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

Tuesday, September 23, 2010

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

APPROVED MINUTES

I. Call to Order

Chairperson Goldman called the meeting to order at 9:38 a.m. He thanked Adam Miller and Vicky Schroeder for their time served on the Commission and introduced Charles Gayney and Robert Hughes.

A. Members Present:

Peter Ajluni, DO
Bradley Cory
James B. Falahee, Jr., JD, Vice-Chairperson
Charles M. Gayney
Edward B. Goldman, Chairperson
Robert L. Hughes (via conference call, left at 11:15 am)
Brian Klott
Gay L. Landstrom (Arrived at 9:44 am)
Michael A. Sandler, MD
Michael W. Young, DO

B. Members Absent:

Marc Keshishian, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
William Hart
Larry Horvath
Natalie Kellogg
Irma Lopez
Nick Lyon
Stanley Nash
Tania Rodriquez
Brenda Rogers

II. Agenda

Motion by Vice-Chairperson Falahee, seconded by Commissioner Sandler, to amend and approve the agenda with the addition of the State Senator Cameron Brown and State Representative Kenneth Kurtz. Motion Carried.

III. State Senator and State Representative

State Senator Cameron Brown, State Representative Kenneth Kurtz, and former Senator Bruce Caswell each gave their appreciation to the Commission.

IV. Declaration of Conflicts of Interests

None.

V. Review of Minutes – June 10, 2010

Motion by Vice-Chairperson Falahee, seconded by Commissioner Ajluni, to approve the minutes of June 10, 2010 as presented. Motion carried.

VI. Bone Marrow Transplantation (BMT) Services – PPS Exemption – Public Hearing Comments

Ms. Rogers gave an overview of the Public Hearing summary. (Attachment A)

A. Public Comment:

Larry Horwitz, Economic Alliance of Michigan
Carol Christner, Karmanos Cancer Institute

B. Commission Discussion:

Discussion followed.

C. Commission Proposed Action:

Motion by Commission Sandler, seconded by Commission Cory to accept the language (Attachment B) as provided and move forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Yes – 8, No – 1, Abstained – 0. Motion Carried.

VII. Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups (NH-HLTCU)

Ms. Rogers gave an overview of the proposed language for the NH-HLTCU standards. (Attachment C)

A. Public Comment:

Andy Ball, HCR Manor Care (Attachment D)
John Weir, Long Term Care Ombudsman (Attachment E)
Pat Anderson, Health Care Association of Michigan, (Attachment F)
Larry Horwitz, Economic Alliance of Michigan
Dawn Jacobs, Michigan Office of Services to the Aging (Attachment G)

C. Commission Discussion:

Discussion followed.

D. Commission Proposed Action:

Motion by Commissioner Cory, seconded by Commissioner Klott, to accept the language (Attachment C) as provided and have the Department carefully consider all testimony presented and adopt those that they think are appropriate and move forward for Public Hearing and to the JLC. Yes – 9, No – 0, Abstained – 0. Motion Carried.

VIII. Magnetic Resonance Imaging (MRI) Services - Replacement

Ms. Rogers gave an overview of the proposed language for the MRI standards. (Attachment H)

A. Public Comment:

None.

B. Commission Discussion:

None.

D. Commission Final Action:

Motion by Commissioner Sandler, seconded by Commissioner Young, to accept the proposed language (Attachment H) and move forward for Public Hearing and to the JLC. Yes – 9, No – 0, Abstained – 0. Motion Carried.

IX. Computed Tomography Standard Advisory Committee (CTSAC) – Status Update

Chairperson Goldman gave a verbal summary of the written report that was provided by Dr. Brooks regarding the CTSAC update. (Attachment I)

X. Standing New Medical Technology Standard Advisory Committee (NEWTAC)

Chairperson Goldman gave a verbal summary of the written report that was provided by Chairperson Keshishian regarding the NEWTAC activity. (Attachment J)

XI. Legislative Report

Mr. Lyons gave a brief verbal legislative report.

XII. Administrative Update

Mr. Hart gave a brief update on the NH-HLTCU bed need calculation.

A. Health Policy Section Update:

Ms. Lopez gave a brief staffing, 2011 calendar, CTSAC, and CCSAC update.

B. CON Evaluation Section Update:

Mr. Horvath gave an update and demonstration on the following:

1. Quarterly Performance Measures (Attachment K)

2. Administrative Rules
3. 2010 CON Seminar
4. Compliance Report (Attachment L)
5. MSU/Survey Mapping Project (Demonstration)

XIII. Legal Activity Report

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

XIV. Future Meeting Dates

December 15, 2010
January 26, 2011 (Special Commission Meeting)
March 24, 2011
June 9, 2011
September 22, 2011
December 15, 2011

XV. Public Comment

Larry Horwitz, Economic Alliance of Michigan

XVI. Review of Commission Work Plan

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

Motion by Commissioner Sandler, seconded by Commissioner Klott, to approve the Work Plan as presented. Motion Carried.

XVII. Adjournment

Motion by Commissioner Sandler, seconded by Vice-Chairperson Falahee, to adjourn the meeting at 11:46 p.m. Motion Carried.

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

Date: August 31, 2010

TO: Irma Lopez

FROM: Brenda Rogers

RE: Summary of Public Hearing Comments on Bone Marrow Transplantation (BMT) Services Standards and MDCH Policy Staff Analysis

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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 BMT Standards at its June 10, 2010 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed BMT Standards on August 5, 2010. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. No testimony was received.

Staff Analysis and Recommendations

Section 4 is being modified to extend the time period to obtain a Prospective Payment System (PPS) exemption for a cancer hospital along with some technical changes.

The Department supports the CON Commission's June 10, 2010 proposed action as written.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

Sec. 1. (1) These standards are requirements for the approval and delivery of services under Part 222 of the Code. Pursuant to Part 222 of the Code, BMT 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(C) of the Code, being Section 333.22225(2)(C) of the Michigan Compiled Laws.

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

(3) An existing BMT service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing BMT service that performs only pediatric procedures shall require separate CON approval in order to perform adult procedures.

Section 2. Definitions

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

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

(b) "Adult" means an individual age 18 or older.

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

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

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

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

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

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

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

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

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

inventory adult and pediatric services separately and shall specify the site at which the BMT service is authorized.

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

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

(n) "Initiate" or "implement" means the performance of the first transplant procedure. The term of an approved CON shall be 18 months or the extended period established by Rule 325.9403(2).

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

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

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

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

(s) "Pediatric" means any patient 20 years of age or less or any patient with congenital conditions or diseases for which BMT is a treatment.

(t) "Planning area" means:

(i) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

(ii) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

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

(v) "Survival rate" means the rate calculated using the Kaplan-Meier technique and the following: (i) the date of transplantation (or, if more than one transplant is performed, the date of the first transplant) must be the starting date for calculation of the survival rate; (ii) for those dead, the date of death is used, if known. If the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival; (iii) for those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival, except for patients described in subsection (v); (iv) any patient who is not known to be dead, but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow up" for the purposes of the survival rate calculation; (v) any patient transplanted between 61 and 120 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date; and (vi) the survival analyses must use the assumption that each patient in the "lost to follow up" category died 1 day after the last date of ascertained survival. However, an applicant may submit additional

analyses that reflect each patient in the "lost to follow up" category as alive at the date of the last ascertained survival.

(w) “Tumor registry” means a manual or computerized data base containing information about all malignancies and only those that are diagnosed and/or treated at the applicant’s facility. The malignancies must be reportable to the Michigan Cancer Surveillance Program as required pursuant to Public Act 82 of 1984, as amended.

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

Section 3. Requirements to initiate a BMT service

Sec. 3. An applicant proposing to initiate a BMT service shall demonstrate the following requirements:

(1) An applicant shall specify in the application whether the proposed service will perform either or both adult and pediatric BMT procedures.

(2) An applicant shall specify the licensed site at which the BMT service will be provided.

(3) An applicant proposing to initiate either an adult or pediatric BMT service shall demonstrate that the licensed site at which the transplants will be offered provides each of the following staff, services, and programs:

(a) operating rooms.

(b) continuous availability, on-site or physically connected, either immediate or on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

(h) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics, or an equivalent organization, either on-site or through written agreement.

(i) a hematopathology lab capable of performing cell phenotype analysis using flow cytometry.

(j) a clinical chemistry lab with the capability to monitor antibiotic and antineoplastic drug levels, available either on-site or through other arrangements that assure adequate availability.

(k) other support services, as necessary, such as physical therapy and rehabilitation medicine.

(l) continuous availability of anatomic and clinical pathology and laboratory services, including clinical chemistry, and immuno-suppressive drug monitoring.

(m) continuous availability of red cells, platelets, and other blood components.

(n) an active medical staff that includes, but is not limited to, the following board-certified or board-eligible specialists. For an applicant that is proposing to perform pediatric transplant procedures, these specialists shall be board-certified or board-eligible in the pediatric discipline of each specialty.

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.

(x) oncology.

(xi) pathology, including blood banking experience.
(xii) pulmonary medicine.
(xiii) radiation oncology.
(xiv) radiology.
(xv) urology.

(o) One or more consulting physicians who are board-certified or board-eligible in each of the following specialties. For an applicant proposing to perform pediatric BMT procedures, these specialists shall have specific experience in the care of pediatric patients.

(i) dermatology.
(ii) immunology.
(iii) neurosurgery.
(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed BMT service. “Implementation plan" means a plan that documents how a proposed BMT service will be initiated within the time period specified in these standards or the CON rules. At a minimum, the implementation plan shall identify:

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

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

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

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

(b) An applicant shall demonstrate that the number of existing pediatric BMT services does not exceed two (2) pediatric BMT services in planning area one identified in Section 2(1)(t)(i) or one (1) pediatric BMT service in planning area two identified in Section 2(1)(t)(ii) and that approval of the proposed application will not result in the total number of pediatric BMT services exceeding the need for each specific planning area.

(6)(a) An applicant proposing to initiate an adult BMT service shall project that at least 30 transplants, of which at least 10 are allogeneic transplant procedures, will be performed in the third 12-months of operation.

(b) An applicant proposing to initiate a pediatric BMT service shall project that at least 10 transplants, of which 5 are allogeneic transplant procedures, will be performed in the third 12-months of operation.

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

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

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

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

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

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

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

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

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

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

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

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

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric BMT service shall submit, in its application, a written consulting agreement with an existing BMT service. 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 allogenic and autologous transplants for either adult and/or pediatrics. The terms of the agreement and the roles and responsibilities of both the existing and proposed service shall include at least the following:

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

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

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

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

(iv) Specify a schedule of site visits by staff of the existing BMT service that, at a minimum, includes:

(A) 3 visits during the first 12-months of operation of the proposed service.

(B) 3 visits during each the second 12-months and third 12-months of operation of the proposed service.

(v) Specify that the purpose of the site visits required by subdivision (iv) is to assess the proposed service and make recommendations related to quality assurance mechanisms of the proposed service, including at least each of the following:

(A) a review of the number of patients transplanted.

(B) transplant outcomes.

(C) all infections requiring treatment or life-threatening toxicity, defined for purposes of this agreement as National Cancer Institutes grade #3 or greater toxicity, excluding hematological toxicity.

(D) all deaths occurring within 100 days from transplant.

(E) each of the requirements of subdivision (iii).

(vi) Specify that a written report and minutes of each site visit shall be completed by the existing BMT service and sent to the proposed service within 2 weeks of each visit, and that copies of the reports and minutes shall be available to the Department upon request. At a minimum, the written report shall address each of the items in subdivision (v).

(vii) Specify that the existing BMT service shall notify the Department and the proposed service immediately if it determines that the proposed service may not be in compliance with any applicable quality assurance requirements, and develop jointly with the proposed service a plan for immediate remedial actions.

(viii) Specify that the existing BMT service shall notify the Department immediately if the consulting agreement required pursuant to these standards is terminated and that the notification shall include a statement describing the reasons for the termination.

(b) For purposes of subsection (10), "existing BMT service" means a service that meets all of the following:

(i) currently is performing and is FACT accredited in, the types of transplants (allogeneic and autologous; adult or pediatric) proposed to be performed by the applicant;

(ii) currently is certified as a National Marrow Donor Program; and

(iii) is located in the United States.

(c) An applicant shall document that the existing BMT service meets the requirements of subsection (b).

Section 4. Requirements for approval – acquisition of a BMT service by a cancer hospital

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

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

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

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

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

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

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

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

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

(g) If the applicant described in this subsection, OR AN APPLICANT PREVIOUSLY APPROVED UNDER THIS SUBSECTION, does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS within 24 months after receiving CON approval under this section OR SUCH LATER DATE AS THE DEPARTMENT MAY HAVE PREVIOUSLY APPROVED, the Department may extend the 24-month deadline to no later than the last session day permitted by the United States Constitution for the ~~next~~ 113TH United States Congress ~~in session after the effective date of these standards~~. Extension of the deadline UNTIL THE END OF THE 113TH CONGRESS shall require THE FILING OF A CON APPLICATION UNDER THIS SECTION THAT PROVIDES demonstration by the applicant, to the satisfaction of the Department, that ~~there has been progress toward achieving the changes in federal law and regulations that are required to secure~~THE APPLICANT IS CONTINUING TO PURSUE the PPS exemption. If the applicant fails to meet the Title XVIII requirements for PPS exemption within the 24-month period, or its possible extensionS, then the Department may expire the CON granted pursuant to this SUBsection ~~and will not be subject to further applications for acquisition~~. However, prior to the ~~final deadline for the expiration of~~DEPARTMENT EXPIRING the CON, the ~~prior~~ ORIGINAL holder of the ~~(~~CON~~/authorization)~~ to provide the BMT service may apply for acquisition of the service, pursuant to all the provisions of this section, except for subsectionS (c) AND (G).

(2) Applicants proposing to acquire an existing BMT service under this section shall not be subject to comparative review.

Section 5. Review standards for comparative reviews

Sec. 5. (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 applicable.

(2) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) being Section 333. 22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects which, 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, in the order in which the applications were received by the Department, based on the date and time stamp placed on the applications by the CON administrative unit of the Department responsible for administering the CON program when an application is submitted.

(3)(a) A qualifying project will have points awarded based on the straight-line distance to the nearest existing BMT service of the type applied for (adult or pediatric), as shown in the following schedule:

Straight-line Distance to Nearest BMT Service	Points Awarded
<75 miles	0
75 – 150 miles	1
>150 miles	2

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

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume. Determine the licensed site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed site by 4.0. The result is the indigent volume factor rounded to the nearest whole number.

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

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total hospital charges expressed as a percentage, rounded to the nearest whole number, as determined by the Michigan Department of Community Health Medical Services Administration. The indigent volume data being used in this subsection is the data in the most current DCH-MSA Disproportionate Share Hospital (DSH) Report at the time the application(s) is deemed submitted by the Department.

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

(d) A qualifying project will have points awarded based on the number of necessary support services/personnel as identified in Section 7 that the applicant has available on-site on the date the application is submitted to the Department, as follows:

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

(ii) a processing and cryopreservation laboratory that meets the standards of the fact or an equivalent organization.

(iii) anatomic and clinical pathology with competency in interpreting pathologic findings related to graft-v-host disease and other opportunistic infections in immuno-compromised hosts.

(IV) therapeutic drug monitoring.

(v) one or more attending physicians with fellowship training, and/or at least 2 years of experience, in pediatric and/or adult BMT, as appropriate.

(vi) board-certified or board-eligible consulting physicians in all of the following areas: anatomic pathology with competence in graft versus host disease and other opportunistic diseases, infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.

(vii) a transplant team coordinator, with experience in evaluating pre and post BMT patients.

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

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

(x) an active, formal multi-disciplinary research program related to BMT.

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

The applicant shall receive points, up to a maximum of three (3), for this criterion according to the following schedule:

Number of BMT Support Personnel/Services Available	Points
zero or one	0
two to five	1
six to nine	2
ten or eleven	3

(4) Submission of conflicting information in this section may result in a lower point award. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from the conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section 6. Requirements for approval -- all applicants

Sec. 6. An applicant shall provide verification of Medicaid participation. An applicant that is initiating a new service or 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 7. Project delivery requirements -- terms of approval

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

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

(b) Compliance with applicable safety and operating standards.

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

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

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

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

(C) a processing and cryopreservation laboratory that meets the standards of the FACT or an equivalent organization.

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

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

(F) therapeutic drug monitoring.

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

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

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

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

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

(B) nurses experienced in the care of BMT patients.

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

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

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

(B) one or more attending physicians with specialized training in pediatric and/or adult BMT, as appropriate. At least one attending physician shall have specialized training in allogeneic transplantation, adult or pediatric, as appropriate. An attending physician shall be board-certified or board-eligible in hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate.

(C) on-site availability of board-certified or board-eligible consulting physicians, adult and/or pediatric, as appropriate, in at least the following specialities: cardiology, gastroenterology nephrology, psychiatry, pulmonary medicine, and critical care medicine.

(D) on-site availability of board-certified or board-eligible consulting physicians in the following areas: anatomic pathology with competence in graft versus host disease (services performing allogeneic transplants) and other opportunistic diseases (services performing allogeneic and autologous transplants), infectious diseases with experience in immuno-compromised hosts, and radiation oncology with experience in total body irradiation.

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

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

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

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

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

(J) designated social services staff.

(K) designated physical therapy staff.

(L) data management personnel designated to the BMT service.

(M) for an applicant performing pediatric BMT, a child-life specialist.

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

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

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

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

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

(D) IRB approval of all clinical research protocols, or if transplantation does not require an IRB-approved clinical research protocol, written policies and procedures that include at least the following: donor, if applicable, and recipient selection, transplantation evaluations, administration of the preparative regimen, post-transplantation care, prevention and treatment of graft-versus-host disease, and follow-up care.

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

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

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

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

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

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

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

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

(d) Compliance with the following terms of approval:

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

(A) An adult BMT service shall perform at least 30 transplants, of which at least 10 are allogeneic transplants, in the third 12-months of operation and annually thereafter.

(B) A pediatric BMT service shall perform at least 10 transplants, of which at least 5 are allogeneic transplants, in the third 12-months of operation. After the third 12-months of operation, an applicant shall perform at least 30 pediatric transplants in any 36-month consecutive period, with no fewer than 5 allogeneic transplants in any 12-month period, beginning with the third 12-months of operation, and thereafter.

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

(ii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; in a format established by the Department; and in a mutually-agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. In addition, an applicant shall report at least the following data for each patient:

(A) disease type.

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

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

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

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

(A) not deny the services to any individual based on ability to pay or source of payment;
(B) provide the services to all individuals in accordance with the patient selection criteria developed by appropriate medical professionals, and approved by the Department; and
(C) maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

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

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

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

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

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

Section 8. Documentation of projections

Sec. 8. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. The applicant shall use relevant and unduplicated data for patients in the same planning area as the proposed BMT service, which are verifiable from the most recent statewide tumor registry. The applicant shall only include new cancer cases that are appropriate for referral for BMT services and from the age grouping of patients based on the type of service to be offered. This specification of projections shall include an assessment of the accuracy of projections, and of the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

Section 9. Health Service Areas

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

HSA	COUNTIES		
1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		

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

Section 10. Department Inventory of BMT Services

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

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

Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal ORGAN Transplantation Services pertaining to BMT services approved by the CON Commission on ~~September 16, 2008~~MARCH 25, 2010 and effective on ~~November 13, 2008~~MAY 28, 2010.

(2) Projects reviewed under these standards shall be subject to comparative review EXCEPT FOR SECTION 4.

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 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 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) AT THE TIME THE APPLICATION IS SUBMITTED, ~~A~~ A qualifying project will ~~have~~ BE DEDUCTED 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 ~~TWO~~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, ~~AND~~ 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) ~~DOES HAVE~~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 ~~IDENTIFIED~~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 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 ~~PRIVATE~~ADJOINING SINK, TOILET, AND SHOWER	10
~~80~~100% private rooms with ~~PRIVATE~~DEDICATED SINK AND SHARED ~~ADJACENT 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 ~~ADJACENT~~ADJOINING toilet AND SINK, and central showers with ~~adjacent private changing room~~ADJOINING SPACE for ~~the resident to~~DRYING AND dress~~ing and undress~~ in VISUAL privacy	3

~~(9) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE NURSING HOME/HLTCU OFFERS OR THREE (3) POINTS IF THE NURSING HOME/HLTCU PROPOSES AN ARRAY OF SERVICES THAT INCLUDES CHOICE IN LIVING ARRANGEMENTS (NURSING FACILITY, SUPPORTIVE LIVING ASSISTANCE, AND/OR INDEPENDENT HOUSING) AND PROMOTES AGING IN PLACE.~~

(~~10~~9) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF IT RESULTS IN A NURSING HOME/HLTCU WITH 150 OR FEWER BEDS.~~WILL BE AWARDED POINTS, FOR AN EXISTING OR PROPOSED NURSING HOME/HLTCU, AS FOLLOWS:~~

~~NUMBER OF BEDS~~	~~Points Awarded~~
~~100 BEDS OR LESS~~	~~10~~
~~101 – 150 BEDS~~	~~5~~

~~151 – 200 BEDS~~	~~3~~

(~~1~~10) A QUALIFYING PROJECT WILL BE AWARDED ~~10~~5 POINTS IF THE APPLICANT PROVIDES ITS AUDITED FINANCIAL STATEMENTS. ~~AN ADDITIONAL FIVE (5) POINTS WILL BE AWARDED IF THE AUDITED FINANCIAL STATEMENTS SHOW A POSITIVE CASH FLOW BALANCE.~~

(1~~2~~1) A QUALIFYING PROJECT WILL BE AWARDED FIVE (5) POINTS IF THE PROPOSED BEDS WILL BE HOUSED IN NEW CONSTRUCTION.

(1~~3~~2) A QUALIFYING PROJECT WILL BE AWARDED 10 POINTS IF THE EXISTING ~~OR PROPOSED~~ NURSING HOME/HLTCU ~~DOES NOT INCLUDE~~ELIMINATES ~~ANY~~ALL OF ITS 3- ~~OR~~AND 4-BED WARDS.

(1~~4~~3) A QUALIFYING PROJECT WILL BE AWARDED ~~10~~5 POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU IS ON OR READILY ACCESSIBLE TO AN EXISTING OR PROPOSED PUBLIC TRANSPORTATION ROUTE ~~AND FIVE (5) POINTS IF THE EXISTING OR PROPOSED NURSING HOME/HLTCU IS NOT ON AN EXISTING ROUTE BUT SUPPLIES A LETTER OF SUPPORT FOR THE PROPOSED PROJECT FROM THE LOCAL PUBLIC TRANSPORTATION AUTHORITY~~.

(1~~5~~4) 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.~~

(~~10~~165) 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 (~~9~~14) 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	

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, until otherwise changed by the Commission, is as follows.

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

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

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

(iv) age 85 +: 37,368 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, until otherwise changed by the Commission, are as follows:

Planning Area	Bed Need	ADC Adjustment Factor
ALCONA	88	0.90
ALGER	68	0.90
ALLEGAN	426	0.95
ALPENA	173	0.95
ANTRIM	142	0.95
ARENAC	112	0.95
BARAGA	50	0.90
BARRY	252	0.95
BAY	552	0.95
BENZIE	118	0.95
BERRIEN	790	0.95
BRANCH	222	0.95
CALHOUN	651	0.95
CASS	234	0.95
CHARLEVOIX	152	0.95
CHEBOYGAN	181	0.95
CHIPPEWA	189	0.95
CLARE	163	0.95
CLINTON	268	0.95
CRAWFORD	104	0.95
DELTA	234	0.95
DICKINSON	174	0.95
EATON	472	0.95
EMMET	172	0.95
GENESEE	1,938	0.95
GLADWIN	170	0.95
GOGEBIC	114	0.95
GD. TRAVERSE	410	0.95
GRATIOT	255	0.95
HILLSDALE	218	0.95
HOUGHTON/KEWEENAW	168	0.95
HURON	226	0.95

APPENDIX B - continued

Planning Area	Bed Need	ADC Adjustment Factor
INGHAM	1,161	0.95
IONIA	258	0.95
IOSCO	207	0.95
IRON	101	0.95
ISABELLA	244	0.95
JACKSON	794	0.95
KALAMAZOO	1,069	0.95
KALKASKA	81	0.90
KENT	2,388	0.95
LAKE	83	0.90
LAPEER	352	0.95
LEELANAU	136	0.95
LENAWEE	487	0.95
LIVINGSTON	592	0.95
LUCE	46	0.90
MACKINAC	79	0.90
MACOMB	4,305	0.95
MANISTEE	154	0.95
MARQUETTE	282	0.95
MASON	166	0.95
MECOSTA	212	0.95
MENOMINEE	140	0.95
MIDLAND	395	0.95
MISSAUKEE	91	0.90
MONROE	645	0.95
MONTCALM	253	0.95
MONTMORENCY	99	0.90
MUSKEGON	779	0.95
NEWAYGO	219	0.95
OAKLAND	5,326	0.95
OCEANA	124	0.95
OGEMAW	144	0.95
ONTONAGON	48	0.90
OSCEOLA	106	0.95
OSCODA	85	0.90
OTSEGO	139	0.95
OTTAWA	1,060	0.95

APPENDIX B - continued

Planning Area	Bed Need	ADC Adjustment Factor
PRESQUE ISLE	115	0.95
ROSCOMMON	186	0.95
SAGINAW	1,039	0.95
ST. CLAIR	754	0.95
ST. JOSEPH	289	0.95
SANILAC	231	0.95
SCHOOLCRAFT	58	0.90
SHIAWASSEE	350	0.95
TUSCOLA	270	0.95
VAN BUREN	325	0.95
WASHTENAW	1,146	0.95
WEXFORD	168	0.95
NW WAYNE	2,563	0.95
SW WAYNE	1,732	0.95
DETROIT	4,435	0.95

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.

1633

HCR ManorCare

Comments on Proposed Revisions to CON Review Standards for Nursing Home and Hospital Long-Term-Care Unit Beds

Presented at CON Commission Meeting on September 23, 2010

HCR Manor Care, Inc., on behalf of its operating companies in Michigan, ("HCR") submits the following comments on proposed revisions to the CON Review Standards for Nursing Home and Hospital Long-Term-Care Unit Beds. HCR ManorCare is a national long-term care provider with 28 nursing home facilities in Michigan.

HCR commends the CON Commission and Department for its willingness to re-examine the comparative review criteria in the current CON Standards. These criteria provide an opportunity for the Commission to raise the bar for new nursing home projects in Michigan and to incorporate standards that incentivize quality of care, innovation, and investment in technological improvements. Specifically:

1. HCR supports the point deduction approach in Section 10(4) (beginning line 682) for applicants with poor operating history. However, it questions an approach that favors high Medicaid utilization over quality. As proposed, an applicant with high Medicaid utilization but a poor operating history would still outscore an applicant with lower Medicaid utilization and none of the quality concerns listed in this Section. Why would the Commission wish to reward low quality operators with more beds simply because they participate in Medicaid? This language sends the wrong message that there is a differential quality standard in Michigan for high Medicaid vs. low Medicaid facilities. HCR requests that the Commission increase the point deduction under Section 10(4) for poor performing applicants to 25 or more points to ensure that such applicants are disfavored in the comparative review process.

2. In Section 10(5), HCR supports awarding points to facilities that embrace culture change. Person-centered care is at the heart of culture change. Currently, Department approved programs focus on traditional nursing homes serving long-term residents. 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. These facilities serve a vital role in the community by allowing prompt discharge of hospital patients in need of post-hospital rehabilitation. Although these facilities also embrace culture change, because their residents are different, the features of person-centered care will also be different. HCR requests that the Commission work with the Department to explore acceptable culture change models for these types of post-acute nursing facility providers.

3. In Section 10(6) (line 717), HCR does not support changes to reduce the points awarded to applicants who are 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. In this challenging fiscal environment, the Commission should be promoting policies that reduce the costs to the Michigan Medicaid program – not policies that maintain high Medicaid costs or that increase such costs. Numerous national studies over the past 10 years have shown a direct correlation between under-funded nursing homes and poor quality. Additionally, an applicant with the ability to fund a project is more likely to implement a successful CON application in a timely manner. Thus, including 10 points or more for 20% cash is good policy for quality reasons and will ensure that "financially fit" applicants are favored.

4. Similarly, HCR opposes revised language in Section 10(10) (line 740) that reduces the points awarded for audited financial statements and to applicants that can demonstrate positive cash flow. Neighboring states, such as Ohio and Illinois, require audited financial statements and financial viability ratios. Additionally, Ohio requires an applicant to submit a financial feasibility study prepared by an independent accounting firm. Michigan standards should include at least basic financial review criteria so the Department can evaluate the applicant's ability to successfully implement the proposed project. Audited financial statements and percentage of cash are straightforward criteria that should have considerable point allocations. HCR strongly supports an

allocation of at least 10 points for each of these criteria. To address current CON policy, the language should allow audited financial statements of the applicant or those of a corporate affiliate that will fund the proposed project in whole or in part.

5. In Section 10(8) (beginning line 725), the Commission should consider language that will improve the nursing home environment for the most residents possible. Although private rooms are clearly desirable, they are also expensive to build and expensive for private-pay residents to occupy. Often, nursing home residents are private pay until they exhaust their resources to qualify for government benefits. A February 2009 article in the New York Times noted that residents want private rooms but, more importantly, they want showers in each room to eliminate the indignity of being wrapped in a sheet and wheeled down the public hallway. HCR believes the additional financial 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. This model would benefit all residents in the facility – not just those that could afford a private room.

6. HCR urges the Commission to allow points for design features that enhance the functionality of the facility and that provide life-enrichment for residents. Given the steady evolution of technology and recognition by CMS that electronic capabilities can improve quality, it is notable that the Standards do not provide any incentives for technological innovation. The following allocations would incentivize these features:

Technology Feature	Points Awarded
Electronic health record and computer point-of-service entry capability (including wireless tablets)	6
Wireless nurse call/paging system including wireless devices carried by direct care staff	6
Wireless internet in total existing and proposed facility	3
Computer stations or internet cafes for resident use as, increasingly, residents are computer savvy and use the internet to maintain contact with their care givers/community physician, family members, clergy or others	3

7. Given the need for post-acute nursing homes to accommodate more complex hospital discharges, HCR would also like to see points awarded in recognition of the additional construction costs associated with development of facilities that meet this vital need in the community as follows: 6 points for facilities that propose to purchase specialized therapy equipment and/or propose a therapy gym of at least 3,000 gsf.

HCR also noted several technical corrections or issues in the proposed language as follows:

- Line 682: New language stating "At the time the application is submitted" is inserted in the wrong place. Points are not deducted at the time an application is submitted. Rather they would be deducted after submission, after determining the application is a "qualifying project," and after the comparative review process begins. The phrase "at the time the applicable is submitted" should be stricken on line 682 and restored in line 689.
- Line 725-728: "Sink" appears twice in the second category and needs to be corrected. Also, it is not clear what would constitute "an adjacent shared" toilet, sink and shower. Does that mean in the same room?
- 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 this language should be to award points if the nursing home does not have 3 or 4 beds wards once the CON is implemented.

Testimony
by

John Weir

Long Term Care(LTC) Ombudsman
State LTC Ombudsman Mentor

Certification of Need Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds

September 23, 2010

Good morning. My name is John Weir and I am a LTC Ombudsman & Mentor for and the State Long-Term Care Ombudsman Prorgam. I also was part of the work group that reviewed the NH/HLTCU comparative review standards.

I wish to address Section 10, as a member of the workgroup it was my understanding, as well as others, that we had reached agreement from the stake holders at the table on including language about air conditioning in the final draft.

Because of that belief, I am requesting that language be added to this section granting **5 points** to existing or proposed projects that are fully air conditioned.

Thank you for your time and consideration in this matter.

I would be happy to try an answer any question you might have.

Certificate of Need Commission
Nursing Home and Hospital Long Term Care Units Standards
Testimony for Health Care Association of Michigan
September 23, 2010

Good morning, I am Pat Anderson the Executive Vice President of the Health Care Association of Michigan. I am here on behalf of our 260 nursing facility members and would like to support most of the proposed standards changes. First, I would like to thank the CON staff for the convening the workgroups over the past few months. These workgroup meetings were very open and productive resulting in revised language that can be accepted.

HCAM does have a few concerns and would like to present the following comments on each of those issues:

Section 9 Requirements for approval to acquire or lease an existing NH/HLTCU
Part 1 (f) and Part 2 (c) which are lines 581 and 616 respectively which deletes Advancing Excellence as a quality improvement program. In Michigan that program's steering committee is called the MI LANE. This is a good program for facilities to utilize for quality of improvement. HCAM would like the program to remain as part of the CON standards. Also, this program is free to those who participate.

Section 10 Comparative Review
Part 4 (D) the reference to an involuntary or voluntary termination of a Medical Assistance Provider agreement or the "threat". The wording on this part is confusing, under federal survey rules if a facility is not in compliance at a certain point a notice is automatically sent to the facility that a termination may occur. The date is typically 5-6 months in the future. The language should be clear in that a termination has to have happened, not just the "normal" notice process to comply with federal law.

Part 10 (formerly 11) awarding of points for audited financial statements. HCAM does not support audited financial statements to be a part of the standards for comparative review. Audited financial statements add information to validate the ability of the facility to complete the project under review. Most facilities do not incur the expense of audited statements unless required by their lending entity, stockholders or governing board. An audit for a facility can cost as much as $25,000; it confirms that the entity has followed the appropriate reporting requirements according to Generally Accepted Accounting Principles (GAAP). HCAM supports the deletion of this part.

Part 12 (formerly 13) awards points to the project for not having wards but does not acknowledge if an existing facility has either reconfigured or built new without wards. In a fairness issue the standard should recognize the efforts made by the facility to remove wards outside of this project under review.

Testimony
by the

Local Area Network for Excellence (LANE)
of Michigan
Advancing Excellence in America's Nursing Homes

Certification of Need Review Standards for Nursing Home and Hospital Long-Term Care Unit Beds

September 23, 2010

Good afternoon. My name is Dawn Jacobs and I am a co-convener of the Michigan Local Area Network for Excellence (LANE) and an assistant State Long-Term Care Ombudsman within in the Michigan Office of Services to the Aging.

The LANE is the local steering committee of the national Advancing Excellence in America's Nursing Home Campaign. Charlotte Kawchak-Belitsky of MPRO is a co-convener. The other members of the Michigan LANE are the Health Care Association of Michigan (HCAM), Ciena Corporation, the Bureau of Health Professions within the Michigan Department of Community Health, the Michigan County Medical Care Facilities Council, NexCare, Optimal Life Designs in Dementia Care, and PHI.

All members of the LANE urge this Commission to retain the language in Section (1)(f) on the nursing home CON standards listing the Advancing Excellence Campaign as an example of a qualifying quality improvement program.

The mission of the Advancing Excellence in America's Nursing Homes Campaign is to help nursing homes achieve excellence in the quality of care and quality of life for the more than 1.5 million residents of America's nursing homes by:

- Establishing and supporting an infrastructure of LANEs such as ours here in Michigan
- Strengthening the nursing home workforce, and
- Improving clinical and organizational outcomes.

The AE Campaign began Phase 2 in October 2009 with a revised set of clinical and organizational outcomes and new targets for excellence. New goals for Phase 2 are advanced care planning and staff satisfaction. Phase 2 goals focus on:

Goal #1: Staff turnover
Goal #2: Consistent assignment
Goal #3: Physical Restraints
Goal #4: Pressure ulcers
Goal #5: Pain management
Goal #6: Advanced care planning
Goal #7: Resident/Family satisfaction
Goal #8: Staff satisfaction

Now, 42% of the nation's homes (6639 facilities) and 42% of Michigan's nursing homes (182 homes) are participating in Phase 2 which requires home's to set performance targets for each of three selected goals. The top three goals selected nationally and in Michigan are pain management, pressure ulcers and resident/family satisfaction.

Planning is already beginning on Phase 3 goals and targets that will very likely include reducing the number and rate of preventable hospital readmissions within 30 days of discharge as well as reducing the number of "health-acquired conditions" or HACs.

The AE Campaign is a free, voluntary, outcomes-driven quality improvement program. In just 4 years, the AE campaign has demonstrated measurable progress toward reducing the prevalence of pressure ulcers, reducing the use of physical restraints, and improving pain management for long-term and short-stay nursing home residents. The Campaign's national objective for reducing physical restraint use was achieved in Phase 1, allowing it to set a lower rate as a new goal for the final year of Phase 1. A list of the participating national organizations that make up the national AE committee is attached as Attachment A.

The national AE campaign has created a wide variety of tools to assist all nursing home in their quality improvement efforts.

- A hallmark of the campaign are online benchmarking tools [www.nhqualitycampaign.org] to see facility targets for improvement that allow the how to not only track their individual progress but to also compare their performance to state and national benchmarks.
- Each of the eight goals have an "Implementation Guide" that lays out a quality improvement process specific to that goal written largely by geriatrician Stephen Levinson, M.D.
- Creation of the first of its kind tracking tool for consistent assignment that is focused on the resident's experience rather than the staff's...how many CNAs did a resident receive care from in a two week period?
- And, new online tracking tools have been posted to serve the same purposes as the federal MDS system that will "go dark" for months during the transition to a new tool.

The AE campaign has been designed to help homes achieve excellence using quality improvement processes while focused on both clinical goals (pressure ulcers, pain management, restraints) and organizational operations (consistent assignment, turnover, resident and staff satisfaction).

All members of the Michigan LANE request that the Advancing Excellence in America's Nursing Homes campaign be specifically listed as an example of "a quality improvement program" in Section 9(f) of the Review Standards for Nursing Home and Hospital Long-Term Unit Beds.

Attachment A

Advancing Excellence in America's Nursing Homes

Campaign Leaders > Steering Committee

Administration on Aging, Department of Health and Human Services

Agency for Healthcare Research and Quality

Alliance for Quality Nursing Home Care

Alzheimer's Association

American Academy of Nursing -- Expert Panel on Aging

American Association for Long Term Care Nursing (AALTCN)

American Association of Homes and Services for the Aging (AAHSA)

American Association of Nurse Assessment Coordinators (AANAC)

American College of Health Care Administrators (ACHCA)

American Health Care Association (AHCA)

American Health Quality Association (AHQA)

American Medical Directors Association (AMDA)

Association of Health Facility Survey Agencies (AHFSA)

Centers for Disease Control and Prevention (CDC)

Centers for Medicare & Medicaid Services (CMS) and its contractors, the Quality Improvement Organizations (QIOs) and State Survey Agencies

Department of Veterans Affairs

Foundation of the National Association of Long Term Care Administrator Boards

Gerontological Advanced Practice Nurses Association (GAPNA)

Institute for Healthcare Improvement (IHI)

National Association of Directors of Nursing Administration in Long Term Care (NADONA/LTC)

Attachment A

National Association of Health Care Assistants (NAHCA)

National Association of State Long-Term Care Ombudsman Programs (NASOP)

National Gerontological Nursing Association (NGNA)

NCCNHR: The National Consumer Voice for Quality Long-Term Care

PHI

Pioneer Network

Service Employees International Union (SEIU)

The Commonwealth Fund

The Evangelical Lutheran Good Samaritan Society

The John A. Hartford Foundation's Institute for Geriatric Nursing

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

The CTSAC has met two times so far, July 22 and August 25, 2010. At our first meeting we reviewed the charge given to us by the CON Commission and began discussion of the issues of the dental, portable and mini-CT scanners, including operational definitions.

At the second meeting Dr. Thomas Slovis presented information on radiation doses for CT scanners in context of radiation safety in general.

At the second meeting the CTSAC also voted to extend the pilot project for point-of-care portable scanners that was established at the time of the last CT standards review. Because of the desire to obtain enough information before the current review, the window of opportunity for obtaining one of these portable scanners was very limited, ending October 1, 2008. However, only 3 hospitals installed such a scanner and only one had provided information on use. In order to get more experience with this type of equipment, the committee voted to extend the pilot project. We will be finalizing an application deadline and reporting requirements at the September CTSAC meeting.

In August we also started the discussion on in-office mini-scanners. Discussion will continue at the September meeting. In September we will also have presentations on dental CT scanners.

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

From: "Keshishian, Marc D., MD" <MKeshishian@bcbsm.com>
To: Irma Lopez <lopez@michigan.gov>, Brenda Rogers <rogersbre@michigan.gov>
CC: "Edward Goldman (egoldman@med.umich.edu)" <egoldman@med.umich.edu>
Date: 9/23/2010 12:19 AM
Subject: New Medical Technology Committee Report

At the last CON meeting there was a request for a review of daVinci robotic surgical system. Based on discussions with practicing physicians, it was found a robotic surgical system is not excessively expensive, is useful, helps to manage risks and is seen as a valuable addition in certain types of surgery. The technology has been available for years. It was initially used in prostate surgery. It is now being used in gynecologic, thoracic, general and bariatric surgery. About forty hospitals in Michigan have a daVinci surgical system. If we were to regulate robotic surgery we would have to grandfather all existing machines and create a rationale for regulation. Given the number of machines available and their usefulness, it was decided to recommend robotic surgery units not be added to CON regulation.

In addition a review of the FDA premarket and 501k approvals for the months of March, April and May 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 canceled.

CERTIFICATE OF NEED

3rd Quarter Program Activity Report to the CON Commission

October 1, 2009 through June 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	101	N/A	305	N/A
Letters of Intent Processed within 15 days	101	100%	305	100%
Letters of Intent Processed Online	98	97%	297	97%

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	68	N/A	218	N/A
Applications Processed within 15 Days	68	100%	218	100%
Applications Incomplete/More Information Needed	37	54%	146	67%
Applications Filed Online*	50	74%	165	76%
Application Fees Received Online*	12	N/A	32	N/A

* 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	37	97%	94	99%
Substantive Applications	29	100%	75	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	3	N/A
Decisions Issued within 10 workings Days	1	100%	3	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	26	93%	64	97%

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	25	N/A	83	N/A
FOIA Requests Processed on Time	25	100%	83	100%
Number of Applications Viewed Onsite	2	N/A	6	N/A

FOIA – Freedom of Information Act.

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

CERTIFICATE OF NEED

3rd Quarter Compliance Report to the CON Commission

October 1, 2009 through June 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	63	273
Approved projects contacted on or before anniversary date	63	273
Approved projects completed on or before 1-year follow up	55/87%	220/81%
CON approvals expired due to noncompliance with Part 222	35	116
Total follow up correspondence sent	244	860
Total approved projects still ongoing	292	

Compliance: The Evaluation Section continues to work towards a public compliance policy, procedures, and schedule. Several compliance investigations are ongoing. In addition, a recent statewide review of approved hospital high occupancy beds was conducted and all approved recipients found compliant to date.

CERTIFICATE OF NEED LEGAL ACTION

(9/23/10)

Case Name	Date Opened	Case Description	Status
Livingston County - Compare Group # 950195 INCLUDES: Livingston Care Center 2009-5815-CON Livingston Health Campus Medilodge of Howell 2009-6458-CON	9/22/08	Livingston County – Comparative Review of nursing home beds – Administrative Appeal. The three applicants are: (1) Trilogy Healthcare of Livingston, LLC, (2) Livingston Care Center, LLC and (3) MediLodge of Howell, Inc. (petitioner).	On June 15, 2010, the Director issued her final decision. We will be closing our files regarding these cases.
Macomb County - Compare Group # 950185 INCLUDES: FountainBleu-Shelby Township 2009-19036-CON Utica Health Campus 2009-19041-CON Medilodge of Richmond 2009-19039-CON Medilodge of Sterling Heights 2009-19040-CON Medilodge of Washington 2009-19042-CON Heartland Health Care Center – Macomb 2009-19038-CON Windemere Park Nursing Center 2009-19043-CON	4/30/09	Macomb County – Comparative Review of nursing home beds – Administrative Appeal. The seven applicants are: ,(1) Fountainbleu, LLC (petitioner) (2) HCR ManorCare Services, LLC (successful applicant) (3) MediLodge of Richmond, LLC (petitioner) (4) MediLodge of Sterling Heights, Inc. (petitioner) (5) Trilogy Healthcare of Macomb, LLC (successful applicant) (6) MediLodge of Washington, LLC (petitioner) and (7) VanDyke Partners, LLC (successful applicant).	The parties agreed to a comprehensive stipulation for dismissal and a partial remand. On August 25, 2010, pursuant to the stipulation, the Macomb County Circuit Court entered an order dismissing the 4 appeals. We will be closing our file regarding these cases.

CERTIFICATE OF NEED LEGAL ACTION

(9/23/10)

Macomb County INCLUDES: Heartland Health Care Center – III	10/15/09	Macomb County – nursing home beds – Administrative Appeal. There was only one applicant, Heartland Health Center – Macomb III.	Due to resolution of Compare Group 95-0185, this matter will most likely be dismissed and we will close our file.
Case Name *Oakland Count y- Compare Group # 950177* INCLUDES: Woodward at Bloomfield Hills 2009-19212-CON McAuley Center 2009-19215-CON Waltonwood at Twelve Oaks – 3 2009-19214-CON Waltonwood at Main – 2 2009-19213-CON The Manor of Farmington Hills 2009-19044-CON Bloomfield Orchard Villa 2009-19136-CON	Date Opened 4/30/09	Case Description Oakland County – Comparative Review of nursing home beds – Administrative Appeal. The six applicants are: ,(1) Manor of Farmington Hills (petitioner), (2) Bloomfield Orchard Villa (petitioner), (3) Woodward at Bloomfield Hills Health Center (approved applicant), (4) Waltonwood at Main (approved applicant), (5) Waltonwood at Twelve Oaks (approved applicant, and (6) McAuley Center (approved applicant).	Status On May 18, 2010, the Director of the Department issued her Final Order determining that the ALJ's Proposal for Decision in Oakland Comparative Appeal was correct. No appeals were filed and we will be closing our file regarding these cases.
Oakland County INCLUDES: West Winds Health Center	4/30/09	Oakland County – nursing home beds – Administrative Appeal. There was only one applicant, West Winds Health Center.	Due to resolution of Compare Group 95-0177, this matter will most likely be dismissed and we will close our file.

CERTIFICATE OF NEED LEGAL ACTION

(9/23/10)

Oakland County – Compare Group #950197 Includes: Medilodge of Novi CON App No: 09-0135 Heartland-West Bloomfield CON App No: 09-0140	04/07/10	Oakland County Comparative Review of nursing home beds – Administrative Appeal.	Due to resolution of Compare Group 95-0177, this matter will most likely be dismissed and we will close our file.
Woodcare X (Caretel) v MDCH Genesee County Cir Docket No.: 08-89784 CZ	10/08/08	Complaint for Mandamus	Parties have stipulated to an order of dismissal which was submitted to the Court on 8/27/09. Order entered 9/24/09 and appealed. CA no 294480.
Woodcare X (Caretel) v MDCH Court of Claims Docket No.: 08-132-MK	12/03/08	Filed for damages and specific performance of a settlement agreement reached 20 years ago.	Court rescheduled trial to 11/10/09, then denied our motion based on government immunity. Appeal filed 10/27/09, and case stayed. No 294824; consolidated with 294480.
Woodcare X (Caretel) v MDCH	10/27/09	Appeal of Mandamus and Court of Claims.	Brief filed. In February, the Court denied a request to lift the automatic stay. Awaiting scheduling of oral argument in consolidated case.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2009												2010										
	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	• R	•	• R	•	•	▮	▮	▮	▮	▮	▮	• —	•	P •	• ▲ F			• —	•	P •	• ▲ F			
Cardiac Catheterization Services															•	•	•	•	•	•	•	PH	▮	▮
Computed Tomography (CT) Scanner Services										PH •	•	•	• R	•	•	•			▮	▮	▮	▮	▮	▮
Hospital Beds and Addendum for HIV Infected Individuals																						PH		
Magnetic Resonance Imaging (MRI) Services																					• R —	P •	•	• ▲ F
Megavoltage Radiation Therapy (MRT) Services/Units																						PH		
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups										PH •	•	•	• R	•	•	•	•	R •	•	•	• R —	P •	•	• ▲ F
Open Heart Surgery Services																						PH		
Positron Emission Tomography (PET) Scanner Services																						PH		
Surgical Services																						PH		
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																					D			
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 R

KEY

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

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

For Approval September 23, 2010

Updated September 9, 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	May 28, 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.

Certificate of Need Commission
Nursing Home and Hospital Long Term Care Units Standards
Testimony for Health Care Association of Michigan
September 23, 2010

Part 13 (formerly 14) refers to the awarding of points if accessible to public transportation. HCAM does not disagree with this language; we just have some concerns on how nursing home providers can impact public transportation routes to meet this requirement.

The other issue HCAM would like the Commission to consider is the inclusion of language that would award points to those applicants who promote the use of technology in their project. CMS and many other entities have proven the value of technology and foster an environment to promote its use as it enhances both the resident's quality of care and quality of life. Some of the technology that should be considered is: electronic health records, wireless pagers for staff, wireless internet through out the facility and readily accessible internet cafes for residents to keep in touch with their family and friends.

Thank you for providing HCAM the opportunity to bring these issues to your attention. If you have any questions I would be glad to address them.