Aging Association of Michigan
   - Requesting a SAC comprised of a consumer majority with diverse geographic, generational and cultural representation.
   - Recommends definitions and methodologies that encompass all current types of LTC options, including home-based services and assisted living.
   - Review 2005 Governor's Medicaid LTC Task Force Report for additional recommendations.
   - Establish quality measures to ensure Nursing Home operators are in compliance with all regulatory standards prior to issuance of an additional CON.

5. Economic Alliance for Michigan
   - Establish quality measure to ensure Nursing Home operators are in compliance with all regulatory standards and building codes prior to issuance of an additional CON.

6. Fair Acres Care Center
   - Recommends additional Medicaid funding for other LTC options, including assisted living and home health care.

7. Heath Care Association of Michigan
   - Recommends extending the New Design Model Pilot Program for an additional 4 years.
   - Recommends establishing a SAC to review the standards.

8. Michigan Poverty Law Program
   - Requesting a SAC with consumer advocates representation.
   - Recommends definitions and methodologies that encompass all current types of LTC options.
   - Review 2005 Governor's Medicaid LTC Task Force Report for additional recommendations.
   - Establish quality measures to ensure Nursing Home operators are in compliance with all regulatory standards prior to issuance of an additional CON.
   - Require all facilities to be dually certified in Medicaid and Medicare.
   - Ensure that all providers are providing care to all patients regardless of individual source of payment on a first come first serve basis.
   - Coordination of Medical Services Administration, Office of Long Term Care Supports and Services, Office of Services to the Aging and the Department of Human Services to provide well-rounding coordinated plan.

9. Michigan Disability Right Coalition
   - Review 2005 Governor's Medicaid LTC Task Force Report for additional recommendations.
   - Establish quality measures to ensure Nursing Home operators are in compliance with all regulatory standards prior to issuance of an additional CON.
   - Recommends definitions and methodologies that encompass all current types of LTC options, including home-based services and assisted living.

10. Michigan State Long Term Care Ombudsman
    - Requesting a SAC comprised of a consumer majority.
    - Establish quality measures to ensure Nursing Home operators are in compliance with all regulatory standards prior to issuance of an additional CON.
    - Ensure that Nursing Home enforcement is strong and consistent.
    - Recommends definitions and methodologies that encompass all current types of LTC options.
    - Require all facilities to be dually certified in Medicaid and Medicare, enforcing that all Medicare certified beds seek Medicaid certification.
    - Ensure that all providers are providing care to all patients regardless of individual source of payment.

11. Spectrum Health
    - Review the definition of replacement zone for an increase in the zone for metropolitan counties.
    - Modify high occupancy language to be facility-specific.
    - Recommends the addition of a category for patients with psychiatric diagnosis in the Special Population Group.
    - Recommends elimination of Section 3(3) in the Addendum for New Design Pilot Program.

12. University of Michigan
    - Recommends establishing clinical certification for skilled facilities, ie. Traumatic brain injury, ventilator-dependent, kidney dialysis, etc.
    - Recommends set list of on-site services and personnel required, ie. Geriatric physician, geriatric pharmacist, occupational and physical therapist, etc.
    - Review Medicaid issues of the availability of Medicaid beds and the difficulty in securing Medicaid coverage for patients.

Standard Advisory Committee

The Department received seven (7) recommendations that the Nursing Home and Hospital Long-Term-Care Unit Beds Standards be reviewed utilizing the appointment of a SAC. Several requests contained specific composition of the SAC. These requests for specific composition should be reviewed and compared to the legal requirements outlined by the statute. The composition of a SAC is determined pursuant to MCL 333.22215(1)(l) as detailed below:

> 333.22215(1)(l) If the commission determines it necessary, appoint standard advisory committees to assist in the development of proposed certificate of need review standards. A standard advisory committee shall complete its duties under this subdivision and submit its recommendations to the commission within 6 months unless a shorter period of time is specified by the commission when the standard advisory committee is appointed. An individual shall serve on no more than 2 standard advisory committees in any 2-year period. **The composition of a standard advisory committee shall not include a lobbyist registered under 1978 PA 472, MCL 4.411 to 4.431, but shall include all of the following:**
>
> **(i) Experts with professional competence in the subject matter of the proposed standard, who shall constitute a 2/3 majority of the standard advisory committee.**
>
> **(ii) Representatives of health care provider organizations concerned with licensed health facilities or licensed health professions.**
>
> **(iii) Representatives of organizations concerned with health care consumers and the purchasers and payers of health care services.**

Additionally, the Nursing Home and Long-Term-Care Unit Beds Workgroup 2005 - 2006 met on five (5) occasions from December 2005 through September 2006. The Workgroup drafted language to allow the addition of beds for an individual facility with high occupancy and established quality criteria for initiation of a new facility, the acquisition of an existing facility and the addition of beds at an existing facility. The draft language was never presented to the Commission for review or action. The Workgroup was unable to reach a reasonable consensus on the issues and ended their work in September of 2006. Taking into consideration the Workgroup's previous difficulties in reaching a consensus on many of the same issues, it is recommended to appoint a SAC pursuant to MCL 333.22215(1)(l).

Quality Measures

The Department received seven (7) recommendations for the inclusion of quality measures for all applicants proposing to initiate service, expand service or acquire a service. The Nursing Home and Long-Term-Care Unit Beds Workgroup 2005 – 2006 evaluated this issued and drafted language on this issue, but due to non-consensus of the Workgroup, the language was not presented to the Commission.

The Nursing Facilities, Staffing, Residents and Facility Deficiencies 1999-2005 Report, prepared and published by the University of California San Francisco in September 2006 was reviewed to evaluate national trends in quality of care provided in nursing homes. It is noted that Michigan is continually above the national average for the number of deficiencies per home and the percentage of facilities receiving a deficiency for actual harm, while the percentage of facilities in Michigan with no deficiencies is well below the national average. The breakdown of the data is as follows:

| Nursing Facilities, Staffing, Residents and Facility Deficiencies, 1999-2005 | | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|---|---|---|---|---|---|---|
| Average Number of Deficiencies per Certified Nursing Facility | Michigan | 9.6 | 8.4 | 9.2 | 9.9 | 10.9 | 8.8 |
| | National Average | 5.9 | 6.3 | 6.3 | 7.0 | 9.2 | 7.1 |
| Percent of Facilities with No Deficiencies | Michigan | 3.1 | 3.1 | 2.4 | 3.8 | 4.3 | 3.9 |
| | National Average | 16.6 | 13.7 | 10.0 | 9.9 | 9.9 | 8.8 |
| Percent of Facilities Receiving a Deficiency for Actual Harm | Michigan | 34.7 | 24.3 | 29.5 | 24.9 | 23.1 | 25.8 |
| | National Average | 23.5 | 21.1 | 18.0 | 16.6 | 15.5 | 16.9 |

Several CON states already have quality measures in their CON standards and the following are offered as examples:

The State of Arkansas will not grant a Permit for Approval to an application in which the applicant has any of the following conditions:

- A project that does not eliminate all three (3) bed units in the applicant's facility, except to comply with specific regulations for intensive care, Alzheimer's, or sub-acute care units.
- A project that does not include a sprinkler system and generator.
- An application for a facility with a current life threatening compliance issues that will not be corrected by the proposed construction.
- An application for a facility with a level H deficiency or higher in the 12 months preceding the date of the application or until the final decision of the Commission.
- An application for a facility where the owner/operator has abandoned one (1) or more LTC facilities either in Arkansas or in another State.
- The Agency may consider an applicant's compliance and enforcement history.

The State of Georgia will not grant a CON to an application in which the applicant has any of the following conditions:

- An application for a facility with uncorrected operational standards in any existing Georgia nursing home owned and/or operated by the applicant or by the applicant's parent organization. Plans to correct physical plan deficiencies in the apply facility must be included in the application.
- An applicant and any facility owned and/or operated by the applicant or its parent organization shall have no previous conviction of Medicaid or Medicare fraud.

The State of Virginia, when having competing applications, will give preference as follows:

- To applicants who can demonstrate a consistent history of compliance with state licensure regulations.
- To applications who are accredited by the Joint Commission on Accreditation of Health Care Organizations or another appropriate accrediting body and who can demonstrate a history of operating accredited facilities.
- To applicants who can demonstrate a consistent pattern of licensure surveys with few deficiencies and a consistent history of few complaints.

It is recommended that the SAC consider inclusion of quality measures for all applicants and the owner/operator proposing to initiate service, expand service or acquire a service, and provide specific criteria. This does not negate the necessity of continued presence of enforcement activity.

Recommendation from the Michigan Medicaid Long-Term-Care Task Force

The Department received six (6) recommendations for the review of the final report of the Michigan Medicaid Long-Term-Care Task Force for additional SAC guidance. The Michigan Medicaid LTC Task Force was created by Governor Granholm via executive order in 2004 to evaluate multiple Medicaid and LTC issues. The final report of the Task Force was published in May 2005 and is available at: http://www.ihcs.msu.edu/LTC/default.htm. It is recommended that the SAC review of the final report of the Michigan Medicaid Long-Term-Care Task Force for guidance in responding to all charge items.

Definitions and Methodologies

The Department received six (6) recommendations to modify the definitions and methodologies of the Nursing Home and Hospital Long-Term-Care Unit Beds Standards to consider additional LTC options currently available. The CON regulation of Nursing Home and Hospital Long-Term Care Beds are statutorily held in Part 222 of the Public Health Code. Pursuant to MCL 333.22215, the Commission may add cover clinical services, as follows:

> MCL 333.22215 (1) The commission shall do all of the following:
> (a) If determined necessary by the commission, revise, add to, or delete 1 or more of the covered clinical services listed in section 22203. If the commission proposes to add to the covered clinical services listed in section 22203, the commission shall develop proposed review standards and make the review standards available to the public not less than 30 days before conducting a hearing under subsection (3).

A covered clinical service is defined as follows:

> MCL 333.22203 (10) "Covered clinical service", except as modified by the commission under section 22215, means 1 or more of the following:
> (a) Initiation or expansion of 1 or more of the following services:
> (i) Neonatal intensive care services or special newborn nursing services.
> (ii) Open heart surgery.
> (iii) Extrarenal organ transplantation.
> (b) Initiation, replacement, or expansion of 1 or more of the following services:
> (i) Extracorporeal shock wave lithotripsy.
> (ii) Megavoltage radiation therapy.
> (iii) Positron emission tomography.
> (iv) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under part 215 and offering inpatient or outpatient surgical services.
> (v) Cardiac catheterization.
> (vi) Fixed and mobile magnetic resonance imager services.
> (vii) Fixed and mobile computerized tomography scanner services.
> (viii) Air ambulance services.
> (c) Initiation or expansion of a specialized psychiatric program for children and adolescent patients utilizing licensed psychiatric beds.
> (d) Initiation, replacement, or expansion of a service not listed in this subsection, but designated as a covered clinical service by the commission under section 22215(1)(a).

While the Commission has the authority to add covered clinical services, an addition of any more LTC services to the definition of covered clinical services is not recommended.

Special Population Group Beds

The Department received one (1) recommendation to expand the Addendum for Special Population Group Beds to include a category for patients with psychiatric diagnosis. Special Population Group Beds need to be reviewed on a larger scale, as MCL 333.22217(1)(b), introduced in the 1980's, statutorily mandated the establishment of the Special Population Group to serve religious patients and patients with specialized health conditions until March 31, 2003, when it was repealed pursuant to P.A. 619. With the removal of MCL 333.22217 by P.A. 619, the Commission has the discretion to eliminate or modify the criteria of the Special Population Groups. It is recommended that the SAC review the Addendum for Special Population Group Bed for elimination of the addendum or modification of the addendum, including but not limited to the inclusion of a category for patients with a psychiatric diagnosis.

New Design Model Pilot Program

The Department received one (1) recommendation to extend the Addendum for New Design Model Pilot Program for an additional four (4) years and one (1) recommendation to eliminate Section 3(3) of the Addendum for New Design Model Pilot Program. In accordance to Section 3(1), the Addendum for New Design Model Pilot Program will be in effect from September 14, 2004, to September 14, 2008. To date, 11 facilities been approved under the pilot program.

Section 3(3) of the Addendum required that all new construction pilot project facilities must have 80% single occupancy rooms and an existing facility must not have any rooms that exceed double occupancy. It is maintained that Section 3(3) is an essential part of the New Design Model Pilot Program and should not be removal of this provision. It is recommended that the SAC review the Addendum for New Design Model Pilot Program for possible elimination, for an extension of the Pilot Program timeframe in Section 3(1), or possible removal of the pilot status to make the New Design Model a permanent addendum of the standards.

High Occupancy Language

The Department received one (1) recommendation to modify the high occupancy provisions in Section 6(c) to be facility specific high occupancy language. The Nursing Home and Long-Term-Care Unit Beds Workgroup 2005 – 2006 evaluated this issued and drafted language on this issue, but due to non-consensus of the Workgroup, the language was not presented to the Commission. In addition, other CON standards offer facility specific high occupancy language. It is recommended that the SAC review the high occupancy provision in Section 6(c) for possible modification to facility specific high occupancy.

Definition of Replacement Zone

The Department received one (1) recommendation to review the definition of replacement zone to increase the three (3) mile replacement zone in metropolitan areas. MCL 333.22229 provides guidelines with regards to a replacement application being subject to comparative review and is as follows:

> MCL 333.22229 (3) Replacement beds in a nursing home that is located in a nonrural county that are proposed for construction on the original site, on a contiguous site, or within a 2-mile radius of the original site are not subject to comparative review. Replacement beds in a nursing home that is located in a rural county that are proposed for construction on the original site, on a contiguous site, or within the same planning area are not subject to comparative review.

It is recommended that the SAC review the definition of replacement zone.

Dual Certification of Medicaid and Medicare

The Department received two (2) recommendations to modify the standards to require dual certification in both Medicaid and Medicare. The Commission is statutorily excluded from requiring an applicant for Nursing Home and Hospital Long-Term Care Unit Beds to participate in Medicaid pursuant to MCL 333.22215(1), as follows:

> MCL 333.22215 (1) The commission shall do all of the following:
> (b) Develop, approve, disapprove, or revise certificate of need review standards that establish for purposes of section 22225 the need, if any, for the initiation, replacement, or expansion of covered clinical services, the acquisition or beginning the operation of a health facility, making changes in bed capacity, or making covered capital expenditures, including conditions, standards, assurances, or information that must be met, demonstrated, or provided by a person who applies for a certificate of need. A certificate of need review standard may also establish ongoing quality assurance requirements including any or all of the requirements specified in section 22225(2)(c). **Except for nursing home and hospital long-term care unit bed review standards, by January 1, 2004, the commission shall revise all certificate of need review standards to include a requirement that each applicant participate in title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.**

It is recommended that the standards continue to comply with statute and not require dual certification in both Medicaid and Medicare.

Ability to Pay

The Department received two (2) recommendations to modify the standards to require acceptance of all patients regardless of ability to pay. The Commission is statutorily excluded from requiring an applicant for Nursing Home and Hospital Long-Term Care Unit Beds to participate in Medicaid and accept all patients pursuant to MCL 333.22215(5), as follows:

> MCL 333.22215 (5) The commission shall not develop, approve, or revise a certificate of need review standard that requires the payment of money or goods or the provision of services unrelated to the proposed project as a condition that must be satisfied by a person seeking a certificate of need for the initiation, replacement, or expansion of covered clinical services, the acquisition or beginning the operation of a health facility, making changes in bed capacity, or making covered capital expenditures. **This subsection does not preclude a requirement that each applicant participate in title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v, or a requirement that each applicant provide covered clinical services to all patients regardless of his or her ability to pay.**

It is recommended that the standards continue to comply with statute and not require the acceptance of all patients regardless of ability to pay.

Project Delivery Requirements

The Department received one (1) recommendation for additional clarification as the requirements of on-site geriatric services needed at a nursing home. It is recommended that the SAC review the project delivery requirements for updating and possible inclusion of specified on-site services.

Technical Changes and Updates

The Department is systematically modifying all Standards to achieve uniformity, as well as in preparation for the launch of the on-line application system. In addition, there are several technical changes that need to be made to these Standards to remove old terminology and clarify current language.

Recommendations

It is recommended that no action be taken on the requests to modify to the definitions and methodologies to include all LTC options, require dual certification, require acceptance of all patients without consideration of ability to pay,

It is recommended that a SAC be appointed to review the following issues:

- Addendum for Special Population Group Bed.
- Establishment of quality measures for all applicants including the owner/operator.
- Addendum for New Design Model Pilot Program.
- High occupancy provision in Section 6(c).
- Definition of replacement zone.
- Project delivery requirements for updating and possible inclusion of specified on-site services.
- The 2005 Michigan Medicaid Long-Term-Care Task Force for guidance in the recommendations on the listed charge items.

# M E M O R A N D U M

**DATE:** June 25, 2007

**TO:** CON Commission

**FROM:** Jan Christensen
Health Policy, Regulation, and Professions Administration

**SUBJECT:** Hospital Movement Fact Finding Committee

In the fall of 2006, the CON Commission asked the Department to review the available factual information that could support the movement of a hospital beyond the established 2 and 5 mile replacement zone limits.

The Department convened an informal workgroup which met on two occasions. In addition, the Department reviewed the available, factual evidence including population trends, building replacement factors, green building design, the previous hospital SAC findings, hospital utilization rates, and health care trends for aging populations. In addition, we requested information supporting proposed hospital movement from those hospitals and health systems interested in moving.

The materials reviewed, informal weekly group membership, and sample letter requesting information is attached.

Results:The Department has reached the following determination:

- While there is considerable information that "green" technology can provide cost savings, this information does not by itself lead to the conclusion that there is a need to rebuild hospitals outside of the replacement zone.

- Hospitals are generally available statewide and access greater than 30 minutes travel time does not appear to be a problem for the state.

- A combination of the other data available to the department at this time requires the conclusion that a change in standards is not necessary.

- The Department has not yet however, received detailed information supporting the specific proposals for individual hospitals who wish to move.

In summary, the Department has completed its review of the currently available information. As is always the case with CON, further future review in response to new or emerging information of a compelling nature may be necessary during the next regular statutory review of the hospital beds need methodology.

JC:ln
Enclosures