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

Wednesday, December 15, 2010

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Goldman called the meeting to order at 9:39 a.m.

Mr. Hart announced the retirees that will be leaving January 1st (Irma Lopez & Stan Nash). He also introduced Melanie Brim as the acting Deputy Director to Health Policy and Regulation.

On behalf of the Commission, Chairperson Goldman welcomed Ms. Brim, thanked Irma and Stan for their years of service, and announced Larry Horwitz's retirement and thanked him for his work over the years.

A. Members Present

Peter Ajluni, DO
James B. Falahee, Jr., JD, Vice-Chairperson
Edward B. Goldman, Chairperson
Marc Keshishian, MD
Brian Klott
Michael A. Sandler, MD
Michael W. Young, DO
Gay L. Landstrom, RN
Robert Hughes
Charles Gayney

B. Members Absent

Bradley Cory

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

William Hart Jr.
Irma Lopez
Melanie Brim
Brenda Rogers
Stan Nash
Jessica Austin
Sallie Flanders
Larry Horvath
Andrea Moore

Natalie Kellogg
Tania Rodriguez

II. Review of Agenda

Motion by Vice-Chairperson Falahee, seconded by Commissioner Ajluni, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of September 23, 2010

Motion by Vice-Chairperson Falahee, seconded by Commissioner Klott, to approve the minutes of September 23, 2010 as presented. Motion Carried.

V. Magnetic Resonance Imaging (MRI) Services - Public Hearing Comments

Ms. Rogers gave a brief summary of the Public Hearing (See Attachment A).

A. Public Comment:
Steven Szelag, University of Michigan Health Systems (UMHS) (See Attachment B)

B. Commission Discussion

C. The Commission asked the Department to provide an update on the intra-operative MRI (IMRI) pilot project and what, if anything needs to be done prior to 2012 when they are next scheduled for review.

D. Motion by Commissioner Sandler, seconded by Commissioner Young, to accept the proposed language (See Attachment C) and move forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Motion Carried.

VI. Nursing Home and Hospital Long-term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU) - Public Hearing Comments

Ms. Rogers gave a brief summary of the Public Hearing (See Attachment D)

A. Public Comment:
Pat Anderson, Health Care Association of Michigan (HCAM)

B. Commission Discussion

C. Motion by Commissioner Sandler, seconded by Commissioner Landstrom, to accept the proposed language (See Attachment E) and move forward to the JLC and Governor for the 45-day review period. The bed need numbers will become effective with the effective date of the standards. Motion Carried.

VII. Computed Tomography Standard Advisory Committee Report (CTSAC) Status Update

Chairperson Goldman gave a brief summary of the written report that was provided by Dr. Brooks (See Attachment F).

VIII. Cardiac Catheterization Standard Advisory Committee (CCSAC) Status Update

Chairperson Goldman gave a brief summary of the CCSAC report that was provided by Dr. Eagle (See Attachment G).

IX. 2- Year Report to the Joint Legislative Committee (JLC) (See Attachment H)

Chairperson Goldman gave a brief summary of the JLC report (See Attachment H).

A. Commission Discussion

B. Public Comment:
Larry Horwitz, Economic Alliance for Michigan (EAM)

C. Motion by Commissioner Ajlini, seconded by Commissioner Keshishian, to accept the proposed language and move forward to the JLC. Motion Carried.

X. Standing New Medical Technology Advisory Committee (NEWTAC) Written Report

Commissioner Keshishian gave a verbal and written report (See Attachment I).

Chairperson Goldman requested the Department send the electronic link for Dr. Richard M. Satava's power point presentation presented at the 2010 CON Seminar to the Commissioners.

XI. Legislative Report

No report.

XII. Administrative Update

Mr. Hart gave a brief administrative update.

A. Health Policy Section
Ms. Lopez gave a brief verbal update and thanked the Commission and staff for their work.

B. CON Evaluation Section Update
Mr. Horvath gave a brief written as well as verbal update.
1. Compliance Report (See Attachment J)
2. Quarterly Report (See Attachment K)
3. FY 2010 Annual Activity Report (See Attachment L)
4. Administrative Rules Update
5. On-line maps

XII. Legal Activity Report

Mr. Potchen gave a brief report of the Attorney General's activities (See Attachment M).

XIII. Future Meeting Dates

Chairperson Goldman reviewed the 2011 meeting dates:

A. January 26, 2011 (Special Commission Meeting)
B. March 24, 2011
C. June 9, 2011
D. September 22, 2011
E. December 15, 2011

XIV. Public Comment:

Barbara Jackson, BCBS (Attachment N)

XVI. Review of Commission Work Plan

Ms. Rogers gave a summary of the work plan (See Attachment O).

A. Commission Discussion

B. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to approve the Work Plan as presented with the addition of IMRI. Motion Carried.

XVII. Adjournment

Motion by Vice-chairperson Falahee, seconded by Commissioner Sandler, to adjourn the meeting at 11:17 a.m. Motion Carried.

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

Date: December 8, 2010

TO: Irma Lopez & Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Magnetic Resonance Imaging (MRI) Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the MRI Standards at its September 23, 2010 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed MRI Standards on October 26, 2010. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from one organization and is summarized as follows:

Steven Szelag, University of Michigan Health System (UMHS)

UMHS strongly supports the continued regulation of MRI services and has no objections to the proposed changes, but recommends that the Commission convene a special workgroup for MRI to explore Section 10 further. UMHS is concerned that when the pilot outlined in Section 10 expires there will again be no provisions setting appropriate volumes and conditions for the initiation, replacement, relocation, acquisition, and expansion of an MRI unit and/or service.

Staff Analysis and Recommendations

The Commission's proposed action did not include language changes to Section 10 of the MRI standards at this time. The proposed changes include the following:

1. Under Section 4, added language that allows for a lower replacement volume for an MRI unit initiated pursuant to Section 3(2)(b)(ii) or 3(2)(b)(iii). The volumes are 4,000 and 3,000 MRI adjusted procedures, respectively, and it is the only fixed MRI unit at the current site.

2. Under Section 12, added language that allows for a lower maintenance volume for an MRI unit initiated pursuant to Section 3(2)(b)(ii) or 3(2)(b)(iii). The volumes are 4,000 and 3,000 MRI adjusted procedures, respectively, and it is the only fixed MRI unit at the current site.

The Department supports the CON Commission's September 23, 2010 proposed action as written.

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments pertaining to the Certificate of Need (CoN) review standards for Magnetic Resonance Imaging (MRI) Services.

UMHS strongly supports the continued regulation of MRI services, and has no objections to the proposed changes published for final action today. However, we do have some additional comments on issues identified only recently, during the writing of our pending CoN application for Intra-Operative MRI (IMRI) services. In 2008 the IMRI provisions were added to the standards as a pilot in Section 10. Section 10 governs the initiation, replacement, and acquisition of a hospital based IMRI service, but will expire and will not be applicable to any application which has not been submitted by December 31, 2010.

UMHS is concerned because IMRI is an essential technology in the surgical care of both children and adults, and once Section 10 expires, the MRI standards will again have no provisions setting appropriate volumes and conditions for the for the initiation, replacement, relocation, acquisition and expansion of an IMRI unit and/or service.

Even though we have yet to activate our IMRI unit, we feel that it is essential to have a continuing provision in place to govern IMRI services, both for pediatric and adult applications.

UMHS understands that the CoN Commission and Department are going to be extremely busy during calendar year 2011 with a multitude of other standards up for review. However, UMHS is requesting that the Commission convene a special workgroup for IMRI next year to consider the issues we have addressed in this testimony.

Thank you for according us the opportunity to make this statement today.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

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

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

(b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section 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 "MRI Service Utilization List," as of the date an application is deemed ~~complete~~ SUBMITTED by the Department.

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

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

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

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

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

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

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

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

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

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

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

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

(p) "Health service area" or "HSA" means the geographic areas set forth in Section 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" means an MRI visit involving an individual who has been admitted to the licensed hospital at the site of the MRI service/unit or in the case of an MRI unit that is not located at that licensed hospital site, an admitted patient transported from a licensed hospital site by ambulance to the MRI service.

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

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

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

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

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

(aa) "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.

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

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

(dd) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with an MRT unit.

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

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

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

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

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

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

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

(ll) "Planning area" means

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(vv) "Site" means

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

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

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

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

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

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

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

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

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

Section 3. Requirements to initiate an MRI service

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) The applicant shall demonstrate that the available MRI adjusted procedures FROM THE AVAILABLE MRI ADJUSTED PROCEDURES LIST OR THE ADJUSTED PROCEDURES FROM THE MRI SERVICE UTILIZATION LIST, AS APPLICABLE, are from the most recently published ~~available~~ MRI ~~adjusted procedures list~~LISTS as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following requirements, as applicable:

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

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

(b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI adjusted procedures per MRI unit UNLESS THE APPLICANT DEMONSTRATES COMPLIANCE WITH ONE OF THE FOLLOWING~~.~~:

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

(I) THE EXISTING FIXED MRI UNIT INITIATED PURSUANT TO SECTION 3(2)(B)(II) HAS PERFORMED AT LEAST 4,000 MRI ADJUSTED PROCEDURES AND IS THE ONLY FIXED MRI UNIT AT THE CURRENT SITE.

(II) THE EXISTING FIXED MRI UNIT INITIATED PURSUANT TO SECTION 3(2)(B)(III) HAS PERFORMED AT LEAST 3,000 MRI ADJUSTED PROCEDURES AND IS THE ONLY FIXED MRI UNIT AT THE CURRENT SITE.

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

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

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

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

Section 5. Requirements to expand an existing MRI service

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

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

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

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

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

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

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

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

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

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

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 12 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

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

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

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

(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section 12 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

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

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

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

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

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

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

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

Section 8. Requirements to establish a dedicated research MRI unit

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

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

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

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

Section 9. Requirements to establish a dedicated pediatric MRI unit

Sec. 9. (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 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:

(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 5 of these standards.

Section 10. Pilot program requirements for approval – applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 10. As a pilot program, an applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate that it meets all of the following:

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

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

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

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

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

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

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

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

(9) The provisions of Section 10 are part of a pilot program approved by the CON commission and shall expire and be of no further force and effect, and shall not be applicable to any application which has not been submitted by December 31, 2010.

Section 11. Requirements for all applicants

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

Section 12. 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:
(a) Compliance with these standards.
(b) Compliance with applicable safety and operating standards.
(c) Compliance with the following quality assurance standards:
(i) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.
(ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
(iii) 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) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board-certified radiologist.
(B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
(C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.
(iv) An applicant shall document that the MRI team members have the following qualifications:

(A) 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.

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

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

(v) 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.

(vi) 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, AS APPLICABLE~~of~~:

(A) 6,000 ~~actual~~ MRI adjusted procedures per unit for fixed MRI services UNLESS COMPLIANT WITH (1) OR (2),

(1) 4,000 MRI ADJUSTED PROCEDURES FOR THE FIXED UNIT INITIATED PURSUANT TO SECTION 3(2)(B)(II) AND IS THE ONLY FIXED MRI UNIT AT THE CURRENT SITE,

(2) 3,000 MRI ADJUSTED PROCEDURES FOR THE FIXED MRI UNIT INITATED PURSUANT TO SECTION 3(2)(B)(III) AND IS THE ONLY FIXED MRI UNIT AT THE HOSPITAL SITE LICENSED UNDER PART 215 OF THE CODE,

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

(C) ~~and a total of~~ 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI UNITS.

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

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

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

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

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

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

For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic.

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

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

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

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

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

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

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

Section 13. 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 "MRI Service Utilization List" as of the date an application is deemed ~~complete~~ SUBMITTED by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section 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 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~~ SUBMITTED by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section 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 8(1) and dedicated pediatric MRI approved pursuant to Section 9 shall be excluded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 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 for each doctor committing available MRI adjusted procedures to that application for a new MRI unit that requires doctor commitments.

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

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

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

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

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

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

(i) The approved CON is withdrawn or expires.

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

(b) The Department shall not consider a data commitment from a doctor for available MRI adjusted procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI service were used to support an application for a new fixed or mobile MRI unit or additional mobile MRI

unit pursuant to Section 3, for which a final decision to disapprove was issued by the Director of the Department until either of the following occurs:

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

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

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

(a) if the applications were ~~filed~~ SUBMITTED on the same designated application date, notify all applicants, simultaneously and in writing, that one or more doctors have submitted data commitments for available MRI adjusted procedures from the same MRI service and that the doctors' data from the same MRI service shall not be considered in the review of any of the pending applications SUBMITTED~~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~~ SUBMITTED on different designated application dates, consider the data commitment ~~submitted~~ in the application SUBMITTED~~filed~~ on the earliest designated application date and shall notify, simultaneously in writing, all applicants of applications SUBMITTED~~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) SUBMITTED~~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~~ SUBMITTED unless an applicant is notified by the Department, pursuant to subsection (5), that one or more committing doctors submitted data commitments for available MRI adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data commitments will not be considered by the Department, the Department shall consider data commitments submitted after the date an application is deemed ~~complete~~ SUBMITTED only to the extent necessary to replace the data commitments not being considered pursuant to subsection (5).

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

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

(a) ON OR AFTER THE DATE AN APPLICATION IS DEEMED SUBMITTED BY THE DEPARTMENT~~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 published by the Department

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

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

(i) The number of actual MRI adjusted procedures;

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

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

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

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section 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, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section 12, and no data will be shown for that service on either list.

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~~MRI Services approved by the CON Commission on September ~~16~~10, ~~2008~~ 2009 and effective November ~~13~~5, ~~2008~~2009.

(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

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

Date: December 8, 2010

TO: Irma Lopez & Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Nursing Homes and Hospital Long Term care Units (NH/HLTCU) Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the NH/HLTCU Standards at its September 23, 2010 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed NH/HLTCU Standards on October 26, 2010. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from five organizations and is summarized as follows:

Meg Tipton, Spectrum Health (SH)

Spectrum Health supports the continued regulation of NH/HLTCU services but has some concerns about the provisions proposed to address the comparative review issues. Spectrum Health recommends that the language in the **Percentage of Medicaid Patient Days** subsection should be revised to reflect "annually, thereafter." This change would ensure the applicant's intention of future Medicaid participation past the minimum requirement of seven years. In the **Compliance Action** subsection, SH recommends the replacement of "participates" with "demonstrates." This change will better reflect the intention of the applicant to provide actual documentation of participation. Further, SH recommends reinstating the original point allocation within the **Applicant's Cash** subsection, stating that nursing homes with adequate cash reserves are able to provide consistently high quality and safe care because they have the resources available. SH also recommends the language requiring "100% private rooms with adjoining sink, toilet and shower" be changed from "100%" to "80%" given that it is difficult for older, "land-locked" nursing homes to make a change to 100% private rooms and bathrooms.

Susan Steinke representing Herself

Supports the continued regulation of NH/HLTCU services but has some concerns about the provisions proposed to address Section 10, specifically:

(2)(a): Recommends restoring the original number of points from "Current" column for actual Medicaid days.

(4): Recommends the number of points deducted in this section be equal to the total amount of points a facility can receive for Medicaid certification and utilization, as an appropriate reflection of the values held in the advocacy community.

(6): Recommends the points be restored in this section to the higher levels as the amount of cash on hand is not the only indicator of viability.

(9): Recommends points are awarded as well for improvements of semi-private rooms.

(10): Recommends that the number of beds be lowered to 120.

(13): Recommends broadening language and awarding more points for both applicants that eliminate 3-4 bed wards as well as facilities that do not currently have these types of wards to eliminate.

Pat Anderson, Health Care Association of Michigan (HCAM)

HCAM supports the continued regulation of NH/HLTCU services but has some concerns about the proposed language.

Line 113- (W)- Definition should read "occupancy rate" which means the percentage which expresses the ratio of the actual number of patient days of care divided by the total number of **available** patient days.

Lines 727-730 (9) - Recommends adjusting the number of points awarded to 10 as recognition for a facility that provides a shower in every room.

Line 735- HCAM does not support this element of the standards, and has consistently throughout this process disagreed with any points given for audited statements.

Line 741- HCAM fully supports the elimination of all 3 and 4 bed wards, believes that this moves the profession in the direction to meeting consumer desires.

Line 748- HCAM recommends that this area of innovation should receive equal recognition to culture change models, and increase points awarded as innovations are costly and the points awarded currently seem extremely small in comparison.

Stephanie Winslow, Aging Services of Michigan (ASM)

ASM supports the continued regulation of NH/HLTCU services but proposes the following changes concerning the proposed language.

Section 10(4) - Recommends that the process include a minimum of a 25 point deduction for chronically poor performers. ASM feels the point deduction approach protects the consumer and alleviates poor quality in nursing homes.

Section 10(6) - ASM opposes the reduction of awarded points for applicants who are willing to invest at least 20% cash into a proposed project. The Commission should promote policies that reduce interest costs to the Michigan Medicaid program - not policies that encourage highly leveraged acquisitions.

Section 10(11)- ASM supports awarding additional points to providers who have submitted audited applicant information statements along with positive cash flow projections. The review of basic financial criteria will enable the Department to evaluate an applicant's ability to successfully implement the proposed project and ensure consumer protection.

Section 10(15) - ASM supports increased point allocations for the use of technology addressed, and the CON process should provide incentives for projects making investments to improve quality and reduce operational costs.

Andrew Ball, HCR Manor Care (HCR)

HCR supports the continued regulation of NH/HLTCU services but recommends the following changes concerning the proposed language.

Section 10(4) – The language sends the wrong message that there is a differential quality standard in Michigan for high Medicaid vs. low Medicaid facilities. Accordingly, the points deducted under Section 10(4) should be increased to 25 points.

Section 10(5) - Suggests that at least one Department-approved culture change program should exist for organizations like HCR, which serve a higher percentage of high-acuity, post hospitalization patients that are admitted on a short-stay basis to receive specialized rehabilitative care.

Section 10(6) - HCR disagrees with the revision to the points awarded for applicants willing to put 20% or more cash into the proposed project. High debt

projects cost the State of Michigan additional money because the Michigan Medicaid program reimburses interest incurred on debt as part of reimbursable "property tax/interest expense/lease" costs. Thus, including 10 points or more for 20% cash is good policy for quality reasons and will ensure that "financially fit" applicants are favored.

Section 10(11) - For the same reasons stated for Section 10(6), HCR supports language that awards points for audited financial statements. The Commission would further strengthen the "financial fitness" requirements in comparative review if additional points were awarded for positive cash flow. Audited financial statements and percentage of cash are straightforward criteria that should have considerable point allocations with at least 10 points for the submission of audited financial statement demonstrating positive cash flow.

Section 10(8) - HCR believes the additional commitment to build in-room showers is well worth the investment and urges the Commission to award 10 points for applicants proposing construction of showers in all semi-private and private rooms in the proposed project.

Section 10(15) - HCR commends the Department and Commission for including new criteria to reward proposed technology features that would enhance the functionality of the facility and provide life-enrichment for residents. Given there is a direct increase in capital costs associated with these improvements, the total points awarded under this Section should be increased to 8 points.

HCR also noted the need for a technical correction in the proposed language as follows, line 747-748:

To avoid penalizing applicants that have already eliminated 3 or 4 bed wards or that never had them, the language should restore the phrase "OR PROPOSED." The point of the language should be to ward points if the nursing home does not have 3 or 4 bed wards once the CON is implemented.

Staff Analysis and Recommendations

The comments resulting from the October 26, 2010 Public Hearing reflect similar comments to those that were provided to the Commission at its September 23, 2010 meeting. Most comments speak to what "points" should be assigned to each of the comparative review criteria, and it appears that respondents are more likely to ask for higher point values for those criteria that may benefit their specific priorities.

During the workgroup meetings, similar discussions took place, and while it was possible to reach some consensus on the criteria to include, assigning a firm numerical value proved to be problematic. One group wanted to make certain

that there was a "level playing field" in the comparative review process, while another group preferred to prioritize the criteria itself. Continuing the discussion of appropriated "point" allocation will likely result in a back and forth exchange as there is no specific science behind the numerical values proposed in any of the versions of draft language.

Keeping in mind that applicants who are in a comparative review situation have already met the standards' requirements for nursing home bed approval, the purpose of comparative review is to determine which of the applicants should actually be awarded the available beds. If all applicants are assured that they are on equal footing for the available beds; the intent/purpose of comparative review seems to be defeated.

The Department defers to the Commission as to whether or not there should be a continued review of the comparative review points allocations for NH/HLTCU beds. If no further review is necessary, the Department supports the language for final action by the Commission and to move forward to the JLC and the Governor for the 45-day review period.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT (HLTCU) BEDS

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval and delivery of NURSING HOMES AND HLTCU services ~~for all projects approved and certificates of need issued~~ under Part 222 of the Code ~~which involve nursing homes and hospital long-term-care units~~.

~~(2)~~ A nursing home licensed under Part 217 and a ~~hospital long-term-care unit (~~HLTCU~~)~~ defined in Section 20106(6) are covered health facilities for purposes of Part 222 of the Code.

~~(3)~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, 9, 12, 13, and 14 of~~ these standards~~, 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 11 of these standards, as applicable, in applying~~AND Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(5) The Department shall use Section 10(2) of these standards, as applicable, in applying Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws.~~

Section 2. Definitions

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

(a) "Acquisition of an existing nursing home/HLTCU" means the issuance of a new nursing home/HLTCU license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangement) of an existing licensed and operating nursing home/HLTCU and which does not involve a change in bed capacity of that health facility.

(b) "ADC adjustment factor" means the factor by which the average daily census (ADC), derived during the bed need methodology calculation set forth in Section 3(2)(d) for each planning area, is divided. For planning areas with an ADC of less than 100, the ADC adjustment factor is 0.90 and for planning areas with an ADC of 100 or more, the ADC adjustment factor is 0.95.

(c) "Applicant's cash" means the total unrestricted cash, designated funds, and restricted funds reported by the applicant as the source of funds in the application.

(d) "Base year" means 1987 or the most recent year for which verifiable data collected as part of the Michigan Department of Community Health Annual Survey of Long-Term-Care Facilities or other comparable MDCH survey instrument are available.

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

(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) "Common ownership or control" means a nursing home, regardless of the state in which it is located, that is owned by, is under common control of, or has a common parent as the applicant nursing home pursuant to the definition of common ownership or control utilized by the Department's Bureau of Health Systems.

(h) "Comparative group" means the applications which have been grouped for the same type of project in the same planning area or statewide special pool group and which are being reviewed comparatively in accordance with the CON rules.

(i) "Converted space" means existing space in a health facility that is not currently licensed as part of the nursing home/HLTCU and is proposed to be licensed as nursing home or HLTCU space. An example is proposing to license home for the aged space as nursing home space.

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

(k) "Department inventory of beds" means the current list, for each planning area maintained on a continuing basis by the Department: (i) licensed nursing home beds and (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed. It does not include (a) nursing home beds approved from the statewide pool and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws.

(l) "Existing nursing home beds" means, for a specific planning area, the total of all nursing home beds located within the planning area including: (i) licensed nursing home beds, (ii) nursing home beds approved by a valid CON issued under Part 222 of the Code which are not yet licensed, (iii) proposed nursing home beds under appeal from a final Department decision made under Part 222 or pending a hearing from a proposed decision issued under Part 222 of the Code, and (iv) proposed nursing home beds that are part of a completed application under Part 222 of the Code which is pending final Department decision. (a) Nursing home beds approved from the statewide pool are excluded; and (b) short-term nursing care program beds approved pursuant to Section 22210 of the Code, being Section 333.22210 of the Michigan Compiled Laws, are excluded.

(m) "Health service area" or "HSA" means the geographic area established for a health systems agency pursuant to former Section 1511 of the Public Health Service Act and set forth in Section 14.

(n) "Hospital long-term-care unit" or "HLTCU" means a nursing care facility, owned and operated by and as part of a hospital, that provides organized nursing care and medical treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(o) "Licensed only facility" means a licensed nursing home that is not certified for Medicare or Medicaid.

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

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

(r) "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 C.

(s) "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 C.

(t) "New design model" means a nursing home/HLTCU built in accordance with specified design requirements as identified in the applicable sections.

(u) ~~"Nonrenewal or revocation of license for cause" means that the Department did not renew or revoked the nursing home's/HLTCU's license based on the nursing home's/HLTCU's failure to comply with state licensing standards.~~

~~(v) "Nonrenewal or termination of certification for cause" means the nursing home/HLTCU Medicare and/or Medicaid certification was terminated or not renewed based on the nursing home's/HLTCU's failure to comply with Medicare and/or Medicaid participation requirements.~~

~~(w)~~ "Nursing home" means a nursing care facility, including a county medical care facility, but excluding a hospital or a facility created by Act No. 152 of the Public Acts of 1885, as amended, being sections 36.1 to 36.12 of the Michigan Compiled Laws, that provides organized nursing care and medical

treatment to seven (7) or more unrelated individuals suffering or recovering from illness, injury, or infirmity. This term applies to the licensee only and not the real property owner if different than the licensee.

(~~x~~V) "Nursing home bed" means a bed in a health facility licensed under Part 217 of the Code or a licensed bed in a hospital long-term-care unit. The term does not include short-term nursing care program beds approved pursuant to Section 22210 of the Code being Section 333.22210 of the Michigan Compiled Laws or beds in health facilities listed in Section 22205(2) of the Code, being Section 333.22205(2) of the Michigan Compiled Laws.

(~~y~~W) "Occupancy rate" means the percentage which expresses the ratio of the actual number of patient days of care provided divided by the total number of patient days. Total patient days is calculated by summing the number of licensed and/or CON approved but not yet licensed beds and multiplying these beds by the number of days that they were licensed and/or CON approved but not yet licensed. This shall include nursing home beds approved from the statewide pool. Occupancy rates shall be calculated using verifiable data from either (i) the actual number of patient days of care for 12 continuous months of data from the MDCH Annual Survey of Long-Term-Care Facilities or other comparable MDCH survey instrument or (ii) the actual number of patient days of care for 4 continuous quarters of data as reported to the Department for purposes of compiling the "Staffing/Bed Utilization Ratios Report," whichever is the most recent available data.

(~~z~~X) "Planning area" means the geographic boundaries of each county in Michigan with the exception of: (i) Houghton and Keweenaw counties, which are combined to form one planning area and (ii) Wayne County which is divided into three planning areas. Section 12 identifies the three planning areas in Wayne County and the specific geographic area included in each.

(~~aa~~Y) "Planning year" means 1990 or the year in the future, at least three (3) years but no more than seven (7) years, established by the CON Commission for which nursing home bed needs are developed. The planning year shall be a year for which official population projections, from the Department of Management and Budget or U.S. Census, data are available.

~~(bb) "Physically conforming beds," for purposes of Section 10(3), means beds which meet the maximum occupancy and minimum square footage requirements as specified in Section 483.70(d)(1) of the Code of Federal Regulations for Medicare certification (42 CFR) or any federal regulations for Medicare certification addressing maximum occupancy and minimum square footage requirements approved subsequent to the effective date of these standards.~~

(~~cc~~Z) "Qualifying project" means each application in a comparative group which has been reviewed individually and has been determined by the Department to have satisfied all of the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards.

(~~dd~~AA) "Relocation of existing nursing home/HLTCU beds" means a change in the location of existing nursing home/HLTCU beds from the licensed site to a different licensed site within the planning area.

(~~ee~~BB) "Renewal of lease" means execution of a lease between the licensee and a real property owner in which the total lease costs exceed the capital expenditure threshold.

(~~ff~~CC) "Replacement bed" means a change in the location of the licensed nursing home/HLTCU, the replacement of a portion of the licensed beds at the same licensed site, or the replacement of a portion of the licensed beds pursuant to the new model design. The nursing home/HLTCU beds will be in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) within the replacement zone.

(~~gg~~DD) "Replacement zone" means a proposed licensed site that is,

(i) for a rural or micropolitan statistical area county, within the same planning area as the existing licensed site.

(ii) for a county that is not a rural or micropolitan statistical area county,

(A) within the same planning area as the existing licensed site and

(B) within a three-mile radius of the existing licensed site.

(~~hh~~EE) "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 C.

(ii) "Staffing/Bed Utilization Ratios Report" means the report issued by the Department on a quarterly basis.

(jj) "Use rate" means the number of nursing home and hospital long-term-care unit days of care per 1,000 population during a one-year period.

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

Section 3. Determination of needed nursing home bed supply

Sec. 3 (1)(a) The age specific use rates for the planning year shall be the actual statewide age specific nursing home use rates using data from the base year.

(b) The age cohorts for each planning area shall be: (i) age 0 - 64 years, (ii) age 65 - 74 years, (iii) age 75 - 84 years, and (iv) age 85 and older.

(c) Until the base year is changed by the Commission in accord with Section 4(3) and Section 5, the use rates for the base year for each corresponding age cohort, established in accord with subsection (1)(b), are set forth in Appendix A.

(2) The number of nursing home beds needed in a planning area shall be determined by the following formula:

(a) Determine the population for the planning year for each separate planning area in the age cohorts established in subsection (1)(b).

(b) Multiply each population age cohort by the corresponding use rate established in Appendix A.

(c) Sum the patient days resulting from the calculations performed in subsection (b). The resultant figure is the total patient days.

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

(e) The following shall be known as the ADC adjustment factor. (i) If the ADC determined in subsection (d) is less than 100, divide the ADC by 0.90. (ii) If the ADC determined in subsection (d) is 100 or greater, divide the ADC by 0.95.

(f) The number determined in subsection (e) represents the number of nursing home beds needed in a planning area for the planning year.

Section 4. Bed need

Sec. 4. (1) The bed need numbers shown in Appendix B and incorporated as part of these standards shall apply to project applications subject to review under these standards, except where a specific CON standard states otherwise.

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

(3) The base year and the planning year that shall be utilized in applying the methodology pursuant to subsection (2) shall be set according to the most recent data available to the Department.

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

(5) New bed need numbers established by subsections (2) and (3) shall supersede the bed need numbers shown in Appendix B and shall be included as an amended appendix to these standards.

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

Section 5. Modification of the age specific use rates by changing the base year

Sec. 5. (1) The base year shall be modified based on data obtained from the Department and presented to the Commission. The Department shall calculate use rates for each of the age cohorts set forth in Section 3(1)(b) and biennially present the revised use rates based on 2006 information, or the most recent base year information available biennially after 2006, to the CON Commission.

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

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

Section 6. Requirements for approval to increase beds in a planning area

Sec. 6. An applicant proposing to increase the number of nursing home beds in a planning area must meet the following as applicable:

(1) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply set forth in Appendix B, unless one of the following is met:

(i) An applicant may request and be approved for up to a maximum of 20 beds if, when the total number of "existing nursing home beds" is subtracted from the bed need for the planning area set forth in Appendix B, the difference is equal to or more than 1 and equal to or less than 20. This subsection is not applicable to projects seeking approval for beds from the statewide pool of beds.

(ii) An exception to the number of beds may be approved, if the applicant facility has experienced an average occupancy rate of 97% for 12 quarters based on the Department's "Staffing/Bed Utilization Ratios Report." The number of beds that may be approved in excess of the bed need for each planning area identified in Appendix B is set forth in subsection (A).

(A) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the occupancy rate for the planning area in which the additional beds are proposed to the ADC adjustment factor for that planning area as shown in Appendix B. The number of beds shall be calculated by (1) dividing the actual number of patient days of care provided during the most recent 12-month period for which verifiable data are available to the Department provided by all nursing home (including HLTCU) beds in the planning area, including patient days of care provided in beds approved from the statewide pool of beds and dividing that result by 365 (or 366 for leap years); (2) dividing the result of step (1) by the ADC adjustment factor for the planning area in which the beds are proposed to be added; (3) rounding the result of step (2) up to the next whole number; and (4) subtracting the total number of beds in the planning area including beds approved from the statewide pool of beds from the result of step (3). If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is equal to or more than 20, the number of beds that may be approved pursuant to this subsection shall be up to that number of beds. If the number of beds necessary to reduce the planning area occupancy rate to the ADC adjustment factor for that planning area is less than 20, the number of additional beds that may be approved shall be that number of beds or up to a maximum of 20 beds.

(iii) An applicant may request and be approved for up to a maximum of 20 beds if the following requirements are met:

(A) The planning area in which the beds will be located shall have a population density of less than 28 individuals per square mile based on the 2000 U.S. Census figures as set forth in Appendix D.

(B) The applicant facility has experienced an average occupancy rate of 92% for the most recent 24 months based on the Department's "Staffing/Bed Utilization Ratios Report."

(2) An applicant proposing to increase the number of nursing home beds in a planning area by beginning operation of a new nursing home/HLTCU or increasing the number of beds to an existing licensed nursing home/HLTCU pursuant to the new design model shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement

Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(A) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(B) electronic nurse call systems shall be required in all facilities;

(C) handrails shall be required on both sides of patient corridors; and

(D) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(c) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining bathroom serving no more than two residents in both the central support inpatient facility and any supported small resident housing units.

(d) The proposed increase, if approved, will not result in the total number of existing nursing home beds in that planning area exceeding the needed nursing home bed supply set forth in Appendix B, unless the following is met:

(i) An approved project involves replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 7. Requirements for approval to relocate existing nursing home/HLTCU beds

Sec. 7. (1) An applicant proposing to relocate existing nursing home/HLTCU beds shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B, if the applicant demonstrates all of the following:

(a) An existing nursing home may relocate no more than 50% of its beds to another existing nursing home, and an existing HLTCU may relocate all or a portion of its beds to another existing nursing home/HLTCU.

(b) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds shall not require any ownership relationship.

(c) The nursing home/HLTCU from which the beds are being relocated and the nursing home/HLTCU receiving the beds must be located in the same planning area.

(d) The nursing home/HLTCU from which the beds are being relocated has not relocated any beds within the last seven (7) years.

(e) The relocated beds shall be licensed to the receiving nursing home/HLTCU and will be counted in the inventory for the applicable planning area.

(f) At the time of transfer to the receiving facility, patients in beds to be relocated must be given the choice of remaining in another bed in the nursing home/HLTCU from which the beds are being transferred or to the receiving nursing home/HLTCU. Patients shall not be involuntary discharged to create a vacant bed.

(2) An applicant proposing to add new nursing home/HLTCU beds, as the receiving existing nursing home/HLTCU under subsection (1), shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B, if the applicant demonstrates all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three

years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The approval of the proposed new nursing home/HLTCU beds shall not result in an increase in the number of nursing home beds in the planning area.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 8. Requirements for approval to replace beds

Sec. 8. An applicant proposing to replace beds must meet the following as applicable.

(1) An applicant proposing to replace beds within the replacement zone shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B if the applicant demonstrates all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUS and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all

licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The proposed project is either to replace the licensed nursing home/HLTCU to a new site or replace a portion of the licensed beds at the existing licensed site.

(c) The proposed site is within the replacement zone.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(2) An applicant proposing to replace a licensed nursing home/HLTCU outside the replacement zone shall demonstrate all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) The total number of existing nursing home beds in that planning area is equal to or less than the needed nursing home bed supply set forth in Appendix B.

(c) The number of beds to be replaced is equal to or less than the number of currently licensed beds at the nursing home/HLTCU at which the beds proposed for replacement are currently located.

(d) The applicant certifies that the requirements found in the Minimum Design Standards for Health Care Facilities of Michigan, referenced in Section 20145 (6) of the Public Health Code, Act 368 of 1978, as amended and are published by the Department, will be met when the architectural blueprints are submitted for review and approval by the Department.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(3) An applicant proposing to replace beds with a new design model shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B if the applicant demonstrates all of the following:

(a) The proposed project results in no more than 100 beds per new design model and meets the following design standards:

(i) For inpatient facilities that are not limited to group resident housing of 10 beds or less, the construction standards shall be those applicable to nursing homes in the document entitled Minimum Design Standards for Health Care Facilities in Michigan and incorporated by reference in Section 20145(6) of the Public Health Code, being Section 333.20145(6) of the Michigan Compiled Laws or any future versions.

(ii) For small resident housing units of 10 beds or less that are supported by a central support inpatient facility, the construction standards shall be those applicable to hospice residences providing an inpatient level of care, except that:

(a) at least 100% of all resident sleeping rooms shall meet barrier free requirements;

(b) electronic nurse call systems shall be required in all facilities;

(c) handrails shall be required on both sides of patient corridors; and

(d) ceiling heights shall be a minimum of 7 feet 10 inches.

(iii) The proposed project shall comply with applicable life safety code requirements and shall be fully sprinkled and air conditioned.

(iv) The Department may waive construction requirements for new design model projects if authorized by law.

(b) The proposed project shall include at least 80% single occupancy resident rooms with an adjoining bathroom serving no more than two residents in both the central support inpatient facility and any supported small resident housing units. If the proposed project is for replacement/renovation of an existing facility and utilizes only a portion of its currently licensed beds, the remaining rooms at the existing facility shall not exceed double occupancy.

(c) The proposed project shall be within the replacement zone unless the applicant demonstrates all of the following:

(i) The proposed site for the replacement beds is in the same planning area, and not within a three mile radius of a licensed nursing home that has been newly constructed, or replaced (including approved projects) within five calendar years prior to the date of the application,

(ii) The applicant shall provide a signed affidavit or resolution from its governing body or authorized agent stating that the proposed licensed site will continue to provide service to the same market, and

(iii) The current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(d) An approved project may involve replacement of a portion of the beds of an existing facility at a geographic location within the replacement zone that is not physically connected to the current licensed site. If a portion of the beds are replaced at a location that is not the current licensed site, a separate license shall be issued to the facility at the new location.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 9. Requirements for approval to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU

Sec. 9. An applicant proposing to acquire an existing nursing home/HLTCU or renew the lease of an existing nursing home/HLTCU must meet the following as applicable:

(1) An applicant proposing to acquire an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B for the planning area in which the nursing home or HLTCU is located if the applicant demonstrates all of the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at Level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the state of Michigan for quality assurance assessment program (QAAP) OR civil monetary penalties (CMP).

(b) The acquisition will not result in a change in bed capacity.

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

(d) The project is limited solely to the acquisition of a nursing home/HLTCU with a valid license.

(e) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department, and

(f) The applicant shall participate in a quality improvement program, ~~such as My Innerview, Advancing Excellence, or another comparable program~~APPROVED BY THE DEPARTMENT, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Systems, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(2) An applicant proposing to acquire an existing nursing home/HLTCU approved pursuant to the new design model shall demonstrate the following:

(a) At the time of application, the applicant, as identified in the table, shall provide a report demonstrating that it does not meet any of the following conditions in 14%, but not more than five, of its nursing homes/HLTCUs:

Type of Applicant	Reporting Requirement
Applicant with only Michigan nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with 10 or more Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan nursing homes/HLTCUs under common ownership or control
Applicant with fewer than 10 Michigan nursing homes/HLTCUs and out of state nursing homes/HLTCUs	All Michigan and out of state nursing homes/HLTCUs under common ownership or control

(i) A state enforcement action resulting in a license revocation, reduced license capacity, or receivership within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(ii) A filing for bankruptcy within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iii) Termination of a Medical Assistance Provider Enrollment and Trading Partner Agreement initiated by the Department or licensing and certification agency in another state, within the last three years, or from the change of ownership date if the facility has come under common ownership or control within 24 months of the date of the application.

(iv) A number of citations at level D or above, excluding life safety code citations, on the scope and severity grid on two consecutive standard surveys that exceeds twice the statewide average, calculated from the quarter in which the standard survey was completed, in the state in which the nursing home/HLTCU is located. For licensed only facilities, a number of citations at two times the average of all licensed only facilities on the last two licensing surveys. However, if the facility has come under common ownership or control within 24 months of the date of the application, the first two licensing surveys as of the change of ownership date, shall be excluded.

(v) Currently listed as a special focus nursing home by the Center for Medicare and Medicaid Services.

(vi) Outstanding debt obligation to the State of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP).

(b) An applicant will continue to operate the existing nursing home/HLTCU pursuant to the new design model requirements.

(c) The applicant shall participate in a quality improvement program, ~~such as My Innerview, Advancing Excellence, or another comparable program~~APPROVED BY THE DEPARTMENT, for five years and provide an annual report to the Michigan State Long-Term-Care Ombudsman, Bureau of Health Systems, and shall post the annual report in the facility if the facility being acquired has met any of conditions in subsections (a)(i), (ii), (iii), (iv), (v), or (vi).

(d) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

(3) An applicant proposing to renew the lease for an existing nursing home/HLTCU shall not be required to be in compliance with the needed nursing home bed supply set forth in Appendix B for the planning area in which the nursing home/HLTCU is located, if the applicant demonstrates all of the following:

(a) The lease renewal will not result in a change in bed capacity.

(b) The licensed site does not change as a result of the lease renewal.

(c) A Plan of Correction for cited state or federal code deficiencies at the health facility, if any, has been submitted and approved by the Bureau of Health Systems within the Department. Code deficiencies include any unresolved deficiencies still outstanding with the Department.

Section 10. Review standards for comparative review

Sec. 10. (1) Any application subject to comparative review, under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and reviewed comparatively with other applications in accordance with the CON rules.

(2) The degree to which each application in a comparative group meets the criterion set forth in Section 22230 of the Code, being Section 333.22230 of the Michigan Compiled Laws, shall be determined based on the sum of points awarded under subsections (a)~~,~~ and (b).

(a) A qualifying project will be awarded points~~, in accordance with the schedule set forth below~~AS FOLLOWS:

(i) For an existing nursing home/HLTCU, the current percentage of ~~the nursing home's/HLTCU's~~ patient days of care reimbursed by Medicaid for the most recent 12 months of operation.

(ii) For a new nursing home/HLTCU, the proposed percentage of ~~the nursing home/HLTCU's~~ patient days of care to be reimbursed by Medicaid in the second 12 months of operation following project completion~~, and annually, thereafter, for at least seven years~~.

Percentage of Medicaid Patient Days (calculated using total patient days for all existing and proposed beds at the facility)	Points Awarded	
	CURRENT	PROPOSED
~~0~~	~~0~~	
~~1 – 19~~	~~3~~	
20 – ~~39~~59%	6	3
~~40 – 59~~	~~9~~	
60 – 100%	~~12~~10	5

(b) A qualifying project will be awarded points as follows:

(i) FOR AN EXISTING NURSING HOME/HLTCU, ~~Nine~~ nine (9) points if~~,~~ 100%, six (6) points if 75%, and ~~three~~ FOUR (~~3~~4) points if 50% of the licensed nursing home beds ~~at the facility~~ are Medicaid certified for the most recent 12 months OF OPERATIONS~~for an existing nursing home/HLTCU~~.

(ii) FOR A NEW NURSING HOME/HLTCU, ~~Nine~~ SEVEN (~~9~~7) points if 100%, ~~six~~ FOUR (4) points if 75%, and ~~three~~ TWO (~~3~~2) points if 50% of the proposed beds ~~at the facility~~ will be Medicaid certified BY THE SECOND 12 MONTHS OF OPERATION FOLLOWING PROJECT COMPLETION~~for a new nursing home/HLTCU~~.

(3) A qualifying project will be awarded points~~, in accordance with the schedule set forth below,~~ based on the most recent 12 months of participation level in the Medicare program for an existing nursing home/HLTCU and the proposed participation level for a new nursing home/HLTCU.

Participation Level	Points Awarded

~~No Medicare certification of any physically conforming existing and proposed beds. 0~~

Medicare certification of at least one (1) bed but less than 100% ~~of all physically conforming existing and proposed beds.~~ 1

Medicare certification of 100% of ~~all physically conforming~~ existing and proposed beds. ~~2~~3

(4) A qualifying project will have 15 points deducted ~~based on~~ IF the applicant HAS ANY OF THE FOLLOWING~~'s record of compliance with applicable federal and state safety and operating standards for any nursing home/HLTCU owned and/or operated by the applicant in Michigan. Points shall be deducted in accord with the schedule set forth below if, after July 11, 1993, the records which are maintained by the Department document (a) any nonrenewal or revocation of license for cause and/or (b) nonrenewal or termination for cause of either Medicare or Medicaid certification of any Michigan nursing home/HLTCU owned and/or operated by the applicant.~~ AT THE TIME THE APPLICATION IS SUBMITTED:

~~Nursing Home/HLTCU Compliance Action~~	~~Points Deducted~~
~~Nonrenewal or revocation of license~~	~~4~~
~~Nonrenewal or termination of:~~	
~~- Certification - Medicare~~	~~4~~
~~- Certification - Medicaid~~	~~4~~

(A) IS CURRENTLY A SPECIAL FOCUS NURSING HOME/HLTCU AS IDENTIFIED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS);
(B) HAS BEEN A SPECIAL FOCUS NURSING HOME/HLTCU WITHIN THE LAST THREE (3) YEARS.
(C) HAS HAD MORE THAN EIGHT (8) SUBSTANDARD QUALITY OF CARE CITATIONS; IMMEDIATE HARM CITATIONS, AND/OR IMMEDIATE JEOPARDY CITATIONS IN THE THREE (3) MOST RECENT STANDARD SURVEY CYCLES (INCLUDES INTERVENING ABBREVIATED SURVEYS, STANDARD SURVEYS, AND REVISITS);
(D) HAS HAD AN INVOLUNTARY TERMINATION OR VOLUNTARY TERMINATION AT THE THREAT OF A MEDICAL ASSISTANCE PROVIDER ENROLLMENT AND TRADING PARTNER AGREEMENT WITHIN THE LAST THREE (3) YEARS;
(E) HAS HAD A STATE ENFORCEMENT ACTION RESULTING IN A REDUCTION IN LICENSE CAPACITY OR A BAN ON ADMISSIONS WITHIN THE LAST THREE (3) YEARS; OR
(F) HAS ANY OUTSTANDING DEBT OBLIGATION TO THE STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP), CIVIL MONETARY PENALTIES (CMP), MEDICAID LEVEL OF CARE DETERMINATION (LOCD), OR PREADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR).

(5) A qualifying project will be awarded ~~nine (9)~~10 points if the applicant ~~currently~~PROVIDES DOCUMENTATION THAT IT ~~provides~~ PARTICIPATES or ~~demonstrates that it will~~FIVE (5) POINTS IF IT PROPOSES TO participate in a culture change model, which contains person centered care, ongoing staff training, and measurements of outcomes. AN ADDITIONAL FIVE (5) POINTS WILL BE AWARDED IF THE CULTURE CHANGE MODEL, EITHER CURRENTLY USED OR PROPOSED, IS A MODEL APPROVED BY THE DEPARTMENT.

(6) A qualifying project will be awarded points based on the proposed percentage of the "Applicant's cash" to be applied toward funding the total proposed project cost ~~in accord with the schedule set forth below~~AS FOLLOWS:

Percentage "Applicant's Cash"	Points Awarded
Over 20~~ percent~~%	~~10~~5
~~15.1 to 20 percent~~	~~8~~
10~~.1 to 15 percent~~ – 20%	~~6~~3
5~~.1 to 10 percent~~ – 9%	~~4~~2
~~1.1 to 5 percent~~	~~2~~
~~0 to 1 percent~~	~~0~~

(7) A qualifying project will be awarded ~~six~~ FIVE (~~6~~5) points if the existing or proposed nursing home/HLTCU is fully equipped with sprinklers.

(8) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU IS FULLY EQUIPPED WITH AIR CONDITIONING.

(~~8~~9) A qualifying project will be awarded points based on the ~~facility design of the existing or proposed nursing home~~PROPOSED PROJECT AS FOLLOWS:

Facility Design	Points Awarded
~~8~~100% PRIVATE ROOMS WITH ADJOINING SINK, TOILET, AND SHOWER	10
~~80~~100% private rooms with DEDICATED SINK AND SHARED ~~private~~ADJOINING toilet, SINK and SHOWER ~~sink, and central showers with adjacent private changing room for the resident to dress and undress in privacy~~	~~6~~5
~~80% private rooms with private toilet, sink, and shower~~	~~6~~
80% private rooms with ~~private~~ DEDICATED sink, shared ADJOINING toilet AND SINK, and central showers with ~~adjacent private changing room~~ADJOINING SPACE for ~~the resident to~~DRYING AND dressING ~~and undress~~ in VISUAL privacy	3

(10) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF IT RESULTS IN A NURSING HOME/HLTCU WITH 150 OR FEWER BEDS.

(11) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE APPLICANT PROVIDES ITS AUDITED FINANCIAL STATEMENTS.

(12) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE PROPOSED BEDS WILL BE HOUSED IN NEW CONSTRUCTION.

(13) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF THE EXISTING NURSING HOME/HLTCU ELIMINATES ALL OF ITS 3- AND 4-BED WARDS.

(14) A QUALIFYING PROJECT WILL BE AWARDED 5 POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU IS ON OR READILY ACCESSIBLE TO AN EXISTING OR PROPOSED PUBLIC TRANSPORTATION ROUTE.

(15) A QUALIFYING PROJECT WILL BE AWARDED NO MORE THAN FOUR (4) POINTS FOR TECHNOLOGICAL INNOVATION AS FOLLOWS:

TECHNOLOGY FEATURE	POINTS AWARDED
ELECTRONIC HEALTH RECORD AND COMPUTER POINT-OF-SERVICE ENTRY CAPABILITY (INCLUDING WIRELESS TABLETS)	1
WIRELESS NURSE CALL/PAGING SYSTEM INCLUDING WIRELESS DEVICES CARRIED BY DIRECT CARE STAFF	1
WIRELESS INTERNET IN TOTAL EXISTING AND PROPOSED FACILITY	1
COMPUTER STATIONS OR INTERNET CAFES FOR RESIDENT USE	1

(156) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT AWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE AWARDED FROM THE CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED. ~~The minimum number of points will be awarded to an applicant under the individual subsections of this Section for conflicting information presented in this Section and related information provided in other sections of the CON application.~~

(1017) The Department shall approve those qualifying projects which, WHEN taken together, do not exceed the need as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsections (2) through (9145) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, WHEN taken together, do not exceed the need, as defined in Section 22225(1), in the order in which the applications were received by the Department, based on the date and time stamp on the application~~,~~ when the application is filed.

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

Sec. 11. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards, including the requirements of Section 10.

(b) Compliance with Section 22230 of the Code shall be based on the nursing home's/HLTCU's actual Medicaid participation within the time periods specified in these standards. Compliance with Section 10(2)(a) of these standards shall be determined by comparing the nursing home's/HLTCU's actual

patient days reimbursed by Medicaid, as a percentage of the total patient days, with the applicable schedule set forth in Section 10(2)(a) for which the applicant had been awarded points in the comparative review process. If any of the following occurs, an applicant shall be required to be in compliance with the range in the schedule immediately below the range for which points had been awarded in Section 10(2)(a), instead of the range of points for which points had been awarded in the comparative review in order to be found in compliance with Section 22230 of the Code: (i) the average percentage of Medicaid recipients in all nursing homes/HLTCUs in the planning area decreased by at least 10 percent between the second 12 months of operation after project completion and the most recent 12-month period for which data are available, (ii) the actual rate of increase in the Medicaid program per diem reimbursement to the applicant nursing home/HLTCU is less than the annual inflation index for nursing homes/HLTCUs as defined in any current approved Michigan State Plan submitted under Title XIX of the Social Security Act which contains an annual inflation index, or (iii) the actual percentage of the nursing home's/HLTCU's patient days reimbursed by Medicaid (calculated using total patient days for all existing and proposed nursing home beds at the facility) exceeds the statewide average plus 10 percent of the patient days reimbursed by Medicaid for the most recent year for which data are available from the Michigan Department of Community Health [subsection (iii) is applicable only to Section 10(2)(a)]. In evaluating subsection (ii), the Department shall rely on both the annual inflation index and the actual rate increases in per diem reimbursement to the applicant nursing home/HLTCU and/or all nursing homes/HLTCUs in the HSA ~~provided to the Department by the Michigan Department of Community Health~~.

(c) For projects involving the acquisition of a nursing home/HLTCU, the applicant shall agree to maintain the nursing home's/HLTCU's level of Medicaid participation (patient days and new admissions) for the time periods specified in these standards, within the ranges set forth in Section 10(2)(a) for which the seller or other previous owner/lessee had been awarded points in a comparative review.

(d) Compliance with applicable operating standards.

(e) Compliance with the following quality assurance standards:

(i) For projects involving replacement of an existing nursing home/HLTCU, the current patients of the facility/beds being replaced shall be admitted to the replacement beds when the replacement beds are licensed, to the extent that those patients desire to transfer to the replacement facility/beds.

(ii) The applicant will assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

(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; and demographic, diagnostic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on an individual basis for each licensed site, in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

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

(2) An applicant shall agree that, if approved, and material discrepancies are later determined within the reporting of the ownership and citation history of the applicant facility and all nursing homes under common ownership and control that would have resulted in a denial of the application, shall surrender the CON. This does not preclude an applicant from reapplying with corrected information at a later date.

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

Section 12. Department inventory of beds

Sec. 12. The Department shall maintain a listing of the Department Inventory of Beds for each planning area.

Section 13. Wayne County planning areas

Sec. 13. (1) For purposes of these standards the cities and/or townships in Wayne County are assigned to the planning areas as follows:

Planning Area 84/Northwest Wayne

Canton Township, Dearborn, Dearborn Heights, Garden City, Inkster, Livonia, Northville (part), Northville Township, Plymouth, Plymouth Township, Redford Township, Wayne, Westland

Planning area 85/Southwest Wayne

Allen Park, Belleville, Brownstown Township, Ecorse, Flat Rock, Gibraltar, Grosse Ile Township, Huron Township, Lincoln Park, Melvindale, River Rouge, Riverview, Rockwood, Romulus, Southgate, Sumpter Township, Taylor, Trenton, Van Buren Township, Woodhaven, Wyandotte

Planning area 86/Detroit

Detroit, Grosse Pointe, Grosse Pointe Township, Grosse Pointe Farms, Grosse Pointe Park, Grosse Pointe Woods, Hamtramck, Harper Woods, Highland Park

Section 14. Health Service Areas

Sec. 14. Counties assigned to each of the HSAs 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	

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7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford
8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

Section 15. Effect on prior CON review standards, comparative reviews

Sec. 15. (1) These CON review standards supersede and replace the CON Standards for Nursing Home and Hospital Long-Term-Care Unit (HLTCU) Beds approved by the CON Commission on ~~March 11~~APRIL 30, 2008 and effective on June 20, 2008.

(2) Projects reviewed under these standards involving a change in bed capacity shall be subject to comparative review except as follows:

(a) replacement of an existing nursing home/HLTCU being replaced in a rural county;

(b) replacement of an existing nursing home/HLTCU in a micropolitan or metropolitan statistical area county that is within two miles of the existing nursing home/HLTCU;

(c) relocation of existing nursing home/HLTCU beds; or

(d) an increase in beds pursuant to Section 6(1)(d)(ii) or (iii).

(3) Projects reviewed under these standards that relate solely to the acquisition of an existing nursing home/HLTCU or the renewal of a lease shall not be subject to comparative review.

APPENDIX A

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

The use rate per 1000 population for each age cohort, for purposes of these standards, EFFECTIVE TBD, AND until otherwise changed by the Commission, is as follows.

(i) age 0 - 64: ~~170~~ 208 days of care

(ii) age 65 - 74: ~~3,126~~2,791 days of care

(iii) age 75 - 84: ~~10,987~~10,047 days of care

(iv) age 85 +: ~~37,368~~36,758 days of care

APPENDIX B

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

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

Planning Area	Bed Need	ADC Adjustment Factor
ALCONA	~~88~~115	0.~~90~~95
ALGER	~~68~~65	0.90
ALLEGAN	~~426~~500	0.95
ALPENA	~~173~~187	0.95
ANTRIM	~~142~~168	0.95
ARENAC	~~112~~100	0.95
BARAGA	~~50~~58	0.90
BARRY	~~252~~275	0.95
BAY	~~552~~603	0.95
BENZIE	~~118~~124	0.95
BERRIEN	~~790~~884	0.95
BRANCH	~~222~~224	0.95
CALHOUN	~~651~~675	0.95
CASS	~~234~~273	0.95
CHARLEVOIX	~~152~~159	0.95
CHEBOYGAN	~~181~~188	0.95
CHIPPEWA	~~189~~202	0.95
CLARE	~~163~~185	0.95
CLINTON	~~268~~319	0.95
CRAWFORD	~~10~~495	0.~~95~~90
DELTA	~~234~~245	0.95
DICKINSON	~~174~~190	0.95
EATON	~~472~~491	0.95
EMMET	~~172~~201	0.95
GENESEE	1,~~938~~880	0.95
GLADWIN	~~170~~184	0.95
GOGEBIC	~~114~~137	0.95
GD. TRAVERSE	~~410~~455	0.95
GRATIOT	~~255~~209	0.95
HILLSDALE	~~218~~233	0.95
HOUGHTON/KEWEENAW	~~168~~222	0.95
HURON	~~226~~237	0.95

APPENDIX B - continued

Planning Area	Bed Need	ADC Adjustment Factor
INGHAM	1,~~161~~048	0.95
IONIA	~~258~~260	0.95
IOSCO	~~207~~204	0.95
IRON	~~101~~120	0.95
ISABELLA	~~244~~245	0.95
JACKSON	~~794~~777	0.95
KALAMAZOO	1,~~069~~077	0.95
KALKASKA	~~81~~95	0.90
KENT	2,~~388~~451	0.95
LAKE	~~83~~88	0.90
LAPEER	~~352~~375	0.95
LEELANAU	~~136~~159	0.95
LENAWEE	~~487~~524	0.95
LIVINGSTON	~~592~~710	0.95
LUCE	~~46~~36	0.90
MACKINAC	~~79~~78	0.90
MACOMB	4,~~305~~255	0.95
MANISTEE	~~154~~169	0.95
MARQUETTE	~~282~~338	0.95
MASON	~~166~~186	0.95
MECOSTA	~~212~~220	0.95
MENOMINEE	~~140~~167	0.95
MIDLAND	~~395~~411	0.95
MISSAUKEE	~~91~~92	0.90
MONROE	~~645~~686	0.95
MONTCALM	~~253~~291	0.95
MONTMORENCY	~~99~~101	0.~~90~~95
MUSKEGON	~~779~~843	0.95
NEWAYGO	~~219~~241	0.95
OAKLAND	5,~~326~~630	0.95
OCEANA	~~124~~152	0.95
OGEMAW	~~144~~134	0.95
ONTONAGON	~~48~~59	0.90
OSCEOLA	~~106~~127	0.95
OSCODA	~~85~~72	0.90
OTSEGO	~~139~~132	0.95
OTTAWA	1,~~060~~145	0.95

APPENDIX B - continued

Planning Area	Bed Need	ADC Adjustment Factor
PRESQUE ISLE	~~115~~124	0.95
ROSCOMMON	~~186~~227	0.95
SAGINAW	1,~~039~~038	0.95
ST. CLAIR	~~754~~811	0.95
ST. JOSEPH	~~289~~290	0.95
SANILAC	~~231~~250	0.95
SCHOOLCRAFT	~~58~~61	0.90
SHIAWASSEE	~~350~~336	0.95
TUSCOLA	~~270~~287	0.95
VAN BUREN	~~325~~365	0.95
WASHTENAW	1,~~146~~268	0.95
WEXFORD	~~168~~170	0.95
NW WAYNE	2,~~563~~305	0.95
SW WAYNE	1,~~732~~542	0.95
DETROIT	4,~~435~~140	0.95
STATEWIDE TOTAL	**46,995**	

APPENDIX C

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM-CARE UNIT BEDS

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

APPENDIX D

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS

Michigan nursing home planning areas with a population density of less than 28 individuals per square mile based on 2000 U.S. Census figures.

Planning Area	Population Density Per Square Mile
Ontonagon	6.0
Schoolcraft	7.6
Luce	7.8
Baraga	9.7
Alger	10.7
Iron	11.3
Mackinac	11.7
Oscoda	16.7
Alcona	17.4
Gogebic	15.8
Montmorency	18.8
Lake	20.0
Presque isle	21.8
Menominee	24.3
Chippewa	24.7
Houghton/Keweenaw	24.7
Missaukee	25.5
Crawford	25.6

Source: Michigan Department of Management and Budget and the U.S. Bureau of the Census

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CON REVIEW STANDARDS
FOR NURSING HOME AND HOSPITAL LONG-TERM CARE UNIT BEDS
--ADDENDUM FOR SPECIAL POPULATION GROUPS

(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; definitions

Sec. 1. (1) This addendum supplements the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds and shall be used for determining the need for projects established to better meet the needs of special population groups within the long-term care and nursing home populations.

(2) Except as provided in sections 2, 3, 4, 5, 6, 7, and 8 of this addendum, these standards supplement, and do not supersede, the requirements and terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) The definitions which apply to the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds shall apply to these standards.

(4) For purposes of this addendum, the following terms are defined:

(a) "Behavioral patient" means an individual that exhibits a history of chronic behavior management problems such as aggressive behavior that puts self or others at risk for harm, or an altered state of consciousness, including paranoia , delusions, and acute confusion.

(b) "Hospice" means a health care program licensed under Part 214 of the Code, being Section 333.21401 et seq.

(c) "Infection control program," means a program that will reduce the risk of the introduction of communicable diseases into a ventilator-dependent unit, provide an active and ongoing surveillance program to detect the presence of communicable diseases in a ventilator-dependent unit, and respond to the presence of communicable diseases within a ventilator-dependent unit so as to minimize the spread of a communicable disease.

(d) "Licensed hospital" means either a hospital licensed under Part 215 of the Code; or a psychiatric hospital or unit licensed pursuant to Act 258 of the Public Acts of 1974, as amended, being sections 330.1001 to 330.2106 of the Michigan Compiled Laws.

(e) "Private residence", means a setting other than a licensed hospital; or a nursing home including a nursing home or part of a nursing home approved pursuant to Section 6.

(f) "Traumatic brain injury (TBI)/spinal cord injury (SCI) patient" means an individual with TBI or SCI that is acquired or due to a traumatic insult to the brain and its related parts that is not of a degenerative or congenital nature. These impairments may be either temporary or permanent and cause partial or total functional disability or psychosocial adjustment.

(g) "Ventilator-dependent patient," means an individual who requires mechanical ventilatory assistance.

Section 2. Requirements for approval -- applicants proposing to increase nursing home beds -- special use exceptions

Sec. 2. A project to increase nursing home beds in a planning area which, if approved, would otherwise cause the total number of nursing home beds in that planning area to exceed the needed nursing home bed supply or cause an increase in an existing excess as determined under the applicable CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds, may nevertheless be approved pursuant to this addendum.

Section 3. Statewide pool for the needs of special population groups within the long-term care and nursing home populations

Sec. 3. (1) A statewide pool of additional nursing home beds of 1,958 beds needed in the state is established to better meet the needs of special population groups within the long-term care and nursing home populations. Beds in the pool shall be allocated as follows:

(a) These categories shall be allocated 1,109 beds and distributed as follows and shall be reduced/redistributed in accordance with subsection (c):

(i) TBI/SCI beds will be allocated 400 beds.

(ii) Behavioral beds will be allocated 400 beds.

(iii) Hospice beds will be allocated 130 beds.

(iv) Ventilator-dependent beds will be allocated 179 beds.

(b) The following historical categories have been allocated 849 beds. Additional beds shall not be allocated to these categories. If the beds within any of these categories are delicensed, the beds shall be eliminated and not be returned to the statewide pool for special population groups.

(i) Alzheimer's disease has 384 beds.

(ii) Health care needs for skilled nursing care has 173 beds.

(iii) Religious has 292 beds.

(c) The number of beds set aside from the total statewide pool established for categories in subsection (1)(a) for a special population group shall be reduced if there has been no CON activity for that special population group during at least 6 consecutive application periods.

(i) The number of beds in a special population group shall be reduced to the total number of beds for which a valid CON has been issued for that special population group.

(ii) The number of beds reduced from a special population group pursuant to this subsection shall revert to the total statewide pool established for categories in subsection (1)(a).

(iii) The Department shall notify the Commission of the date when action to reduce the number of beds set aside for a special population group has become effective and shall identify the number of beds that reverted to the total statewide pool established for categories in subsection (1)(a).

(iv) For purposes of this subsection, "application period" means the period of time from one designated application date to the next subsequent designated application date.

(v) For purposes of this subsection, "CON activity" means one or more of the following:

(A) CON applications for beds for a special population group have been submitted to the Department for which either a proposed or final decision has not yet been issued by the Department.

(B) Administrative hearings or appeals to court of decisions issued on CON applications for beds for a special population group are pending resolution.

(C) An approved CON for beds for each special population group has expired for lack of appropriate action by an applicant to implement an approved CON.

(d) By setting aside these beds from the total statewide pool, the Commission's action applies only to applicants seeking approval of nursing home beds pursuant to sections 4, 5, 6, and 7. It does not preclude the care of these patients in units of hospitals, hospital long-term care units, nursing homes, or other health care settings in compliance with applicable statutory or certification requirements.

(2) Increases in nursing home beds approved under this addendum for special population groups shall not cause planning areas currently showing an unmet bed need to have that need reduced or planning areas showing a current surplus of beds to have that surplus increased.

Section 4. Requirements for approval for beds from the statewide pool for special population groups allocated to TBI/SCI patients

Sec. 4. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of TBI/SCI patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) A continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) A transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

(c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(2) Beds approved under this subsection shall not be converted to general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON review standards for nursing home and hospital long-term care unit beds and shall not be offered to individuals other than TBI/SCI patients.

Section 5. Requirements for approval for beds from the statewide pool for special population groups allocated to behavioral patients

Sec. 5. The CON Commission determines there is a need for beds for applications designed to determine the efficiency and effectiveness of specialized programs for the care and treatment of behavioral patients as compared to serving these needs in general nursing home unit(s).

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate with credible documentation to the satisfaction of the Department each of the following:

(a) Individual units shall consist of 20 beds or less per unit.

(b) The facility shall not be awarded more than 40 beds.

(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.

(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.

(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(f) Staff will be specially trained in treatment of behavioral patients.

(2) Beds approved under this subsection shall not be converted to general nursing home use without a CON for nursing home and hospital long-term care unit beds under the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(3) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 6. Requirements for approval for beds from the statewide pool for special population groups allocated to hospice patients

Sec. 6. The CON Commission determines there is a need for beds for patients requiring both hospice and long-term nursing care services within the long-term care and nursing home populations.

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) An applicant shall be a hospice certified by Medicare pursuant to the Code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.

(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.

(c) An application shall propose 30 beds or less.

(d) An applicant for beds from the special statewide pool of beds shall not be approved if any application for beds in that same planning area has been approved from the special statewide pool of beds allocated for hospice.

(2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 7. Requirements for approval for beds from the statewide pool for special population groups allocated to ventilator-dependent patients

Sec. 7. The CON Commission determines there is a need for beds for ventilator-dependent patients within the long-term care and nursing home populations

(1) An applicant proposing to begin operation of a new nursing home/HLTCU or add beds to an existing nursing home/HLTCU under this section shall demonstrate, with credible documentation to the satisfaction of the Department, each of the following:

(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.

(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.

(c) The proposed unit will serve only ventilator-dependent patients.

(2) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 8. Acquisition of nursing home/HLTCU beds approved pursuant to this addendum

Sec. 8. (1) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to religious shall meet the following:

(a) The applicant is a part of, closely affiliated with, controlled, sanctioned or supported by a recognized religious organization, denomination or federation as evidenced by documentation of its federal tax exempt status as a religious corporation, fund, or foundation under section 501(c)(3) of the United States Internal Revenue Code.

(b) The applicant's patient population includes a majority of members of the religious organization or denomination represented by the sponsoring organization.

(c) The applicant's existing services and/or operations are tailored to meet certain special needs of a specific religion, denomination or order, including unique dietary requirements, or other unique religious needs regarding ceremony, ritual, and organization which cannot be satisfactorily met in a secular setting.

(d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(2) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to TBI/SCI shall meet the following:

(a) The beds will be operated as part of a specialized program exclusively for TBI/SCI patients. At the time an application is submitted, the applicant shall demonstrate that it operates:

(i) a continuum of outpatient treatment, rehabilitative care, and support services for TBI/SCI patients; and

(ii) a transitional living program or contracts with an organization that operates a transitional living program and rehabilitative care for TBI/SCI patients.

(b) The applicant shall submit evidence of accreditation of its existing outpatient and/or residential programs by the Commission on Accreditation of Rehabilitation Facilities (CARF) or another nationally-recognized accreditation organization for rehabilitative care and services.

(c) Within 24-months of accepting its first patient, the applicant shall obtain CARF or another nationally-recognized accreditation organization for the nursing home beds proposed under this subsection.

(d) A floor plan for the proposed physical plant space to house the nursing home beds allocated under this subsection that provides for:

(i) Individual units consisting of 20 beds or less per unit, not to be more than 40 beds per facility.

(ii) Day/dining area within, or immediately adjacent to, the unit(s), which is solely for the use of TBI/SCI patients.

(iii) Direct access to a secure outdoor or indoor area at the facility appropriate for supervised activity.

(e) The applicant proposes programs to promote a culture within the facility that is appropriate for TBI/SCI patients of various ages.

(3) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to Alzheimer’s disease shall meet the following:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.

(b) The specialized program will participate in the state registry for Alzheimer's disease.

(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.

(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.

(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.

(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(g) Staff will be specially trained in Alzheimer's disease treatment.
(h) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(4) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to behavioral patients shall meet the following:
(a) Individual units shall consist of 20 beds or less per unit.
(b) The facility shall not be awarded more than 40 beds.
(c) The proposed unit shall have direct access to a secure outdoor or indoor area for supervised activity.
(d) The unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the behavioral patients.
(e) The physical environment of the unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.
(f) Staff will be specially trained in treatment of behavioral patients.
(g) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(5) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to hospice shall meet the following:
(a) An applicant shall be a hospice certified by Medicare pursuant to the code of Federal Regulations, Title 42, Chapter IV, Subpart B (Medicare Programs), Part 418 and shall have been a Medicare certified hospice for at least 24 continuous months prior to the date an application is submitted to the Department.
(b) An applicant shall demonstrate that, during the most recent 12-month period prior to the date an application is submitted to the Department for which verifiable data are available to the Department, at least 64% of the total number of hospice days of care provided to all of the clients of the applicant hospice were provided in a private residence.
(c) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

(6) An applicant proposing to acquire nursing home/HLTCU beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall meet the following:
(a) An applicant proposes a program for caring for ventilator-dependent patients in licensed nursing home beds.
(b) An application proposes no more than 40 beds that will be licensed as nursing home beds.
(c) The proposed unit will serve only ventilator-dependent patients.
(d) All beds approved pursuant to this subsection shall be dually certified for Medicare and Medicaid.

Section 9. Project delivery requirements -- terms of approval for all applicants seeking approval under Section 3(1) of this addendum

Sec. 9. (1) An applicant shall agree that if approved, the services shall be delivered in compliance with the terms of approval required by the CON Review Standards for Nursing Home and Hospital Long-term Care Unit Beds.

(2) An applicant for beds from the statewide pool for special population groups allocated to religious shall agree that, if approved, the services provided by the specialized long-term care beds shall be delivered in compliance with the following term of CON approval:
(a) The applicant shall document, at the end of the third year following initiation of beds approved an annual average occupancy rate of 95 percent or more. If this occupancy rate has not been met, the applicant shall delicense a number of beds necessary to result in a 95 percent occupancy based upon its average daily census for the third full year of operation.

(3) An applicant for beds from the statewide pool for special population groups allocated to Alzheimer's disease shall agree that if approved:

(a) The beds are part of a specialized program for Alzheimer's disease which will admit and treat only patients which require long-term nursing care and have been appropriately classified as a patient on the Global Deterioration Scale (GDS) for age-associated cognitive decline and Alzheimer's disease as a level 4 (when accompanied by continuous nursing needs), 5, or 6.

(b) The specialized program will participate in the state registry for Alzheimer's disease.

(c) The specialized program shall be attached or geographically adjacent to a licensed nursing home and be no larger than 20 beds in size.

(d) The proposed Alzheimer's unit shall have direct access to a secure outdoor or indoor area at the health facility, appropriate for unsupervised activity.

(e) The Alzheimer's unit shall have within the unit or immediately adjacent to it a day/dining area which is solely for the use of the Alzheimer's unit patients.

(f) The physical environment of the Alzheimer's unit shall be designed to minimize noise and light reflections to promote visual and spatial orientation.

(g) Staff will be specially trained in Alzheimer's disease treatment.

(4) An applicant for beds from the statewide pool for special population groups allocated to hospice shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall maintain Medicare certification of the hospice program and shall establish and maintain the ability to provide, either directly or through contractual arrangements, hospice services as outlined in the Code of Federal Regulations, Title 42, Chapter IV, Subpart B, Part 418, hospice care.

(b) The proposed project shall be designed to promote a home-like atmosphere that includes accommodations for family members to have overnight stays and participate in family meals at the applicant facility.

(c) An applicant shall not refuse to admit a patient solely on the basis that he/she is HIV positive, has AIDS or has AIDS related complex.

(d) An applicant shall make accommodations to serve patients that are HIV positive, have AIDS or have AIDS related complex in nursing home beds.

(e) An applicant shall make accommodations to serve children and adolescents as well as adults in nursing home beds.

(f) Nursing home beds shall only be used to provide services to individuals suffering from a disease or condition with a terminal prognosis in accordance with Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws.

(g) An applicant shall agree that the nursing home beds shall not be used to serve individuals not meeting the provisions of Section 21417 of the Code, being Section 333.21417 of the Michigan Compiled Laws, unless a separate CON is requested and approved pursuant to applicable CON review standards.

(h) An applicant shall be licensed as a hospice program under Part 214 of the Code, being Section 333.21401 et seq. of the Michigan Compiled Laws.

(i) An applicant shall agree that at least 64% of the total number of hospice days of care provided by the applicant hospice to all of its clients will be provided in a private residence.

(5) An applicant for beds from the statewide pool for special population groups allocated to ventilator-dependent patients shall agree that, if approved, all beds approved pursuant to that subsection shall be operated in accordance with the following CON terms of approval.

(a) An applicant shall staff the proposed ventilator-dependent unit with employees that have been trained in the care and treatment of ventilator-dependent patients and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of ventilator-dependent patients.

(ii) A program director that is a registered nurse.

(b) An applicant shall make provisions, either directly or through contractual arrangements, for at least the following services:

(i) respiratory therapy.

(ii) occupational and physical therapy.
(iii) psychological services.
(iv) family and patient teaching activities.
(c) An applicant shall establish and maintain written policies and procedures for each of the following:
(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the ventilator-dependent unit. At a minimum, the criteria shall address the amount of mechanical ventilatory dependency, the required medical stability, and the need for ancillary services.
(ii) The transfer of patients requiring care at other health care facilities.
(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge.
(iv) Patient rights and responsibilities in accordance with Sections 20201 and 20202 of the Code, being Sections 333.20201 and 333.20202 of the Michigan Compiled Laws.
(v) The type of ventilatory equipment to be used on the unit and provisions for back-up equipment.
(d) An applicant shall establish and maintain an organized infection control program that has written policies for each of the following:
(i) use of intravenous infusion apparatus, including skin preparation, monitoring skin site, and frequency of tube changes.
(ii) placement and care of urinary catheters.
(iii) care and use of thermometers.
(iv) care and use of tracheostomy devices.
(v) employee personal hygiene.
(vi) aseptic technique.
(vii) care and use of respiratory therapy and related equipment.
(viii) isolation techniques and procedures.
(e) An applicant shall establish a multi-disciplinary infection control committee that meets on at least a monthly basis and includes the director of nursing, the ventilator-dependent unit program director, and representatives from administration, dietary, housekeeping, maintenance, and respiratory therapy. This subsection does not require a separate committee, if an applicant organization has a standing infection control committee and that committee's charge is amended to include a specific focus on the ventilator-dependent unit.
(f) The proposed ventilator-dependent unit shall have barrier-free access to an outdoor area in the immediate vicinity of the unit.
(g) An applicant shall agree that the beds will not be used to service individuals that are not ventilator-dependent unless a separate CON is requested and approved by the Department pursuant to applicable CON review standards.
(h) An applicant shall provide data to the Department that evaluates the cost efficiencies that result from providing services to ventilator-dependent patients in a hospital.

(6) An applicant for beds from the statewide pool for special population groups allocated to TBI/SCI patients shall agree that if approved:
(a) An applicant shall staff the proposed unit for TBI/SCI patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:
(i) A medical director with specialized knowledge, training, and skills in the care of TBI/SCI patients.
(ii) A program director that is a registered nurse.
(iii) Other professional disciplines required for a multi-disciplinary team approach to care.
(b) An applicant shall establish and maintain written policies and procedures for each of the following:
(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for TBI/SCI patients. At a minimum, the criteria shall address the required medical stability and the need for ancillary services, including dialysis services.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Upon admission and periodically thereafter, a comprehensive needs assessment, a treatment plan, and a discharge plan that at a minimum addresses the care needs of a patient following discharge, including support services to be provided by transitional living programs or other outpatient programs or services offered as part of a continuum of care to TBI patients by the applicant.

(iv) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(v) Quality assurance and assessment program to assure that services furnished to TBI/SCI patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the TBI patient receiving such services.

(7) An applicant for beds from the statewide pool for special population groups allocated to behavioral patients shall agree that if approved:

(a) An applicant shall staff the proposed unit for behavioral patients with employees that have been trained in the care and treatment of such individuals and includes at least the following:

(i) A medical director with specialized knowledge, training, and skills in the care of behavioral patients.

(ii) A program director that is a registered nurse.

(iii) Other professional disciplines required for a multi-disciplinary team approach to care.

(b) An applicant shall establish and maintain written policies and procedures for each of the following:

(i) Patient admission criteria that describe minimum and maximum characteristics for patients appropriate for admission to the unit for behavioral patients.

(ii) The transfer of patients requiring care at other health care facilities, including a transfer agreement with one or more acute-care hospitals in the region to provide emergency medical treatment to any patient who requires such care.

(iii) Utilization review, which shall consider the rehabilitation necessity for the service, quality of patient care, rates of utilization and other considerations generally accepted as appropriate for review.

(iv) quality assurance and assessment program to assure that services furnished to behavioral patients meet professional recognized standards of health care for providers of such services and that such services were reasonable and medically appropriate to the clinical condition of the behavioral patient receiving such services.

(v) Orientation and annual education/competencies for all staff, which shall include care guidelines, specialized communication, and patient safety.

Section 10. Comparative reviews, effect on prior CON review standards

Sec. 10. (1) Projects proposed under Section 4 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(2) Projects proposed under Section 5 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(3) Projects proposed under Section 6 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(4) Projects proposed under Section 7 shall be considered a distinct category and shall be subject to comparative review on a statewide basis.

(5) These CON review standards supercede and replace the CON Review Standards for Nursing Home and Long-term Care Unit Beds--Addendum for Special Population Groups approved by the Commission on March 11, 2008 and effective on June 2, 2008.

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The CTSAC has met four more times since, the last Commission meeting: September 29, October 27, November 17, and December 9, 2010. At the meeting on September 29 there was a presentation on dental CT scanners by Dr James Geist, Professor of Oral and Maxillofacial Radiology, University of Detroit Mercy School of Dentistry, and Dr Rhonda Henessey, member (former chair) of the Michigan Board of Dentistry. The CTSAC also passed an extension of the pilot project on Portable Point of Care scanners, with more discussion of reporting metrics to follow.

At the October 27 meeting the committee completed work on the extension of the pilot project for Portable Point of Care scanners, with definition of eligibility for hospitals to participate in the pilot project and reporting requirements. In addition, the committee formed a sub-committee to draft a proposal for a similar pilot project for in-office Mini-CT Scanners.

On November 17 CTSAC discussed the proposal for the second pilot project brought forth by the subcommittee. The motion was defeated by a vote of 2 yes and 10 no. The volume requirements for these mini-CT scanners remain the same as for the standard fixed scanners (7500 CT equivalents).

At the same November meeting a proposal to exclude Dental CT Scanners from CON regulation altogether, by changing the definition of which scanners were included and which excluded by the current standards, was defeated by a vote of 3 yes and 9 no.

At the same November meeting there was a discussion regarding proposed changes in CT volume requirements for establishing a new CT service or expanding an existing one, but no motion was made.

At the December 9 meeting a motion was made to modify the CT volume requirements for replacing an existing scanner so that hospitals could replace obsolete equipment that are not meeting the current volume requirements because they are not receiving sufficient patient referrals due to the obsolescence of the equipment. Concerns were raised about patient safety by the use of the older scanners that cannot provide scans with the lower doses more modern equipment can. The motion passed unanimously.

A motion was made and passed unanimously to reduce the volume requirements for a Dental CT scanner from 200 scans/year to 100 scans/year specifically for the Upper Peninsula (Health Service Area 8) since currently there are no Dental CT scanners there and patients have to travel either to the Lower Peninsula or to Wisconsin to receive a dental CT scan. A dentist wishing to initiate a dental CT scan service in the UP would still have to file a CON application and meet all other parts of the standards.

Near the end of the meeting the CT volume requirements proposal first discussed in November was brought up again due to concerns about what constitutes “excess capacity” for scanners and how this “excess” could be shared to allow initiation of new CT services. The discussion will continue at the January 2011 meeting.

The major activity of the January meeting will be to approve the proposed changes to the language of the CT CON standards, for recommendation to the Commission at its March 2011 meeting.

Submitted by: Sharon L. Brooks, DDS, MS, Chair, CTSAC
December 13, 2010

December 9, 2010

Dear Colleagues:

As chair of the committee, Certificate of Need (CON) Commission Cardiac Catheterization Services Standard Advisory Committee (CCSAC), I am happy to provide you a brief report regarding our deliberations as of the time of this writing.

The committee has now met twice. The first meeting was largely devoted to understanding the charge for our committee and identifying resources that we feel will be necessary in order to make recommendations to the commission. The second meeting was devoted to a number of presentations which relate to certificate of need activities regarding cath labs both in the state, in the nation, and in Europe.

As list of those presentations and the topics covered is provided in Appendix A. Our third meeting will occur on January 11th. Currently there is an extensive array of presentations that we plan for that meeting. The presenters and topics are listed in Appendix B.

Following the January 11th meeting, I believe that we will have heard or seen most of the information that will be helpful to our deliberations. I would suspect that our committee will then go one by one through each charge and bring forward a set of recommendations. Meetings three through six, if needed, will be devoted to this task.

If you have questions about our activities or suggestions for important information that is not included in the above notes, please let me know. On behalf of all of our committee members, we appreciate the opportunity to serve the commission and the state in this important process.

Sincerely,

Kim A. Eagle, M.D.
Albion Walter Hewlett Professor of Internal Medicine
Chief of Clinical Cardiology
Director, Cardiovascular Center

KAE/lgh

SAC Committee
Planned Agenda for January 11th meeting

Dear Colleagues;

Thank you so much for your terrific effort and for all the data gathering and presentations that characterized our second meeting. I am supplying you with the list of planned presentations for our next meeting which will occur on January 11th. This is a draft. I understand that these may change depending on availability of information, etc.

Doug Weaver will present the Wennberg paper which looked at small area variation and coronary artery procedures. He will also present information regarding international standards as they relate to cardiac procedure volumes. Finally, he will review the article published in 2006 by Mauro Moscucci which characterized risk adjusted mortality based on operator volume for the state of Michigan.

Art Riba will be talking with Hitinder Gurm of the Blue Cross Blue Shield of Michigan Registry in order to gain information that applies to the degree that Michigan's "Primary PCI without surgical back-up programs" are complying with the state regulations regarding volumes and outcomes. It appears that Hitinder Gurm will be available to present this data.

The staff (Sally) will look to see if the state is currently monitoring whether Michigan hospitals are meeting the volume requirements and other requirements in the state of Michigan regulations. She will also look to see if there is information from the minutes of the last CON commission which established the number of 48 primary PCIs as a minimum volume per institution per year.

Hitinder Gurm will present information regarding state hospital PCI volumes per site and state operator volumes per year based on Blue Cross Blue Shield of Michigan information.

Art Riba and Frank Sotille will look at the paper by Jeremy Buckley, Brahmajee Nallamothu and others as it relates to access to primary PCI in the state of Michigan. Since neither Brahmajee Nallamothu or Eric Bates are able to present to our group, Art Riba will do this..

Frank Sotille and Doug Weaver will work with staff to do a deeper dive into what procedures are being done by hospitals of different geographic location and size in the state of Michigan.

Staff (Brenda) along with Alice Betz will present information related to what other states are currently doing surrounding certificate of need regulations as it relates to cardiac cath, PCI, elective PCI without surgical back up, and primary PCI without surgical back-up.
Kim Eagle will present information from the GRACE Registry examining the relation between outcomes of patients with acute coronary syndromes and availability of onsite cath labs.

Doug Weaver will present information available from the ACTION registry about quality of care relating to availability of PCI.

Ted Schreiber will present information from a recent meta-analysis which looked at the question of outcomes of acute coronary syndromes in hospitals with and without PCI capabilities. He will also present recent recommendations that are being implemented in the state of New York.

David Dobes will work with staff and others looking at the general distribution of various procedures in the state.

Robert Goodman will present information from Blue Cross Blue Shield looking at the linkage between diagnostic coronary angiography and subsequent percutaneous coronary intervention within 2 weeks at another hospital.

Barry Lewis will present information pertaining to cath lab equivalents.

Once again, on behalf of the entire Committee, thank you to all of you for your excellent presentations and work to date and for your effort going forward. Please let me know if I have mischaracterized your next presentation.

Sincerely yours.

Kim Eagle

STATE OF MICHIGAN

JENNIFER GRANHOLM,
Governor

Michigan Certificate of Need Commission

CAPITOL VIEW BUILDING
201 TOWNSEND STREET
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MEMORANDUM

Date: December 15, 2010

To: Joint Legislative Committee (JLC)

From: Certificate of Need (CON) Commission

RE: Recommendations Pertaining to the CON Program

MCL 333.22215(1)(f) requires the Commission, by January 1, 2005, and every 2 years after January 1, 2005, to "make recommendations to the joint committee regarding statutory changes to improve or eliminate the certificate of need program."

Accordingly, the Commission respectfully submits the following:

Based on our ongoing review of the program, the Commission believes and unanimously recommends that the program should be fully supported as it is serving a valuable need. In our bipartisan judgment, we have found that CON meets the three statutory objectives for the program, i.e., affordability, accessibility, and quality of health care in Michigan. We recommend no statutory changes to the current list of covered services at this time.

In addition to the responsibility of submitting the 2-year report to the JLC, MCL 333.22215(1)(e) of the CON law requires the Commission to "Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission." Copies of FY2009 and FY2010 CON Program Annual Activity Reports are being provided. Along with the annual reports, the Department provides quarterly program section performance reports to the Commission demonstrating the effectiveness of the CON program in processing letters of intent, applications, emergency applications, and amendments as well as issuing decisions within the specified time frames set forth in the Administrative Rules.

Pursuant to MCL 333.22215 (1)(m), the CON Commission is to "… review and, if necessary, revise each set of certificate of need review standards at least every 3 years." A Public Hearing is held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. The following review standards are up for review in 2011: Cardiac

Catheterization Services, Hospital Beds and Addendum for HIV Infected Individuals, Megavoltage Radiation Therapy (MRT) Services/Units, Open Heart Surgery Services, Positron Emission Tomography (PET) Scanner Services, and Surgical services. Currently, there are standard advisory committees (SACs) reviewing CON Review Standards for Cardiac Catheterization and CON Review Standards for Computed Tomography (CT). The Commission actively seeks input from the public and always includes opportunities through public comment/hearings prior to any Commission action.

Finally, we would like to provide the JLC a brief summary of our activities and accomplishments since the January 2009 report. A summary of the approved changes to various CON Review Standards is attached.

The CON Commission appreciates the continuing support of the Governor and the Legislature for the CON program.

Respectfully yours,

Edward B. Goldman, JD, Chairperson

James B. Falahee, Jr., JD, Vice-Chairperson

Peter Ajluni, DO

Bradley N. Cory

Charles M. Gayney

Robert L. Hughes

Marc D. Keshishian, MD

Brian A. Klott

Gay L. Landstrom, RN

Michael A. Sandler, MD

Michael W. Young, DO

cc: Janet Olszewski, Director, MDCH
Kurt Krause, Chief Deputy Director, MDCH
Melanie Brim, Interim Deputy Director, Health Policy, Regulation & Professions Administration, MDCH
Joseph Potchen, First Assistant Attorney General, Attorney General's Office

bc: William J. Hart, Director, Health Policy and Access to Care Division, MDCH
Larry Horvath, Manager, CON Program Section, MDCH
Irma Lopez, Manager, Health Policy Section, MDCH
Brenda Rogers, Special Assistant to the Commission, Health Policy Section, MDCH

SUMMARY OF CON REVIEW STANDARDS REVISIONS
(FY2009 – FY2010)

During FY2009, the Certificate of Need Commission revised the review standards for Bone Marrow Transplantation (BMT) Services, Hospital Beds, Magnetic Resonance Imaging (MRI) Services, and Megavoltage Radiation Therapy (MRT) Services/Units.

The revisions to the CON Review Standards for BMT Services were modified under Section 8(1)(g) to change the period of the extension for the prospective payment system (PPS) exemption and have been implemented.

The revisions to the CON Review Standards for Hospital Beds include the following and have been implemented:

- Definitions for "acquiring a hospital," "host hospital," and "licensed site" clarified based on current Department practice.
- Clarified language under Section 6(2)(b) & (b)(i), renewal of lease for long-term (acute) care hospitals (LTACH) and subsequent addition of beds for LTACHs and the host hospital respectively, based on current Department practice.
- Updated Appendix A.
- Re-calculated the bed need with the base year of 2006 and the planning year of 2011. Updated Appendix C.
- Other technical changes.

The revisions to the CON Review Standards for MRI Services include the following and have been implemented:

- Definition for intra-operative magnetic resonance imaging (IMRI).
- Added a new Section 11, “Requirements for approval – applicants proposing to initiate, replace, or acquire a hospital based IMRI.” This new section includes the following provisions:
    - The proposed site is a licensed hospital under part 215 of the Code.
    - The proposed site has an existing fixed MRI service that has been operational for the previous 36 consecutive months and is meeting its minimum volume requirements.
    - The proposed site has an existing and operational surgical service and is meeting its minimum volume requirements pursuant to the CON Review Standards for Surgical Services.
    - The applicant shall have experienced one of the following: 1) at least 1,500 oncology discharges in the most recent year of operation; 2) at least 1,000 neurological surgeries in the most recent year of operation; or 3) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.
    - The proposed IMRI unit must be located in an operating room or a room adjoining an operating room allowing for transfer of the patient between the operating room and this adjoining room.
    - Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under the section unless the patient meets one of the following criteria: 1) the patient has been admitted to an inpatient unit; or 2) the patient is having the study performed on an outpatient basis, but is in need of general anesthesia or deep sedation as defined by the American Society of Anesthesiologists.
    - The approved IMRI unit will not be subject to MRI volume requirements.
    - The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need or to satisfy MRI CON Review Standards requirements.
    - The applicant agrees to operate the IMRI unit in accordance with all applicable project delivery requirements set forth in the standards.
    - The provisions are part of a pilot program approved by the CON Commission and shall expire

and be of no further force and effect, and shall not be applicable to any application which has not been submitted by December 31, 2010.

- Data to be reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic.
- Other technical changes.

The revisions to the CON Review Standards for MRT Services/Units include the following and have been implemented:

- Modified the definition of "heavy particle accelerator" to specifically include carbon ions.
- Added definitions for "high MRT (HMRT) unit" and "hospital MRT service" for purposes of Section 10.
- Modified the definitions for "non-special MRT unit" and "special purpose MRT unit."
- Removed references to heavy particle accelerator under sections 5 and 6 since they would no longer be considered special purpose MRT units.
- Added a new Section 10, "Requirements for approval – applicants proposing to initiate an MRT service utilizing an HMRT unit." This new section includes the following provisions:
  - The applicant shall be a single legal entity authorized to do business in Michigan.
  - The applicant shall be a collaborative consisting of, at a minimum, at least 40% of all Michigan hospital MRT services with more than 30,000 equivalent treatment visits (ETVs). Utilizing the April 30, 2008 revised list published by the Department, there are nine services with more than 30,000 ETVs, meaning that four would have to participate in the collaborative.
  - The collaborative shall include hospital MRT services from more than one planning area from either or both of the following: i) the participating services under subsection (b) (those above 30,000 ETVs); ii) hospital MRT services with the highest number ETVs in a planning area.
  - For purposes of Section 10, the ETVs shall be those from the April 30, 2008 list (revised) published by the Department. The list will be updated every three years.
  - Language under Section 10(1)(e) describes participation in only **one** collaborative and includes MRT services that are owned by, under common control of, or has a common parent.
  - Language under Section 10(1)(f) requires those MRT services that have been approved but not operational, or have a pending application, for a heavy particle accelerator to surrender the CON or application in order to participate in the proposed collaborative for an MRT service utilizing an HMRT unit. The CON or application, as applicable, must be surrendered when the application is approved.
  - Language under Section 10(1)(g) requires those MRT services that have been approved and are operational for a heavy particle accelerator to surrender the CON in order to participate in the proposed collaborative for an MRT service utilizing an HMRT unit. The CON must be surrendered when the HMRT unit becomes operational.
  - The applicant shall provide documentation of its process, policies, and procedures, acceptable to the Department, that allows any other interested entities to participate in the collaborative utilizing an HMRT unit.
  - The applicant shall provide an implementation plan, acceptable to the Department, for financing and operating the proposed MRT service utilizing an HMRT unit which includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.
  - MRT services utilizing an HMRT unit shall be provided to adult and pediatric patients.
  - The MRT service utilizing an HMRT shall have simulation capabilities available for use in treatment planning.
  - MRT services utilizing an HMRT unit demonstrate compliance with the staffing requirements of Section 4(3).
  - Additional project delivery requirements for MRT services utilizing an HMRT unit have been included:
    - ✓ All patients treated shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit for treatment of

specific cancer conditions. The number of patients treated, number enrolled in research studies, and the types of cancer conditions involved, shall be provided to the Department as part of the con Annual Survey.

- ✓ Upon completion of any study, and authorization by study sponsor, the findings and summary of any research studies, consistent with patient confidentiality, shall be provided to the Department by the applicant.
- ✓ The MRT service utilizing an HMRT unit shall provide the Department, on an annual basis, following the initiation of the service, with updates to the information provided and approved by the Department pursuant to subsections 10(1)(h), (i), (j), (k), and 10(2).
- ✓ On an annual basis, following the initiation of the service, the Department will assess the affordability of the project by evaluating the "Hospital Cost Report" and any other applicable information supplied to the Centers of Medicare and Medicaid Services (CMS) and the Michigan Medical Services Administration (MSA). This allows for MDCH oversight of affordability.
- ✓ Upon review, by the Department, of the information submitted under c) and d) above, and the Department's finding that the service has not fulfilled project delivery requirements, the Department may order changes with regard to the provision of the HMRT service to assure fulfillment of project delivery requirements. The Department may elect to verify the information and data through on-site review of appropriate records.

- ➢ Replaced reference to heavy particle accelerator with HMRT units where applicable in the project delivery requirements and Table 1 in Section 13.
- ➢ Updated the following project delivery requirement [Section 16(1)(c)(iv)] as shown: " All MRT treatments shall be performed pursuant to a radiation oncologist and at least one radiation oncologist will be immediately available during the operation of the unit(s)." Immediately available is already defined in the standards as "continuous availability of direct communication with the MRT unit in person or by radio, telephone, or telecommunication."
- ➢ Other technical changes.

The revisions to the CON Review Standards for PET Scanner Services include the following and have been implemented:

- ➢ Requirements for conversion from mobile to fixed PET services.
- ➢ Utilizing fixed PET scans to expand to a mobile service instead of initiating a mobile PET service.
- ➢ Language that allows a "free" replacement of the current PET scanner to a PET/CT scanner.
- ➢ Language to allow for relocation of a unit or service.
- ➢ Requirements for a dedicated pediatric PET scanner.
- ➢ PET equivalents updated.
- ➢ Elimination of 85/15 rule [where at least 85 percent of the data was from a single planning area in which 85 percent of the proposed mobile PET service (patient visits) would be provided] for mobile PET scanner services.
- ➢ Commitment of data for a given PET unit reduced from lifetime to five years.

During FY2010, the Certificate of Need Commission revised the review standards for Air Ambulance Services, BMT Services, Heart/Lung and Liver (HLL) Transplantation Services, MRI Services, Neonatal Intensive Care Services/Beds (NICU), Pancreas Transplantation Services, and Psychiatric Beds and Services.

The revisions to the CON Review Standards for Air Ambulance Services include the following and have been implemented:

- ➢ Updated the definition of "air ambulance service."
- ➢ Redefined "base of operations."
- ➢ Added a definition for "existing air ambulance."
- ➢ Expanded the definition of patient transport to include advance life support intercepts.

- Added a new definition for organ transport and allowance for an organ transport to count for volume purposes for an air ambulance with two (2) air ambulances or at the time of application for expansion to a second unit.
- Modified the expansion language to utilize only historical volume.
- Modified the replacement language for an air ambulance to mirror the expansion language within the standards.
- Updated the methodology for projecting patient transports.
- Updated the project delivery requirements.
- Other technical changes.

The revisions to the CON Review Standards for BMT Services include the following and have been implemented:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Definition for "licensed site" clarified based on current Department practice.
- Under Section 2(1)(t), redefined planning area to add a second adult planning area.
- Under Section 2(1)(w), added a definition for Tumor Registry as referenced in Section 8.
- "Implementation plan" moved to Section 3(4).
- Under Section 3(5), identified a cap of three in planning area one and a cap of one in planning area two.
- Under Section 3(6), the volume projection for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
- Under Section 3(10), added language to clarify that the written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (fact) accredited transplant unit that performs both allogeneic and autologous transplants for either adult and/or pediatrics.
- Under Section 3(10)(a)(iv)(A) and (B), reduced the number of site visits to three.
- Under sections 3(10)(b)(i), 7(1)(c)(i)(D) and (E), 7(1)(c)(iv)(A) and (B), 7(1)(c)(vi)(D), 7(1)(d)(v), modified language based on the recommendation that autologous only programs would no longer be allowed.
- Acquisition language (previous Section 8) moved to Section 4. For administrative feasibility, changed “the CON granted pursuant to this Section shall automatically expire” to “the Department may expire the CON granted pursuant to this Section.”
- Under Section 5(3)(a), modified to award points based on the straight-line distance to the nearest existing bmt program of the type applied for (adult or pediatric) instead of being based on the number of BMT services within the health service area (HSA).
- Clarified Section 5(3)(b)(ii) based on administrative practice.
- Under Section 5(3)(d), added language to award points based on the number of necessary support services/personnel as identified in Section 6 (project delivery requirements) that the applicant has available on-site on the date the application is submitted to the Department.
- Based on current administrative practice, modified the language in Section 5(4) consistent with recent changes in other CON review standards.
- Split Section 7(1)(c)(iv)(C) into two subsections: 7(1)(c)(iv)(C) and (D).
- Under Section 7(1)(d)(i)(A) and (B), the volume maintenance for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
- Under Section 8, added language to identify the source of data for documentation of projections.
- Other technical changes.

The revisions to the CON Review Standards for HLL Transplantation Services include the following and have been implemented:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.

- "Implementation plan" moved to Section 3(2).
- Definition for "licensed site" clarified based on current Department practice.
- Removed definition for “transplant and health policy center” as it is no longer referenced in the standards.
- Removed definition for “transplant support program” as it is not referenced in the standards.
- Under Section 3(5), added liver transplantation services to the joint sharing arrangement language.
- Under Section 5(1) and (2), added language relevant to the joint sharing arrangement and consistent with Section 4(1) and (2).
- Based on current administrative practice, modified the language in Section 6(4) consistent with recent changes in other CON review standards.
- Added language under Section 7(1)(c)(ii) to clarify the requirements to comply with the Organ Procurement and Transplantation Network (OPTN). Removed sections 8, 9, and 10 as they are no longer needed given the clarification to Section 7(1)(c)(ii).
- Updated the language under Section 7(1)(c)(ix) as required by the federal OPTN.
- Other technical changes.

The revisions to the CON Review Standards for MRI Services include the following and have been implemented:

- Streamlined Section 1.
- Technical edits in Section 2.
- Added an exclusion in Section 2 (1)(dd) for MRI Simulators. The MRI simulator language is consistent with the requirements in the CON Review Standards for Computed Tomography (CT) Scanner Services. The use of an MRI simulator would not need an approval for an MRI CON if used only for Megavoltage Radiation Therapy (MRT) treatment planning purposes. In the event that the facility wants to use the MRI for billable diagnostic procedures, then the facility would need an approved MRI CON.
- Streamlined and reorganized Sections 3 - 7.
- Added an exception to the criteria for conversion of a mobile to a fixed MRI in Section 3(2)(b)(iii) to allow for a hospital with 3,000 MRI adjusted procedures, 24-hour emergency care services, and at least 20,000 emergency room visits within a 12-month period to convert from a mobile to a fixed. Further, a maintenance volume of 3,000 actual MRI adjusted procedures per unit was added to the project delivery requirements, Section 12(1)(d)(i).
- Modified Section 3(2)(d) to clarify that an applicant applying under Section 3(2)(b)(iii) shall locate the fixed MRI unit at the same site as the existing host site.
- Eliminated the draft contract requirement within expansion and replacement for mobile services.
- Modified the expansion criteria for mobile services to utilize only historical utilization (adjusted procedures), not physician commitments (available adjusted procedures).
- Eliminated the exception for relocating outside of the relocation zone, but within the planning area, as this exception is obsolete and not utilized.
- Modified the project delivery requirements.
- Other technical edits including those based on administrative practice.

The revisions to the CON Review Standards for NICU Services/Beds include the following and have been implemented:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Under subsections 9(1) and (3), modified the language consistent with recent changes in other CON review standards.
- Other technical changes.

The revisions to the CON Review Standards for Pancreas Transplantation Services include the following and have been implemented:

- Streamlined Section 1.
- Definitions for "initiate or implement" and "licensed site" clarified based on current Department practice.

- "Implementation plan" moved to Section 3(2).
- The projected and maintenance volume for pancreas transplantation procedures is changed from 12 to 2. These changes occur in sections 3(3) and 4(1)(i). This conforms to the OPTN requirement of 1 every 6 months.
- Tied to item 4, a maintenance requirement of 80 kidney transplants and/or pancreas transplantation procedures to be performed biennially (every two years). This change can be found in Section 4(1)(c)(ii).
- Other technical changes.

The revisions to the CON Review Standards for Psychiatric Beds and Services include the following and have been implemented:

- Section 1 streamlined.
- Based on current administrative practice, the high occupancy language of Section 7(3) was revised to clarify that the planning area must be at a bed need of zero or over-bedded to use the provision.
- Based on current administrative practice, modified the language in Section 10(4).
- Added criteria under Section 11(2) that requires outstanding debt obligations owed to the state of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP) have been paid in full.
- Added quality criteria under Section 11(3) that requires the health facility for the proposed project has not been cited for a state or federal code deficiency within the 12 months prior to the submission of the application including requirements if there have been code deficiencies.
- Updated the bed need numbers with a base year of 2008 and the planning year of 2015, the ratio per 10,000 adult population, and the use rate per 1000 population age 0-17 (Appendices A – D). The effective date for the bed need methodology numbers is the same as the effective date of the Standards.)
- Other technical changes.

Tania Rodriguez - Fwd: New Medical Technology Committee Report

From: Brenda Rogers
To: Tania Rodriguez
Date: 12/14/2010 2:34 PM
Subject: Fwd: New Medical Technology Committee Report
CC: Irma Lopez

Marc's email/report needs to be copied for the binders - see below.

Thanks,

Brenda

>>> "Keshishian, Marc D., MD" <MKeshishian@bcbsm.com> 12/14/2010 2:28 PM >>>
A review of the FDA premarket for June, July and August 2010 and the 501k approvals for June, July, August and September 2010 was done. It was the opinion of the reviewers that the newly approved equipment did not warrant further evaluation to be added to the CON standards. Therefore the new medical technology subcommittee meeting was cancelled.

Marc D. Keshishian, MD
Chairperson
New Medical Technology Advisory Committee

CERTIFICATE OF NEED

4th Quarter Compliance Report to the CON Commission

October 1, 2009 through September 30, 2010 (FY 2010)

This report is to update the Commission on Department activities to monitor compliance of all Certificates of Need recipients as required by Section 22247 of the Public Health Code.

MCL 333.22247

(1) The department shall monitor compliance with all certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department shall do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(g) Take any other action as determined appropriate by the department.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	2nd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	53	326
Approved projects contacted on or before anniversary date	53	326
Approved projects completed on or before 1-year follow up	39/74%	259/79%
CON approvals expired due to noncompliance with Part 222	101	217
Total follow up correspondence sent	297	1,157
Total approved projects still ongoing	302	

Compliance: The Evaluation Section has initiated four (4) non-compliance investigations related to open heart surgical, surgical, and CT scanner services. One (1) of the four investigations has been resolved with a compliance agreement and monetary penalty. The other three investigations are ongoing.

CERTIFICATE OF NEED

4th Quarter Program Activity Report to the CON Commission

October 1, 2009 through September 30, 2010 (FY 2010)

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

Measures

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

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	130	N/A	435	N/A
Letters of Intent Processed within 15 days	130	100%	435	100%
Letters of Intent Processed Online	128	98%	425	98%

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

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	84	N/A	302	N/A
Applications Processed within 15 Days	84	100%	302	100%
Applications Incomplete/More Information Needed	30	36%	176	58%
Applications Filed Online*	84	100%	249	83%
Application Fees Received Online*	3	4%	35	12%

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

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

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	28	100%	122	99%
Substantive Applications	28	100%	103	100%
Comparative Applications	0	N/A	17	100%

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

Measures – continued

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

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	1	N/A	4	N/A
Decisions Issued within 10 workings Days	1	100%	4	100%

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

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	21	100%	85	98%

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

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

Other Measures

Activity	Most Recent Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	44	N/A	127	N/A
FOIA Requests Processed on Time	44	100%	127	100%
Number of Applications Viewed Onsite	5	N/A	11	N/A

FOIA – Freedom of Information Act.

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

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED PROGRAM

ANNUAL ACTIVITY REPORT

October 2009 through September 2010
(FY2010)

Michigan Department of Community Health

Jennifer Granholm, Governor
Janet Olszewski, Director

http://www.michigan.gov/con

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EXECUTIVE SUMMARY

One of the Michigan Department of Community Health's ("MDCH" or "Department") duties under Part 222 of the Public Health Code, MCL 333.22221(b), is to report to the Certificate of Need ("CON") Commission annually on the Department's performance under this Part. This is the Department's 22nd report to the Commission and covers the period beginning October 1, 2009 through September 30, 2010 ("FY 2010"). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Administration

The Department through its Health Policy Section provides support for the CON Commission ("Commission") and its standards advisory committees ("SAC"). The Commission is responsible for setting review standards and designating the list of covered services. The Commission may utilize a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

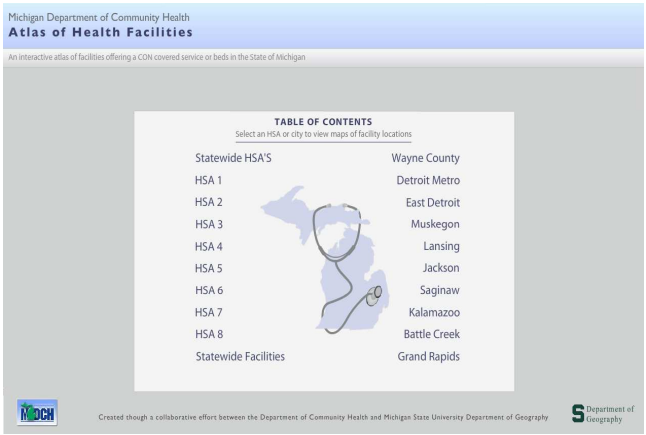
The Department through its Evaluation Section manages and reviews all incoming letters of intent, applications and amendments. These functions include determining if a CON is required for a proposed project as well as providing the necessary application materials when applicable. In addition, the Section is responsible for monitoring implementation of approved projects as well as the long term compliance with the terms and conditions of approvals.

During FY 2010, the Evaluation Section continued its work to move the program into the digital age. Staff continued to improve the online application and management information system (CON e-Serve). The first module was released in 2006. Today, the vast majority of Letters of Intent, CON applications, and amendments are filed online. The Michigan CON program is still the only program nationally to have an online application system.

In April 2008, the Section released its first Michigan Atlas of Licensed Health Facilities in collaboration with the Michigan State University Department of Geography. This fiscal year the Atlas was transformed to a dynamic web-based mapping system that allows users to select various types of facilities as well as select individual facilities to see the types of covered services offered and the facilities most recent utilization data from the annual CON survey of approved facilities.

The utilization data comes from a new online survey system developed in collaboration with the Southeastern Michigan Health Association. This online system has greatly reduced the amount of department staff time necessary to collect annual utilization data from approved facilities while assuring timely data to the Commission for policy and standards development.

These three initiative have greatly increased the availability of CON related information and data to improve and streamline the review process, better inform policy makers, and enhance community knowledge about Michigan's health care system.



http://health.geo.msu.edu/atlas.html

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a certificate of need, unless elsewhere specified in Part 222, for any of the following activities:

a) Acquire an existing health facility or begin operation of a health facility.
b) Make a change in the bed capacity of a health facility.
c) Initiate, replace, or expand a covered clinical service.
d) Make a covered capital expenditure.

CON Application Process

To apply for a CON, the following steps must be completed:

- Letter of Intent filed and processed prior to submission of an application,
- CON application filed on appropriate date as defined in the CON Administrative Rules,
- Application reviewed by the Evaluation Section,
- Issuance of Proposed Decision by the Bureau of Legal and Policy Affairs,
  - Appeal if applicant disagrees with the Proposed Decision issued,
- Issuance of the Final Decision by the MDCH Director.

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish time lines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

FY 2010 in Review

In FY 2010, there were 435 Letters of Intent received resulting in 303 applications filed for CON review and approval, including four (4) emergency applications. In addition, the Department received 85 amendments to previously approved applications. In total, the Department approved 254 proposed projects resulting in approximately $795,886,286 of new capital expenditures into Michigan's healthcare system.

As required by Administrative Rules, the Department was timely in processing pending CON applications and issuing its decisions on pending applications. These measures along with the other information contained in this report aid the Commission in its duties as set forth in Part 222 of the Public Health Code.

The CON Commission also reviewed and revised seven (7) different Review Standards: Air Ambulance Services; Bone Marrow Transplantation Services; Heart, Lung, and Liver Transplantation Services; Magnetic Resonance Imaging Services; Neonatal Intensive Care Unit Services; Pancreas Transplantation Services; and Psychiatric Beds and Services.

Report

This report is filed by the Department in accordance with MCL 333.2221(f). The report presents information about the nature of these CON applications and decisions as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data presented represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

1972 Legislation was introduced in the Michigan legislature to enact the Certificate of Need (CON) program. The Michigan CON program became effective on April 1, 1973.

1974 Congress passed the National Health Planning and Resources Development Act (PL 93-641) including funding incentives that encouraged states to establish a CON program. The purpose of the act was to facilitate recommendations for a national health planning policy. It encouraged state planning for health services, manpower, and facilities. And, it authorized financial assistance for the development of resources to implement that policy. Congress repealed PL 93-641 and certificate of need in 1986. At that time, federal funding of the program ceased and states became totally responsible for the cost of maintaining CON.

1988 The goal of the program is to balance cost, quality, and access issues and ensure that only needed services are developed in Michigan. However, the program's ability to meet these goals was significantly diluted by the fact that most application denials were overturned in the courts. In order to address this, Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development process and reduce the number of services requiring a CON.

Prior to the 1988 CON Reform Act, the Department found that the program was not serving the needs of the state optimally. It became clear that many found the process to be excessively unclear and unpredictable. To strengthen CON, the 1988 Act established a specific process for developing and approving standards used in making CON decisions. The review standards establish how the need for a proposed project must be demonstrated. Applicants know before filing an application what specific requirements must be met.

The Act also created the CON Commission. The CON Commission, whose membership is appointed by the Governor, is responsible for approving CON review standards. The Commission also has the authority to revise the list of covered clinical services subject to CON review. However, the CON sections inside the Department are responsible for day-to-day operations of the program, including supporting the Commission and making decisions on CON applications consistent with the review standards.

1993 Amendments to the 1988 Act required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards.

2002 Amendments to the 1988 Act expanded the CON Commission to 11 members, eliminated the previous ad hoc committees, and established the use of standard advisory committees or other private consultants/organizations for professional and technical assistance.

Present The CON program is now more predictable so that applicants reasonably can assess, before filing an application, whether a project will be approved. As a result, there are far fewer appeals of Department decisions. Moreover, the 1988 amendments appear to have reduced the number of unnecessary applications, i.e., those involving projects for which a need cannot be demonstrated.

The standards development process now provides a public forum for consideration of cost, quality, and access and involves organizations representing purchasers, payers, providers, consumers, and experts in the subject matter. The process has resulted in CON review standards that are legally enforceable, while assuring that standards can be revised promptly in response to the changing health-care environment.

ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM

Commission The Commission is an 11-member body. The Commission, appointed by the Governor and confirmed by the Senate, is responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. Appendix I is a list of the CON commissioners for FY2010.

NEWTAC The New Technology Advisory Committee is a standing committee responsible for advising the Commission on the new technologies, including medical equipment and services that have not yet been approved by the federal Food and Drug Administration for commercial use.

SAC Standards Advisory Committees ("SAC") may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to, the standards. The committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of health-care providers, professionals, purchasers, consumers, and payers.

MDCH The Michigan Department of Community Health is responsible for administering the CON program and providing staffing support for the Commission. This includes promulgating applicable rules, processing and rendering decisions on applications, and monitoring and enforcing the terms and conditions of approval. These functions are within the Bureau of Legal and Policy Affairs.

Policy Section The Policy Section within the Bureau provides professional and support staff assistance to the Commission and its committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and committee meetings.

Evaluation Section The Evaluation Section also within the Bureau has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The section is responsible for reviewing all Letters of Intent and applications as prescribed by the Administrative Rules. Staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms for completion by the applicant and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON Review Standards, and preparation of a Program and Finance report documenting the analysis and findings. These findings are used by the Director to make a final decision to approve or deny a project.

In addition to the application reviews, the Section reviews requests for amendments to approved CONs as allowed by the Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The Section is also responsible for monitoring the implementation of approved projects as well as the long-term compliance with the terms and conditions of approvals.

The Section also provides the Michigan Finance Authority ("MFA") information when healthcare entities request financing through MFA bond issues and Hospital Equipment Loan Program ("HELP") loans. This involves advising on whether a CON is required for the item(s) that will be bond financed.

CERTIFICATE OF NEED PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a Certificate of Need.

Letter of Intent — An applicant must file an LOI with the Department and, if applicable, the regional CON review agency. The CON Evaluation Section identifies for an applicant all the necessary application forms required based on the information contained in the LOI.

Application — An applicant files on or before the designated application date an application with the Department and, if applicable, the regional review agency. The Evaluation Section reviews an application to determine if it is complete. If not complete, additional information is requested. The review cycle starts after an application is deemed complete or received in accordance with the Administrative Rules.

Review Types and Time Frames — There are three review types: nonsubstantive, substantive individual and comparative. Nonsubstantive reviews that involve projects such as replacement of covered equipment or changes in ownership that do not require a full review. Substantive individual reviews involve projects that require a full review but are not subject to comparative review as specified in the applicable CON Review Standards. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON Review Standard, such as hospital and nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.

Review Process — The Evaluation Section reviews the application. Each application is reviewed separately unless part of a comparative review. Each application review includes a program and finance report documenting the Department's analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the CON law and the applicable CON Review Standards.

Proposed Decision — The Bureau of Legal and Policy Affairs in which the Evaluation Section resides issues a proposed decision to the applicant within the required time frame. This decision is binding unless reversed by the Department Director or appealed by the applicant. The applicant must file an appeal within 15 days of receipt of the proposed decision if the applicant disagrees with the proposed decision or its terms and conditions. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.

Final Decision — If the proposed decision is not appealed, a final decision is made by the Director of the Department of Community Health in accordance with MCL 333.22231. If a hearing on the proposed decision is requested, the final decision by the Director is not issued until completion of the hearing and any filing of exceptions to the proposed decision by the Administrative Tribunal. A final decision by the Director may be appealed to the applicable circuit court.

LETTERS OF INTENT

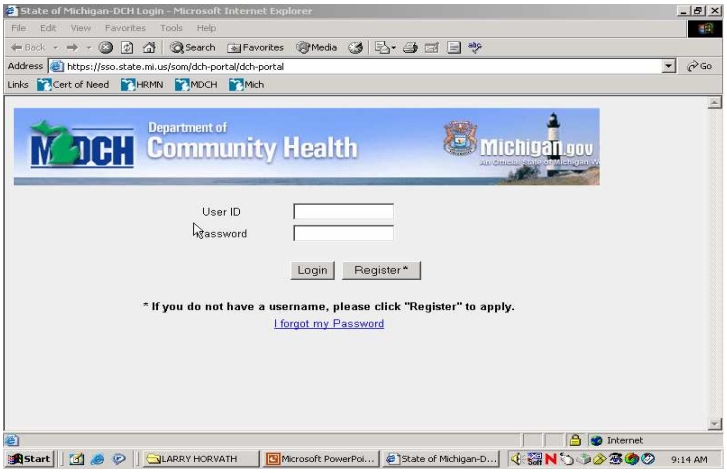
The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent ("LOIs") must be processed within 15 days of receipt. Processing an LOI includes entering data in the program's management information system, verifying proof of documentation to do business in Michigan and ownership, determining the type of review for the proposed project, and notifying the applicant of applicable application forms to be completed.

Table 1 provides an overview of the number of Letters of Intent received and processed in accordance with the above-referenced Rule.

TABLE 1
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2006 - FY2010

	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days
FY2006	562	548	98%
FY2007	582	579	99%
FY2008	521	517	99%
FY2009	335	333	99%
FY2010	435	435	100%

In FY 2010, all LOIs were processed in a timely manner as required by Rule and available for public viewing on the online application system. The online system allows for quicker receipt and processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.



In 2006, Michigan became the first state to have an online application and information system. Today 100% of all Letters of Intent and more than 95% of all applications are submitted on-line.

TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive, and comparative. The Rules specify the time frames by which the Bureau must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes potentially eligible for type of projects for nonsubstantive review:

- Acquire an existing health facility;
- Replace a health facility within the replacement zone and below the covered capital expenditure;

- Add a host site to an existing mobile network/route that does not require data commitments;
- Replace or upgrade a covered clinical equipment; or
- Acquire or relocate an existing freestanding covered clinical service.

The Rules allow the Bureau up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

Substantive individual review projects require a full review but are not subject to comparative review and not eligible for nonsubstantive review. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as computed tomography (CT) scanner services. The Bureau must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the Bureau no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a window date exceed the current need. A comparative window date is one of the three dates during the year on which projects subject to comparative review must be filed. Those dates are the first working day of February, June, and October.

Section 22229 established the covered services and beds that were subject to comparative review. Pursuant to Part 222, the CON Commission may change the list subject to comparative review.

Figure 1 delineates services/beds subject to comparative review.

*FIGURE 1: Services/Beds Subject to Comparative Review in FY2010**	
Neonatal Intensive Care	Nursing Home Beds for Special Population Groups
Hospital Beds	Psychiatric Beds
Hospital Beds (HIV)	Transplantations (excluding Pancreas)
Nursing Home Beds	

Note: See individual CON Review Standards for more information.

Table 2 shows the number of applications received by the Department by review type.

TABLE 2
APPLICATIONS RECEIVED BY REVIEW TYPE
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Nonsubstantive	162	170	183	115	144
Substantive Individual	212	135	165	78	131
Comparative	9	15	37	26	22
TOTALS	383	320	385	219	297

Note: Does not include emergency CON or swing bed applications.

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Evaluation Section to determine if additional information is needed within 15 days of receipt of an application. Processing of applications includes: updating the management information system, verifying submission of required forms, and determining if other information is needed in response to applicable Statutes and Standards.

TABLE 3
APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Applications Received*	383	320	388	220	303
Processed within 15 Days	383	320	387	219	303
Percent Processed within 15 Days	100%	100%	100%	100%	100%

Note: Includes emergency CON and swing bed applications.

Table 4 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 4
AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE
FY2006- FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Nonsubstantive	35	37	40	38	37
Substantive Individual	109	126	116	113	113
Comparative	108	132	151	260*	153

Note: Average review cycle accounts for extensions requested by applicants.

- In FY 2009, the average days for comparative review applications increased substantially due to multiple revisions to the nursing homes review standards.

EMERGENCY CERTIFICATES OF NEED

Table 5 shows the number of emergency CONs issued. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs when applicable. Rule 9227 permits up to 10 working days to determine if an emergency application is eligible for review under Section 22235. Although it is not required by Statute, the Bureau attempts to issue emergency CON decision to the Director for final review and approval within 10 days from receipt of request.

TABLE 5
EMERGENCY CON DECISIONS ISSUED
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Emergency CONs Issued	3	5	3	1	4
Percent Issued within 10 Working Days	100%	100%	67%	100%	100%

PROPOSED DECISIONS

Part 222 establishes a 2-step decision making process for CON applications that includes both a proposed decision and final decision. After an application is deemed complete and reviewed by the Evaluation Section, a proposed decision is issued by the Bureau to the applicant and the Department Director according to the time frames established in the Rules.

Table 6 shows the number of proposed decisions by type issued within the applicable time frames set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

TABLE 6
PROPOSED DECISIONS ISSUED
FY2006- FY2010

	Nonsubstantive		Substantive		Comparative	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
FY2006	162	100%	175	99%	3	100%
FY2007	152	99%	162	98%	15	100%
FY2008	176	99%	145	99%	6	50%
FY2009	130	100%	114	99%	20	90%
FY2010	123	99%	103	100%	17	100%

Table 7 compares the number of proposed decisions by decision type made.

TABLE 7
COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE
FY2006- FY2010

	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
FY2006	213	126	4	1%	343
FY2007	263	60	10	3%	333
FY2008	282	50	5	2%	337
FY2009	240	25	19	7%	284
FY2010	212	27	7	3%	246

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.

If a proposed decision is disapproved, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may also request that the Department consider new information. The Administrative Rules allow an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable statutory requirements to satisfy the requirements for approval.

FINAL DECISIONS

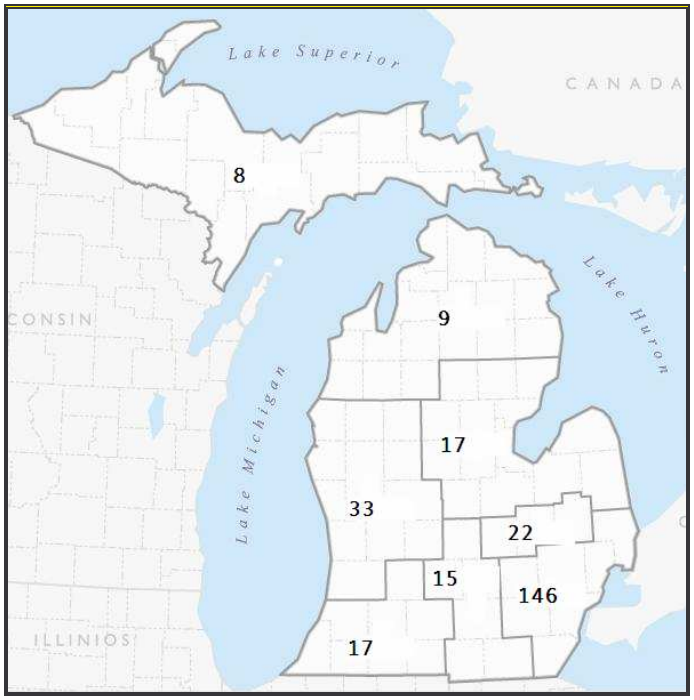
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and relate to the proposed project. In addition, the conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered. If approved with stipulations, the requirements must be germane to the proposed project and agreed to by the applicant.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that some tables will not equal other tables, as many applications fall into more than one category.

Table 8 and Figure 2 display the number of final decisions issued.

TABLE 8 FINAL DECISIONS ISSUED FY2006- FY2010	
FY2006	345
FY2007	319
FY2008	354
FY2009	271
FY2010	269

Figure 2
FY 2010 FINAL DECISIONS ISSUED BY HEALTH SERVICE AREAS



Note: Figure does not include 2 out-state decisions.

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

Acquire, Begin Operation of, or Replace a Health Facility
Under Part 222, a health facility is defined as a general hospital, hospital long-term care unit, psychiatric hospital or unit, nursing home, freestanding surgical outpatient facility (FSOF), and health maintenance organization under limited circumstances. This category includes projects to construct or replace a health facility, as well as projects involving the acquisition of an existing health facility through purchase or lease.

Change in Bed Capacity
This category includes projects to increase in the number of licensed hospital, nursing home, or psychiatric beds; change the licensed use; and relocate existing licensed beds from one geographic location to another without an increase in the total number of beds.

Covered Clinical Services
This category includes projects to initiate, replace, or expand a covered clinical service: neonatal intensive care services, open heart surgery, extrarenal organ transplantation, extracorporeal shock wave lithotripsy, megavoltage radiation therapy, positron emission tomography, surgical services, cardiac catheterization, magnetic resonance imager services, computerized tomography scanner services, and air ambulance services.

Covered Capital Expenditures

This category includes capital expenditure project in a clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. As of January 2, 2010, the covered capital expenditure threshold was $2,942,500. The threshold is updated every January.

TABLE 9
FINAL DECISIONS ACTIVITY CATEGORY
FY2006 - FY2010

Approved	FY2006	FY2007	FY2008	FY2009	FY2010
Acquire, Begin, or Replace a Health Facility	57	51	71	49	44
Change in Bed Capacity	26	29	20	37	43
Covered Clinical Services	255	237	228	190	192
Covered Capital Expenditures	33	30	30	35	39
Disapproved					
Acquire, Begin, or Replace a Health Facility	2	2	2	1	5
Change in Bed Capacity	0	1	1	2	13
Covered Clinical Services	2	1	2	0	2
Covered Capital Expenditures	0	0	1	0	9

Note: Totals above may not match Final Decision totals because applications may include multiple categories.

Table 10 provides a comparison of the total number of final decisions and total project costs by decision type.

TABLE 10
COMPARISON OF FINAL DECISIONS BY DECISION TYPE
FY2006 - FY2010

	Approved	Approved With Conditions	Disapproved	TOTALS
		Number of Final Decisions		
FY2006	234	106	3	345
FY2007	257	58	4	319
FY2008	291	59	4	354
FY2009	240	27	3	271
FY2010	225	29	15	269
		Total Project Costs		
FY2006	$1,559,834,963	$837,565,409	$22,706,628	$2,397,465,372
FY2007	$1,577,574,167	$325,128,269	$ 1,765,604	$1,904,468,040
FY2008	$2,794,327,552	$719,560,182	$26,055,809	$3,539,943,543
FY2009	$ 791,637,143	$317,924,357	$ 931,675	$1,110,493,175
FY2010	$ 712,964,774	$ 82,921,512	$36,912,278	$ 832,798,564

Note: Final decisions include emergency CON applications.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

Table 11 provides a comparison for various stages of the CON process.

TABLE 11
CON ACTIVITY COMPARISON
FY2006 - FY2010

	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
Letters of Intent Submitted				
FY2006	562	N/A	$3,156,853,978	N/A
FY2007	582	4%	$3,316,323,030	5%
FY2008	521	(10%)	$3,032,871,348	(9%)
FY2009	335	(36%)	$851,958,151	(72%)
FY2010	435	30%	$1,675,525,170	97%
Applications Submitted				
FY2006	383	N/A	$2,696,930,804	N/A
FY2007	320	(16%)	$3,097,185,206	15%
FY2008	388	21%	$2,577,833,078	(17%)
FY2009	219	(44%)	$604,642,399	(77%)
FY2010	303	38%	$1,503,768,132	149%
Final Decisions Issued				
FY2006	345	N/A	$2,397,456,372	N/A
FY2007	319	(8%)	$1,904,468,040	(21%)
FY2008	354	11%	$3,539,943,543	86%
FY2009	271	(23%)	$1,110,493,175	(69%)
FY2010	269	(1%)	$ 832,798,564	(25%)

Note: Final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments include:

- **Cost overruns.** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first $1 million and 10 percent of all costs over $1 million. Fluctuations in construction costs can cause projects to exceed approved amounts.

- **Changes in the scope of a project.** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project.

- **Changes in financing.** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

Rule 9413 permits that the review period for a request to amend a CON-approved project be no longer than the original review period.

TABLE 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision.

TABLE 12
AMENDMENTS RECEIVED AND DECISIONS ISSUED
FY2006 - FY2010

	FY2006	FY2007	FY2008	FY2009	FY2010
Amendments Received	77	61	68	90	85
Amendment Decisions Issued	97	61	71	91	87
Percent Issued within Required Time Frame	87%	98%	71%	93%	98%

NEW CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2010. One hundred and twenty-seven (127) of the 254 approvals in FY 2010 were for new or additional capacity. The remaining approvals were for replacement equipment, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2010

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
Air Ambulances	10	13	1	1
Cardiac Catheterization Services	64	191	1	9
Open Heart Surgical Services	34	N/A	0	N/A
Surgical Services	246	1,343	3	17
CT Scanners Services	290	381	19	24
MRI Services	251	208	9	11
PET Services	70	26	6	0
Lithotripsy Services	71	11	5	0
MRT Services	65	117	0	7
Transplant Services	5	N/A	2	N/A
Hospitals	174	26,238	0	33
NICU Services	22	621	0	0
Short-term Nursing (Swing Beds)	31	294	2	15
Nursing Homes/HLTCU	439	47,293	23	1,167
Psychiatric Hospitals/Units	62	2,242	0	3

Note: Table 13 does not account for facilities closed, services or equipment no longer operational, or beds delicensed and returned to the various bed pools.

COMPLIANCE ACTIONS

There were 326 projects requiring follow-up for FY 2010 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14.**

TABLE 14 FOLLOW UP AND COMPLIANCE ACTIONS FY2006 - FY2010					
	FY2006	**FY2007**	**FY2008**	**FY2009**	**FY2010**
Projects Requiring Follow-up	310	413	417	379	326
Approved CONs Expired	N/A	24	88	155	217
Compliance Orders Issued	0	2	1	4	0

Note: CONs are expired due to non-compliance with terms and conditions of approval or recipient has notified the Department that the approved-project was not implemented or the site is no longer providing the covered service/beds.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. The fees are based on total project costs and are set forth in **Figure 3**.

FIGURE 3 CON APPLICATION FEES	
Total Project Costs	**CON Application Fee**
$0 to 500,000	$1,500
$500,001 to 4,000,000	$5,500
$4,000,001 and above	$8,500

Table 15 analyzes the number of applications by fee assessed.

TABLE 15 NUMBER OF CON APPLICATIONS BY FEE FY2006 - FY2010					
CON Fee	**FY2006**	**FY2007**	**FY2008**	**FY2009**	**FY2010**
$ 0*	4	6	4	1	6
$1,500	84	75	128	103	113
$5,500	191	141	151	76	107
$8,500	104	98	109	39	77
TOTALS	383	320	392	219	303

* No fees are required for emergency CON and swing beds applications.
Note: Table 15 may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.

Table 16 provides information on CON costs and source of funds.

TABLE 16 CON PROGRAM COST AND REVENUE SOURCES FOR FY2006 – FY2010					
	FY2006	**FY2007**	**FY2008**	**FY2009**	**FY2010**
Program Cost	$1,877,100	$1,741,300	$1,960,655	$1,871,395	$1,972,254
Fees/Funding	$1,884,849	$1,688,000	$1,743,926	$1,095,048	$1,423,451
Fees % of Costs	100%	97%	89%	59%	%72

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY 2010, the CON Commission revised the review standards for Air Ambulance Services, Bone Marrow Transplantation (BMT) Services, Heart/Lung and Liver (HLL) Transplantation Services, Magnetic Resonance Imaging (MRI) Services, Neonatal Intensive Care Services/Beds (NICU), Pancreas Transplantation Services, and Psychiatric Beds and Services.

The revisions to the CON Review Standards for Air Ambulance Services received final approval by the CON Commission on June 10, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective August 12, 2010. The final language changes include the following:

- Updated the definition of “air ambulance service.”
- Redefined “base of operations.”
- Added a definition for “existing air ambulance.”
- Expanded the definition of patient transport to include advance life support intercepts.
- Added a new definition for organ transport and allowance for an organ transport to count for volume purposes for an air ambulance with two (2) air ambulances or at the time of application for expansion to a second unit.
- Modified the expansion language to utilize only historical volume.
- Modified the replacement language for an air ambulance to mirror the expansion language within the standards.
- Updated the methodology for projecting patient transports.
- Updated the project delivery requirements.
- Other technical changes.

The revisions to the CON Review Standards for BMT Services received final approval by the CON Commission on March 25, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective May 28, 2010. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Definition for "licensed site" clarified based on current Department practice.
- Under Section 2(1)(t), redefined planning area to add a second adult planning area.
- Under Section 2(1)(w), added a definition for Tumor Registry as referenced in Section 8.
- "Implementation plan" moved to Section 3(4).
- Under Section 3(5), identified a cap of three in planning area one and a cap of one in planning area two.
- Under Section 3(6), the volume projection for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
- Under Section 3(10), added language to clarify that the written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (fact) accredited transplant unit that performs both allogeneic and autologous transplants for either adult and/or pediatrics.
- Under Section 3(10)(a)(iv)(A) and (B), reduced the number of site visits to three.
- Under sections 3(10)(b)(i), 7(1)(c)(i)(D) and (E), 7(1)(c)(iv)(A) and (B), 7(1)(c)(vi)(D), 7(1)(d)(v), modified language based on the recommendation that autologous only programs would no longer be allowed.
- Acquisition language (previous Section 8) moved to Section 4. For administrative feasibility,

changed “the CON granted pursuant to this Section shall automatically expire” to “the Department may expire the CON granted pursuant to this Section.”
- Under Section 5(3)(a), modified to award points based on the straight-line distance to the nearest existing bmt program of the type applied for (adult or pediatric) instead of being based on the number of BMT services within the health service area (HSA).
- Clarified Section 5(3)(b)(ii) based on administrative practice.
- Under Section 5(3)(d), added language to award points based on the number of necessary support services/personnel as identified in Section 6 (project delivery requirements) that the applicant has available on-site on the date the application is submitted to the Department.
- Based on current administrative practice, modified the language in Section 5(4) consistent with recent changes in other CON review standards.
- Split Section 7(1)(c)(iv)(C) into two subsections: 7(1)(c)(iv)(C) and (D).
- Under Section 7(1)(d)(i)(A) and (B), the volume maintenance for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
- Under Section 8, added language to identify the source of data for documentation of projections.
- Other technical changes.

The revisions to the CON Review Standards for HLL Transplantation Services received final approval by the CON Commission on March 25, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective May 28, 2010. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- "Implementation plan" moved to Section 3(2).
- Definition for "licensed site" clarified based on current Department practice.
- Removed definition for “transplant and health policy center” as it is no longer referenced in the standards.
- Removed definition for “transplant support program” as it is not referenced in the standards.
- Under Section 3(5), added liver transplantation services to the joint sharing arrangement language.
- Under Section 5(1) and (2), added language relevant to the joint sharing arrangement and consistent with Section 4(1) and (2).
- Based on current administrative practice, modified the language in Section 6(4) consistent with recent changes in other CON review standards.
- Added language under Section 7(1)(c)(ii) to clarify the requirements to comply with the Organ Procurement and Transplantation Network (OPTN). Removed sections 8, 9, and 10 as they are no longer needed given the clarification to Section 7(1)(c)(ii).
- Updated the language under Section 7(1)(c)(ix) as required by the federal OPTN.
- Other technical changes.

The revisions to the CON Review Standards for MRI Services received final approval by the CON Commission on September 10, 2009 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective November 5, 2009. The final language changes include the following:

- Streamlined Section 1.
- Technical edits in Section 2.
- Added an exclusion in Section 2 (1)(dd) for MRI Simulators. The MRI simulator language is consistent with the requirements in the CON Review Standards for Computed Tomography (CT) Scanner Services. The use of an MRI simulator would not need an approval for an MRI CON if used only for Megavoltage Radiation Therapy (MRT) treatment planning purposes. In the event that the facility wants to use the MRI for billable diagnostic procedures, then the facility would need an approved MRI CON.
- Streamlined and reorganized Sections 3 - 7.
- Added an exception to the criteria for conversion of a mobile to a fixed MRI in Section 3(2)(b)(iii) to allow for a hospital with 3,000 MRI adjusted procedures, 24-hour emergency care services, and at least 20,000 emergency room visits within a 12-month period to convert from a mobile to a fixed. Further, a maintenance volume of 3,000 actual MRI adjusted procedures per unit was added to the project delivery requirements, Section 12(1)(d)(i).
- Modified Section 3(2)(d) to clarify that an applicant applying under Section 3(2)(b)(iii) shall locate the fixed MRI unit at the same site as the existing host site.
- Eliminated the draft contract requirement within expansion and replacement for mobile services.
- Modified the expansion criteria for mobile services to utilize only historical utilization (adjusted procedures), not physician commitments (available adjusted procedures).
- Eliminated the exception for relocating outside of the relocation zone, but within the planning area, as this exception is obsolete and not utilized.
- Modified the project delivery requirements.
- Other technical edits including those based on administrative practice.

The revisions to the CON Review Standards for NICU received final approval by the CON Commission on June 10, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective August 12, 2010. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Under subsections 9(1) and (3), modified the language consistent with recent changes in other CON review standards.
- Other technical changes.

The revisions to the CON Review Standards for Pancreas Transplantation Services received final approval by the CON Commission on September 10, 2009 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective November 5, 2009. The final language changes include the following:

- Streamlined Section 1.
- Definitions for "initiate or implement" and "licensed site" clarified based on current Department practice.
- "Implementation plan" moved to Section 3(2).
- The projected and maintenance volume for pancreas transplantation procedures is changed from 12 to 2. These changes occur in sections 3(3) and 4(1)(i). This conforms to the OPTN requirement of 1 every 6 months.

- Tied to item 4, a maintenance requirement of 80 kidney transplants and/or pancreas transplantation procedures to be performed biennially (every two years). This change can be found in Section 4(1)(c)(ii).
- Other technical changes.

The revisions to the CON Review Standards for Psychiatric Beds and Services received final approval by the CON Commission on September 10, 2009 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective November 5, 2009. The final language changes include the following:

- Section 1 streamlined.
- Based on current administrative practice, the high occupancy language of Section 7(3) was revised to clarify that the planning area must be at a bed need of zero or over-bedded to use the provision.
- Based on current administrative practice, modified the language in Section 10(4).
- Added criteria under Section 11(2) that requires outstanding debt obligations owed to the state of Michigan for Quality Assurance Assessment Program (QAAP) or Civil Monetary Penalties (CMP) have been paid in full.
- Added quality criteria under Section 11(3) that requires the health facility for the proposed project has not been cited for a state or federal code deficiency within the 12 months prior to the submission of the application including requirements if there have been code deficiencies.
- Updated the bed need numbers with a base year of 2008 and the planning year of 2015, the ratio per 10,000 adult population, and the use rate per 1000 population age 0-17 (Appendices A – D). The effective date for the bed need methodology numbers is the same as the effective date of the Standards.)
- Other technical changes.

Edward B. Goldman, JD, CON Commission Chairperson
James B. Falahee, Jr., JD, CON Commission Vice-Chairperson (Eff. 3/26/10)
Thomas M. Smith, CON Commission Vice-Chairperson (9/10/09 – 3/25/10; appointment expired 4/9/10, replaced by Brian A. Klott)
Peter Ajluni, DO
Bradley N. Cory
Dorothy E. Deremo (Appointment expired 1/1/10 and replaced by Gay Landstrom)
Charles M. Gayney (Eff. 9/3/10, replaced Adam Miller)
Robert L. Hughes (Eff. 9/3/10, replaced Vicky Schroeder)
Marc D. Keshishian, MD
Brian A. Klott (Eff. 4/10/10, replaced Thomas M. Smith)
Gay L. Landstrom (Eff. 3/5/10, replaced Dorothy E. Deremo)
Adam A. Miller (Resigned and replaced by Charles M. Gayney)
Michael A. Sandler, MD
Vicky Schroeder (Resigned and replaced by Robert L. Hughes)
Michael W. Young, DO

For a list and contact information of the current CON Commissioners, please visit our web site at www.michigan.gov/con.

CERTIFICATE OF NEED LEGAL ACTION

(12/06/10)

Woodcare X (Caretel) v MDCH Genesee County Cir Docket No.: 08-89784 CZ	10/08/08	Complaint for Mandamus seeking Medicare only certification.	Parties stipulated to a dismissal order to allow for consolidation with appeal in the related Court of Claims case.
Woodcare X (Caretel) v MDCH Court of Claims Docket No.: 08-132-MK	12/03/08	Complaint seeking damages and specific performance of a settlement agreement reached 20 years ago.	Court denied DCH's motion based on governmental immunity. Appeal filed 10/27/09, and case stayed.
Woodcare X (Caretel) v MDCH Court of Appeals No: 294480 and 294824 (consolidated)	10/27/09	Appeal of Mandamus and Court of Claims.	Briefs filed. The Court of Appeals scheduled oral argument for January 4, 2011.

CON Leg Action; report 12/06/10

DIST a 12-1-10

Attachment N

Blue Cross
Blue Shield
Of Michigan

600 E. Lafayette Blvd.
Detroit, Michigan 48226-2998

Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Commission Meeting
December 15, 2010

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

BCBSM and BCN also support CON processes and continue to be an open-minded, active participant in all aspects of the CON program. We applaud the CON Commission, MDCH staff, and all committee and work group members for their efforts during these objective review endeavors. In addition, we value the process transparency which elicits in-depth clinical and provider expertise as well as consumer, purchaser, and payor input.

BCBSM/BCN supported evaluating CT Review Standards and commends the CON Commission for convening this SAC to do so. Again, as stated in prior testimony, based on internal operating and clinical group feedback, BCBSM/BCN had concerns regarding the proliferation of CT unit applications, locations and utilization along with safety issues. An internal review of the statewide CT access during 2006, 2007 and 2010 showed sufficient access with availability ranging from same or next day service to just a few days wait.

Per Dr. Brook's (CT SAC chair) report, thus far the general positions endorsed by the committee address BCBSM/BCN's concerns, although these recommendations will not be final until its last meeting next month. We are also satisfied with this group's assessment and proposed standard incorporation of patient safety issues such as radiation exposure and specialty scanner pilots, in conjunction with utilization and access driven issues.

The CON program is intended to ensure that Michigan residents have access to quality health care services. Thus, on behalf of our stakeholders and members, BCBSM and BCN continue to support the CON program and ongoing regulation of high tech high cost health care services. As always, BCBSM/BCN commends the CON Commission and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program to help ensure the delivery of high quality, safe and effective care to patients across the state.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

Attachment O

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2010												2011											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Bone Marrow Transplantation (BMT) Services	•	P•	•▲F			•—	•	P•	•▲ F			R												
Cardiac Catheterization Services**			•	•	•	•	•	•	•	PH	▮	▮	▮	▮	▮	▮	▮	•R—	•	•P	•▲F			
Computed Tomography (CT) Scanner Services**	• R	•	•	•			▮	▮	▮	▮	▮	▮	▮	•	•—	•	•P	•▲F						
Hospital Beds and Addendum for HIV Infected Individuals										PH•	•	•	•R											
Magnetic Resonance Imaging (MRI) Services									• R—	P•	•	•▲F												
Megavoltage Radiation Therapy (MRT) Services/Units										PH	•	•	•R											
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	•R	•	•	•	•	R•	•	•	• R—	P•	•	•▲F												
Open Heart Surgery Services										PH	•	•	•R											
Positron Emission Tomography (PET) Scanner Services										PH	•	•	•R											
Surgical Services										PH	•	•	•R											
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																								
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

KEY

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

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

For Approval December 15, 2010

Updated December 8, 2010

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy & Regulation Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	August 12, 2010	2013
Bone Marrow Transplantation Services	December 3, 2010	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2011
Magnetic Resonance Imaging (MRI) Services	November 5, 2009	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	2011
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2013
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 20, 2008	2013
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	November 5, 2009	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2013

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

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