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

Tuesday, December 12, 2006

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

APPROVED MINUTES

I. Call To Order

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

A. Members Present:

Norma Hagenow, Chairperson
Edward B. Goldman, Vice-Chairperson
Peter Ajluni, DO
Roger G. Andrzejewski (Left @ 12:32 p.m.)
Bradley N. Cory
Dorothy E. Deremo
Marc Keshishian
Adam Miller
Michael A. Sandler, MD
Kathie VanderPloeg-Hoekstra
Michael W. Young, DO

B. Members Absent:

None.

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

Lakshmi Amarnath
Umbrin Ateequi
Jan Christensen
Carol Halsey
William Hart
John Hubinger
Matt Jordan
Joette Laseur
Irma Lopez
Andrea Moore
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Commissioner Hagenow proposed an amendment to move item IX on the agenda to item VII in order to keep all of the Bone Marrow Transplantation (BMT) discussion together.

Motion by Commissioner Miller, seconded by Commissioner Young, to accept the agenda with the amendment. Motion Carried.

III. Declaration of Conflicts of Interest

Commissioner Sandler stated that he could have a potential conflict of interest in regards to the discussion of BMT. Commissioner Goldman also stated that he too may have a potential conflict of interest in regards to BMT.

IV. Review of Minutes – September 19, 2006

There was a brief discussion regarding the content and length of the minutes. A suggestion was made that when abstentions are taken during voting, that they are shown in the minutes.

Motion by Commissioner Goldman, seconded by Commissioner Deremo, to accept the Minutes of September 19, 2006 as presented. Motion Carried.

V. BMT Services

A. Department Update

Mr. Christensen provided a brief oral update and also provided a written report (Attachment A). Discussion followed.

B. Public Comment.

Patrick O'Donovan, William Beaumont Hospitals (Attachment B)
Frank Vicini, MD, William Beaumont Hospitals
Voranit Ratanatharathorn, MD, Karmanos Cancer Institute (Attachment C)
Carol Christner, Karmanos Cancer Institute
Robert Chapman, MD, Henry Ford – Josephine Ford Cancer Center
Terence Thomas, St. John Health
Mark Hutchinson, St. Mary's Health Care
Larry Horwitz, Economic Alliance for Michigan (Attachment D)
Ken Trester, Oakwood
Robert Meeker, Spectrum Health

C. Commission Final Action.

Ms. Rogers gave a brief overview of the BMT language (Attachment E).

Motion by Commissioner Deremo, seconded by Commissioner Young, to approve the technical changes to the BMT language and move the language forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Motion Carried, 9-0. Commissioner Sandler and Commissioner Goldman abstained.

VI. Hospital Beds (HB)

A. Department Update

Mr. Christensen gave an oral report and provided a written report (Attachment F). He reported that there was a Hospital Bed Fact Finding meeting scheduled, but was canceled due to weather. He reported that the meeting has been rescheduled and they will report the information back to the Commission for consideration at the next meeting. Discussion followed.

B. Public Comment.

James Ball, General Motors
James Falahee, Bronson Healthcare
Terry Gerald, Detroit Medical Center
Patrick O'Donovan, William Beaumont Hospitals
Larry Horwitz, Economic Alliance of Michigan
Michelle Ciokajlo, St. John Health

C. Commission Final Action.

Mr. Horvath provided an oral and written report (Attachment G) to the Commissioner's with the technical amendments to the HB Standards.

Motion by Commissioner Goldman, seconded by Commissioner Ajluni, to substitute the document Certificate of Need (CON) Review Standards for Hospital Beds with the document that Mr. Horvath provided with the technical amendments made to the Standards.

Motion by Commissioner Deremo to table the Goldman/Ajluni Motion. Motion Carried.

Motion by Commissioner Goldman, seconded by Commissioner Deremo, to approve the HB Standards with the technical amendments and strike the words "OTHER THAN EXISTING HOSPITAL BEDS" on line 614 under Section 13 (1). Motion Carried.

Motion by Commissioner Goldman, seconded by Commissioner Young, to move the approved HB Standards with the amendments to the JLC and Governor for the 45-day review period, allow the Department to make any grammatical changes as needed, and allow the Department to further look at Section 13 for any additional changes they would recommend. Motion Carried.

Commissioner Hagenow presented a letter (Attachment H) to the Commissioners for review to send to the JLC in regards to the process and progress of the Commission regarding BMT services.

Motion by Commissioner Deremo, seconded by Commissioner Sandler, to send the letter to the JLC. Motion Carried.

Lunch Break from 12:32 p.m. to 1:10 p.m.

VII. Public Comment Regarding Positron Emission Tomography (PET) Scanner Services and Magnetic Resonance Imaging (MRI) Services

A. Public Comment.

PET Scanner Services

Conrad Nagle, William Beaumont Hospitals

Carol Christner, Karmanos Cancer Institute
Robert Meeker, Spectrum Health
Larry Horwitz, Economic Alliance for Michigan (spoke about both PET and MRI)

MRI Services

Dennis Boe, Marquette General Health System

B. Commission Final Action for PET

Motion by Commissioner Sandler, seconded by Commissioner Keshishian, to approve the PET language with the modification of changing 3 years to 5 years in Sections 18, 20 and 21, and move forward to the JLC and Governor for the 45-day review period. Motion Carried.

C. Commission Final Action for MRI

Motion by Commissioner Sandler, seconded by Commissioner Goldman, to accept the MRI Standards with the technical amendments and move forward to the JLC and Governor for the 45-day review period. Motion Carried.

Commissioner Sandler provided a brief oral and written report (Attachment I) on the progress of the MRI Workgroup. He stated that items 2 and 4 of the report have been withdrawn and the Department will draft language for item 5 for proposed action in March. As far as items 1 and 3, no changes will be recommended unless the Department changes its policy position.

The Commission accepted the report.

VIII. Psychiatric Beds and Services Workgroup Update

Commissioner Deremo provided a brief oral and written report (Attachment J) regarding the progress of the Workgroup.

IX. 2-Year Report to Joint Legislative Committee

Ms. Rogers reviewed the letter (Attachment K) regarding the work the Commission has done over the past 2-years that will be sent to the JLC.

Motion by Commissioner Keshishian, seconded by Commissioner Cory, to move the letter forward to the JLC for review. Motion Carried.

X. New Medical Technology

Commissioner Hagenow provided a brief update as to where they are in the process of compiling the Committee.

Ms. Rogers stated that the Department has no information to report at this time.

XI. Legislative Report

Mr. Christensen provided a brief update on BMT attempted legislation. Discussion followed.

XII. Compliance Report

Mr. Christensen provided a brief update on Open Heart Services. Discussion followed.

XIII. CON Program Update

Ms. Rogers stated that the updated report (Attachment L) was provided to the Commissioners in their binders and there is nothing else to add at this time.

XIV. Administrative Update

Mr. Hart provided a brief update. Discussion followed.

XV. Future Meeting Dates – 2007

March 13
June 13
September 18
December 11

XVI. Review of Commission Work Plan

A. Ms. Rogers provided a brief overview of the Draft Work Plan. Discussion followed.

B. Public Comment

Melissa Cupp, Wiener and Associates (Attachment M)
Paul Verlee and Jeff Pries, Fair Acres Care Center (Attachment N)
Larry Horwitz, Economic Alliance for Michigan

C. Commission Final Action

Motion by Commissioner Goldman, seconded by Commissioner Cory, to approve the Work Plan and request that the Department provide information on the Special Pool Beds, i.e., distribution of remaining 22 beds and 2% allocation, at the next meeting. Motion Carried.

XVII. Adjournment

Motion by Commissioner Cory, seconded by Commissioner Goldman, to adjourn the meeting at 2:38 p.m. Motion Carried.

MDCH UPDATE TO THE CON COMMISSION
BONE MARROW TRANSPLANTATION (BMT) SSERVICES (12.12.06)

The Certificate of Need Commission requested that the Department of Community Health seek out information regarding whether there is a lack of access to BMT Services in either, or both, the western and northern portions of Michigan.

Pursuant to the Commission's request above, the Department contacted representatives of Marquette General Hospital and Munson Hospital and presented the question to them. Staff of the Department also met with representatives from Spectrum Health to discuss a possible lack of access to BMT Services.

The representative of Marquette General Hospital expressed that as far as BMT Services were considered, access was not an issue at this time and they could not rationalize, nor justify a need for a separate program in the Upper Peninsula. He noted that BMT is a highly specialized service and further noted that there is no growing need for the service in Northern Michigan. Marquette utilizes BMT Services based at the University of Michigan and in Wisconsin for any clients in need of BMT Services. The staff at Marquette work closely with the BMT programs to support the patient(s) in advance of the treatment and post-treatment. The argument that a patient in the Upper Peninsula would make a decision to not access BMT Services based solely upon a program not being within a short driving distance was viewed as illogical. The geographic and time distances that people currently travel for medical services, basic or specialized, greatly exceed any 30 mile or 30 minute amounts.

The Department is awaiting input from Munson on this issue.

Representatives from Spectrum Health met with Department staff on November 15, 2006 in Lansing. They reported that in the year 2004, and based on the Spectrum Health Cancer Registry totals, they identified 100 specifically diagnosed cancer cases (patients over the age of 20) that may be treated using BMT Services. They further reported that, based on the professional judgment of Spectrum's physicians, of the 100 cases 53% would actually qualify for bone marrow transplantation. The Department questions whether 53% is an appropriate rate. It will work to identify the projected rates that clinical staffs in existing BMT programs apply in their projections. Spectrum was asked to review its estimates while at the same time the Department will gather information related to the cancer diagnoses that Spectrum foresees being used to identify potential unmet need. In order to assure appropriate comparisons, the list of diagnoses provided by Spectrum will be merged with the diagnoses identified by the BMT Workgroup members. It will then become possible to compare Spectrum's projections of potential qualifying cases to those used in counties in southeast Michigan. The representatives from Spectrum were agreeable and expressed a willingness to continue working with the Department in this endeavor.

BMT-O Donovan

Dist 2 12-12-06 MTG

CON Commission Public Comment
Bone Marrow Transplant Standards
December 12, 2006

My name is Patrick O'Donovan, director of planning for the Beaumont Hospitals. Beaumont supports the proposed technical revisions in the BMT standards; however, we also believe that in order for Michigan to take full advantage of the improvements in cancer and other care related to the use of umbilical cord stem cells, the Commission needs to adopt an institution-specific, needs based methodology for bone marrow transplant programs.

When the BMT standards were last reviewed by the C.O.N. Commission in 1997, much of the discussion (attached) centered on whether BMT should remain under C.O.N. at all. While the CON Commission decided to keep BMT as a covered service—a decision not followed by most other states—they also decided to adopt the changes of the national accrediting organization for BMT services—FACT—by reducing the minimum number of transplants necessary for quality purposes from 15 per year to 10 per year.

For the last 18 months, Beaumont has tried to persuade the CON Commission to revisit the arcane, 20-year-old cap on the number of BMT programs allowed in this state. When we heard the Karmanos Cancer Institute testify that Michigan lags behind other states in both patient treatment and research using stem cells, and that for this reason the legislature should support the development of a statewide network of umbilical cord blood banks, we felt this justified the establishment of institution-specific criteria to expand this service to more patients who can benefit from the use of stem cells in their treatment. PA 619 specifically provides for the input of a joint legislative committee on C.O.N. review standards. We met with members of the Joint Legislative Committee on CON regarding our concerns that the proposed standards do not address the arbitrary limit on the number of BMT programs offered in Michigan. I believe you have received several letters from legislators who share our concern over patient access to care.

The limit on the number of BMT programs is limiting patient access to life-saving care. There is no other CON standard that considers "excess capacity" at another institution as a reason to not allow programs at institutions whose patient volumes can justify a program. Therefore, Beaumont Hospitals urges the Commission to take action to today to quickly establish an institution specific needs methodology for BMT. Attached is a proposed charge for a workgroup or SAC, along with a suggested methodology. Thank you for your consideration.

12-12conpatrickbmt.doc

BMT – [illegible]

Oakwood Healthcare, Inc.

One Parklane Boulevard
Suite 1000 E
Dearborn, MI 48126
313.253.6000
313.253.6033 fax

Oakwood

December 8, 2006

John C. Ruckdeschel, M.D.
President and CEO
Karmanos Cancer Institute
4100 John R.
Detroit, MI 48201

Dr. Ruckdeschel:

Oakwood Healthcare System recently learned that attempts are being made to change the Certificate of Need Standards for Bone Marrow Transplantation (BMT) programs in Michigan. We are opposed to this effort for a number of reasons, including potential quality concerns; increased costs that will be realized by patients; and the excess capacity for BMT that currently exists in Southeast Michigan.

In July of 2006 Oakwood Healthcare System closed its BMT program. The transplant center began operations in 1995, with our first transplant occurring in 1996. During the ten year period that our program was open, only 108 transplants were conducted. The low quantity of transplants performed was a key factor in our decision to close the program. According to the Foundation for the Accreditation of Cellular Therapy (FACT), one of the two indices of BMT quality is the number of transplants performed. We believe patients needing BMT are best served receiving treatment at high volume centers.

Finally, the number of transplants performed in Michigan has been steadily declining. In 2001, 498 transplants were performed, by 2005 that number had decreased to 438. Information from the Center for International Blood and Marrow Transplant Research has reinforced that this is downward trend occurring worldwide. Michigan's existing BMT programs are currently functioning below their total capacity. Any additional programs in the state would dilute the pool of qualified staff, increase cost of treatment and create quality-of-care concerns.

Thank you for your time.

Sincerely,

Gerald D. Fitzgerald
President & CEO

Attachment D

Certificate of Need Commission Meeting December 12, 2006
Testimony by The Economic Alliance for Michigan
the statewide business-labor coalition

PROPOSED BMT STANDARDS

EAM urges Commission to give final approval to updated BMT Standards. EAM extensively reviewed the BMT issue at its own meetings and by listening carefully during a year's worth of CON Commission and Work Group deliberations. EAM has not yet heard convincing evidence that more BMT programs would resolve significant problems regarding affordability, accessibility or quality of BMT services in southeast Michigan, though we remain open to new information. We note the following:

- For the past five years, BMT volumes have somewhat decreased in Michigan and elsewhere in the U.S..
- No convincing evidence yet presented about future growth in BMT utilization. In fact, EAM received testimony about other medical and pharmaceutical responses to diseases previously treated by BMT.
- **Even if significant more volume developed, there needs to be a convincing case that expanded demand would best be met by adding more programs, as opposed to higher utilization at current programs, which certainly are not at stressed levels.**

Accordingly, we urge Commission to continue to be open to additional facts and arguments. But for now there is not justification for further deliberation on adding adult BMT programs in Southeast Michigan issue or convening further sessions of a Work Group or a Standard Advisory Committee.

However, we do agree with Commissioners' comments in September that there MAY be need for an adult BMT program in western Michigan where there is apparent geographic access problem:

- Commission reached a balanced judgment at its last meeting on September 19, 2006 in distinguishing between real access issues in western Michigan vs. lack of that in southeastern Michigan. EAM applauds Commission for being open to having adult BMT program in West Michigan IF there is a projected significant volume to assure program efficiency and program quality.
- This would be similar to Commission prior action in dividing state into eastern and western planning areas for pediatric BMT. The result was a pediatric BMT program in western Michigan.

Finally, we think that Commission followed a very deliberative process in considering the BMT issue, but do agree there is a need for an expanded effort to inform legislators about the Commission's very careful process.

HOSPITAL BED STANDARDS

We recommend final approval to the various consensus changes in the pending standards:

- **High-Occupancy Liberalization**: We support the compromise of the high occupancy change to 80% for 24 months, plus the additional bump for pediatric and obstetrical services.
- **No need for modification of Limited Access Area exception to bed need.**
- **Maintaining current replacement zone criteria of 2 and 5 miles:** 2 miles in the nine most populated counties, 5 miles in all other Michigan counties. EAM's Health Group concluded that bigger catchment areas are more appropriate in less populated areas and the current diameters were reasonable.
- **Eliminating illogic of excluding Critical Access Hospital beds from the inventory**. By not counting those CAH beds, typically found in smaller sub-areas, CON bed need standards indicated the wondrous anomaly of a need for more beds sub-areas with low hospital occupancy rates.

We also support the overdue establishment of comparative review criteria for acute-care hospital beds:

- **There soon could be sub-areas with bed need as hospitals close and populations shift over time. Commission needs to fill the absence of any standards for deciding who gets to fill the need for acute-care beds, as it has long done for psychiatric and nursing home/long term care beds.**

- **An Informal group has successfully worked to resolve technical and language issues.** Consensus on wording seems to have been reached among various hospitals previously disputing the precise language.
- **However, efforts needed to further strengthen these criteria by including quality and community benefit and perfecting market share language. We urge Comm. to support adding these, and possibly other factors to the Standards, by adding this objective of a well-balanced set of comparative review criteria for hospital beds to your Work Plan.** The informal group, in cooperation with MDCH and all other interested parties, could then report on its progress in securing agreement on how to operationalize these criteria at the next Commission meeting.

No Demonstration YET of Need for New Hospitals, even if Relocated from Outside Replacement Zone:

- **EAM's Board, when it met just last Friday, emphasized that it continues to be open to demonstrated community need for any additional service or facility IF there is a compelling public policy case for modifying CON constraints.** EAM has heard from organizations wanting to build new hospitals and add new services, but our members still await promised data to justify that.
- **Closing hospitals duplicative with nearby facilities is commendable. But there has to be a community need in another area to justify building a hospital there.**
- **The New York State Hospital Closing Commission recently proposed closing 40 hospitals, accounting for 10% of its licensed beds, and consolidating various health services. The New York Commission focused on there being a low and cost-generating 64% statewide occupancy rate.**
- **It is striking and troubling that hospital organizations in Michigan, which has about 10 percentage points less occupancy -- 54% in 2003 – are saying there is a need for additional service programs and hospitals in new areas. New hospitals in southeast Michigan are being proposed for locations already served by multiple hospitals within 10 miles, and many much less than 10 miles.**

PROPOSED PET STANDARDS

- **We continue to oppose combined clinical and research units for ANY imaging equipment, whether PET or other methodology.** EAM thinks that CON properly encourages research by maintaining the Commission's long-standing exemption from the minimum volume requirements for 100% research units. Our policy group maintained its opposition to combined units because that would mean some provides could initiate an imaging service at lower indicated community need -- and lower clinical utilization:
- **Utilization data supporting a new program should last for the duration of the program.** Recycling the data after any number of yours means double-counting the need justification.
- **Exclusive pediatric PET scanner language is unnecessary.**

PROPOSED MRI STANDARDS

We urge final approval of the MRI standards as you previously approved them, including updating patient weighting factors, modifying the replacement zone and dollar threshold levels.

We agree with the Department that the case has not yet been made for further easing of the current much more liberal criteria for converting mobile host sites to fixed MRI units in rural areas. However, as always we are ready to work with those advocating further easing of rural standards IF they can make the case, particularly to our rural and agricultural-sector members, that having more fixed units would improve affordability for costs, quality and accessibility for rural residents.

CONCLUSION

We commend the Commission for its deliberative process on such a range of issues. But we also urge the Commission to now move forward so it can deal next with the other important CON issues on its agenda that have been awaiting resolution of the issues before you today.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

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

(3) ~~A bone marrow transplantation service listed on the Department inventory that is not located at a licensed hospital site and that performs only autologous bone marrow transplantation procedures using stem cells obtained from the peripheral circulation shall be required to obtain CON approval to provide a bone marrow transplantation service that performs allogeneic bone marrow transplantation procedures or bone marrow transplantation procedures that use stem cells obtained from any other source other than the peripheral circulation.~~ A bone marrow transplantation service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic bone marrow transplant procedures.

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

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

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

Section 2. Definitions

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

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

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

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

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

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

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

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

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

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

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

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

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

(m) "Health service area" or "HSA" means the geographic area set forth in Section ~~8~~9.

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

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

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

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

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

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

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

(r) "Licensed site" means either:

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

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

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

and1396r-8 to 1396v.

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

(u) "Planning area" means:

(i) for an adult bone marrow transplantation service, the state of Michigan.

(ii) for a pediatric bone marrow transplantation service, either:

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

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

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

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

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

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

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

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

(3) An applicant proposing to initiate either an adult or pediatric bone marrow transplantation service shall demonstrate that the licensed hospital site at which the transplants will be offered provides each of the following staff, services, and programs:~~, as of the date an application is submitted to the Department:~~

(a) operating rooms.

(b) continuous ~~on-site~~ availability, ON-SITE OR PHYSICALLY CONNECTED, either immediate or

on-call, of CT scanning, magnetic resonance imaging, ultrasound, angiography, and nuclear medicine services.

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

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

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

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

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

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

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

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

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.

(x) oncology.

(xi) pathology, including blood banking experience.

(xii) pulmonary medicine.

(xiii) radiation oncology.

(xiv) radiology.

(xv) urology.

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

(i) dermatology.

(ii) immunology.

(iii) neurosurgery.

(iv) orthopedic surgery.

(4) An applicant must provide, ~~at the time the CON application is submitted,~~ an implementation plan for the proposed bone marrow transplantation service.

(5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation services in the planning area identified in Section 2(1)(~~s~~)(U)(i) does not exceed three (3) adult bone marrow transplantation services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding three (3) in the planning area.

(b) An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) pediatric bone marrow transplantation services in planning area one identified in Section 2(1)(~~s~~)(U)(ii)(A) or one (1) pediatric bone marrow transplantation service in planning area two identified in Section 2(1)(~~s~~)U)(ii)(B) and that approval of the proposed

application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific pediatric planning area.

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

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

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

(7) An applicant shall provide ~~on-site~~ 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, ~~at the time an application is submitted to the Department,~~ that the licensed hospital site at which the proposed bone marrow transplantation service is proposed has an institutional review board.

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

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

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

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

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

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

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

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

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

(iv) pediatric psychologists.

(v) child life specialists.

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

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

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

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

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

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

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

(A) 6 visits during the first 12-months of operation of the proposed service.

(B) 4 visits during each the second 12-months and third 12-months of operation of the proposed service.

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

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

(B) transplant outcomes.

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

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

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

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

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

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

(c) For purposes of subsection (10), "existing bone marrow transplantation service" means a service that meets all of the following:

(i) currently is ~~and has been~~ performing~~,~~ AND IS FOUNDATION FOR ACCREDITATION OF CELL THERAPY (FACT) ACCREDITED IN, ~~for at least 3 years,~~ the types of transplants (allogeneic or autologous; adult or pediatric) proposed to be performed by the applicant; ~~AND WILL CONTINUE TO PERFORM THESE TYPES OF TRANSPLANTS THROUGHOUT THE CONSULTING AGREEMENT PERIOD.~~.

~~(ii) performed at least 15 pediatric allogeneic transplants or 40 adult allogeneic transplants in the most recent 12-month period prior to the date an application is submitted to the Department.~~

~~(iii)~~ (II) currently is certified ~~by the~~ AS A National Marrow Donor Program; and

~~(iv)~~ (III) is located in the United States.

(d) An applicant shall document that the existing bone marrow transplantation service meets the requirements of subsection (c).

Section 4. Additional requirements for applications included in comparative reviews

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

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

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

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

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

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

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

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

(3) Each application in a comparative ~~review~~ 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 ~~one~~ TWO or more ~~of the~~ competing applications ~~satisfies~~SATISFY all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, WHEN taken together, do not exceed the need, as defined in Section 22225(1) OF THE CODE, ~~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, 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,~~ in the order in which the applications were received by the Department, based on the date and time stamp placed on the applicationS ~~for CON form (form T-150-G-1.01 or any subsequent replacement form)~~ by ~~the Health Facilities Section(or the administrative unit of~~ the Department IN ACCORDANCE WITH RULE 325.9123.~~, responsible for administering the CON program) when an application is submitted.~~

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

Section 5. Requirements for approval -- all applicants

Sec. 5. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. AN APPLICANT THAT IS INITIATING A NEW SERVICE OR IS A NEW PROVIDER NOT CURRENTLY ENROLLED IN MEDICAID SHALL PROVIDE A SIGNED AFFIDAVIT STATING THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

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

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

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

(b) Compliance with applicable safety and operating standards.

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

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

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

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

(C) a processing and cryopreservation laboratory that meets the standards of the Foundation for Accreditation of ~~Hematopoietic~~ Cell Therapy (FA~~H~~CT) or an equivalent organization.

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

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

(F) therapeutic drug monitoring.

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

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

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

(iii) An applicant shall establish and maintain written policies related to outpatient care for bone

marrow transplantation patients, including at least the following:

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

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

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

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

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

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

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

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

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

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

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

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

(I) designated social services staff.

(J) designated physical therapy staff.

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

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

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

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

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

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

(C) long-term management and evaluation, including education of the patient, liaison with the

patient's attending physician, and the maintenance of active patient records for at least 5 years.

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

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

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

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

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

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

(xii) A pediatric bone marrow transplant service shall maintain membership status in ~~either~~ the ~~Pediatric~~ CHILDREN'S Oncology Group (~~P~~COG)~~, or the Children's Cancer Group (CCG)~~. ~~If an applicant organization discontinues membership in either the POG or the CCG, an applicant shall obtain membership in the alternate organization within six months of discontinuing its membership~~.

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

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

(d) Compliance with the following terms of approval:

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

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

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

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

(ii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, demographic and diagnostic information, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; in a

format established by the Department; and in a mutually-agreed upon media. The Department may elect to verify the data through on-site review of appropriate records. In addition, an applicant shall report at least the following data for each patient:

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

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

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

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

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

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

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

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

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

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

Section 7. Documentation of projections

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 9. Health Service Areas

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

HSA	COUNTIES

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

Section 10. Department Inventory of Bone Marrow Transplantation Services

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

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

Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Transplantation Services pertaining to bone marrow transplantation services approved by the CON Commission on ~~March 9, 2004~~JUNE 22, 2005 and effective on ~~June 4, 2004~~SEPTEMBER 21, 2005.

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

MDCH UPDATE TO THE CON COMMISSION
HOSPITAL BEDS (12.12.06)

In response to the Commission's request to the department at its September 2006, meeting, the department is gathering information that will enable it to develop recommendation(s) related to hospital beds in Michigan. Specifically, the department is soliciting data and input related to three initial, key questions:

1) Whether there is a compelling community need for new hospitals in Michigan;

2) How this would be accomplished (e.g., relocations, replacements, new beds, transferred beds etc); and

3) What criteria and data should be used in the decision making.

A meeting was scheduled for December, 1; however, due to inclement weather, the meeting has been rescheduled.

For the purpose of beginning to frame the full discussion that will need to occur, the department is initially asking for input from a small group of agencies and organizations. We recognize that additional input to the department will be necessary as it formulates its state agency recommendations. Initially, a fact-finding group asked to assist departmental CON staff includes:

Greg Dobis, McLaren Health Care Corporation
Patrick O'Donovan, William Beaumont Hospital
Cheryl Miller, Trinity Health
Amy Barkholz, Michigan Hospital Association
Ashton Shortridge, MSU Geography Department
Joe Messina, MSU Geography Department
Larry Horwitz, Economic Alliance of Michigan
Lody Zwarensteyn, Alliance for Health in Michigan
Maureen Halligan, Genesys Health System
Robert Hoban, St. John Hospital
Ken Trester, Oakwood Healthcare, Inc.

The department was also asked to explore the issue of LTACHs and any broad implications for such entities. At this time, the department recommends that the LTAC topic be discussed within the context of the broader hospital bed issue.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.22217, 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 services for all projects approved and certificates of need issued under Part 222 of the Code that involve (a) increasing licensed beds in a hospital licensed under Part 215 or (b) physically relocating hospital beds from one licensed site to another geographic location or (c) replacing beds in a hospital or (d) acquiring a hospital or (e) beginning operation of a new hospital.

(2) A hospital licensed under Part 215 is a covered health facility for purposes of Part 222 of the Code.

(3) An increase in licensed hospital beds is a change in bed capacity for purposes of Part 222 of the Code.

(4) The physical relocation of hospital beds from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.

(5) An increase in hospital beds certified for long-term care is a change in bed capacity for purposes of Part 222 of the Code and shall be subject to and reviewed under the CON Review Standards for Long-Term-Care Services.

(6) The Department shall use sections 3, 4, 5, 6, 7, 8, 10, 16, and 17 of these standards and Section 2 of the Addendum for Projects for HIV Infected Individuals, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.

(7) The Department shall use Section 9 of these standards and Section 3 of the Addendum for Projects for HIV Infected Individuals, as applicable, in applying Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

Section 2. Definitions

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

(a) "Acquiring a hospital" means the issuance of a new hospital license as the result of the acquisition (including purchase, lease, donation, or other comparable arrangements) of a hospital with a valid license and which does not involve a change in bed capacity.

(b) "Alcohol and substance abuse hospital," for purposes of these standards, means a licensed hospital within a long-term (acute) care hospital that exclusively provides inpatient medical detoxification and medical stabilization and related outpatient services for persons who have a primary diagnosis of substance dependence covered by DRGs 433 - 437.

(c) "Base year" means the most recent year that final MIDB data is available to the Department unless a different year is determined to be more appropriate by the Commission.

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

(#) "CLOSE A HOSPITAL" MEANS AN APPLICANT WILL DEMONSTRATE TO THE SATIFACTION OF THE DEPARTMENT THAT A HOSPITAL LICENSED UNDER PART 215, AND WHOSE LICENSED CAPACITY FOR THE MOST RECENT 24 MONTHS PRIOR TO SUBMISSION OF THE APPLICATION WAS AT LEAST 80% FOR ACUTE CARE BEDS, WILL CLOSE AND SURRENDER ITS ACUTE CARE

HOSPITAL LICENSE UPON COMPLETION OF THE PROPOSED PROJECT.

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

(#) "COMMON OWNERSHIP OR CONTROL" MEANS A HOSPITAL THAT IS OWNED BY, IS UNDER COMMON CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT HOSPITAL.

(#) "COMPARE GROUP" MEANS THE APPLICATIONS THAT HAVE BEEN GROUPED FOR THE SAME TYPE OF PROJECT IN THE SAME SUBAREA AND ARE BEING REVIEWED COMPARATIVELY IN ACCORDANCE WITH THE CON RULES.

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

(g) "Department inventory of beds" means the current list maintained for each hospital subarea on a continuing basis by the Department of (i) licensed hospital beds and (ii) hospital beds approved by a valid CON issued under either Part 221 or Part 222 of the Code that are not yet licensed. The term does not include hospital beds certified for long-term-care in hospital long-term care units.

(h) "Discharge relevance factor" (%R) means a mathematical computation where the numerator is the inpatient hospital discharges from a specific zip code for a specified hospital subarea and the denominator is the inpatient hospital discharges for any hospital from that same specific zip code.

(#) "DISPROPORTIONATE SHARE HOSPITAL PAYMENTS" MEANS THE MOST RECENT PAYMENTS TO HOSPITALS IN THE SPECIAL POOL FOR NON-STATE GOVERNMENT-OWNED OR OPERATED HOSPITALS TO ASSURE FUNDING FOR COSTS INCURRED BY PUBLIC FACILITIES PROVIDING INPATIENT HOSPITAL SERVICES WHICH SERVE A DISPROPORTIONATE NUMBER OF LOW-INCOME PATIENTS WITH SPECIAL NEEDS AS CALCULATED BY THE MEDICAL SERVICES ADMINISTRATION WITHIN THE DEPARTMENT.

(i) "Existing hospital beds" means, for a specific hospital subarea, the total of all of the following: (i) hospital beds licensed by the Department; (ii) hospital beds with valid CON approval but not yet licensed; (iii) proposed hospital beds under appeal from a final decision of the Department; and (iv) proposed hospital beds that are 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 Department decision.

(#) "GROSS HOSPITAL REVENUES" MEANS THE HOSPITAL'S REVENUES AS STATED ON THE MOST RECENT MEDICARE AND MICHIGAN MEDICAID FORMS FILED WITH THE MEDICAL SERVICES ADMINISTRATION WITHIN THE DEPARTMENT.

(j) "Health service area" OR "HSA" means the groups of counties listed in Section 18.

(k) "Hospital bed" means a bed within the licensed bed complement at a licensed site of a hospital licensed under Part 215 of the Code, excluding (i) hospital beds certified for long-term care as defined in Section 20106(6) of the Code and (ii) unlicensed newborn bassinets.

(l) "Hospital" means a hospital as defined in Section 20106(5) of the Code being Section 333.20106(5) of the Michigan Compiled Laws and licensed under Part 215 of the Code. The term does not include a hospital or hospital unit licensed or operated by the Department of Mental Health.

(m) "Hospital long-term-care unit" or "HLTCU" means a nursing care unit, owned or operated by and as part of a hospital, licensed by the Department, and providing organized nursing care and medical treatment to 7 or more unrelated individuals suffering or recovering from illness, injury, or infirmity.

(n) "Hospital subarea" or "subarea" means a cluster or grouping of hospitals and the relevant portion of the state's population served by that cluster or grouping of hospitals. For purposes of these standards, hospital subareas and the hospitals assigned to each subarea are set forth in Appendix A.

(o) "Host hospital," for purposes of these standards, means an existing licensed hospital, which delicenses hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow a long-term (acute) care hospital, or alcohol and substance abuse hospital, to begin operation.

(p) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility authorized by license and listed on that licensee's certificate of licensure or (ii) in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by license and listed on that licensee's certificate of licensure.

(q) "Limited access area" means those geographic areas containing a population of 50,000 or more based on the planning year and not within 30 minutes drive time of an existing licensed acute care hospital with 24 hour/7 days a week emergency services utilizing the slowest route available as defined by the Michigan Department of Transportation (MDOT) and as identified in Appendix E. Limited access

areas shall be redetermined when a new hospital has been approved or an existing hospital closes.

(r) "Long-term (acute) care hospital," for purposes of these standards, means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with 42 CFR Part 412.

(s) “Market forecast factors” (%N) means a mathematical computation where the numerator is the number of total inpatient discharges indicated by the market survey forecasts and the denominator is the base year MIDB discharges.

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

(#) “MEDICAID VOLUME” MEANS THE NUMBER OF MEDICAID RECEIPENTS SERVED AT THE HOSPITAL AS STATED ON THE MOST RECENT MEDICARE AND MICHIGAN MEDICAID FORMS FILED WITH THE MEDICAL SERVICES ADMINISTRATION WITHIN THE DEPARTMENT.

(u) "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 B.

(v) "Michigan Inpatient Data Base" or "MIDB" means the data base compiled by the Michigan Health and Hospital Association or successor organization. The data base consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

(w) "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 B.

(x) "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation in a different subarea as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.

(y) "New hospital" means one of the following: (i) the establishment of a new facility that shall be issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site that is not in the same hospital subarea as the currently licensed beds, (iii) currently licensed hospital beds at a licensed site in one subarea which are proposed for relocation to another geographic site which is in the same subarea as determined by the Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.

(z) "OBSTETRICS PATIENT DAYS OF CARE" MEANS INPATIENT DAYS OF CARE FOR PATIENTS IN THE APPLICANT’S MICHIGAN INPATIENT DATABASE DATA AGES 15 THROUGH 44 WITH DRGS 370 THROUGH 375 (OBSTETRICAL DISCHARGES).

(AA) "Overbedded subarea" means a hospital subarea in which the total number of existing hospital beds in that subarea exceeds the subarea needed hospital bed supply as set forth in Appendix C.

(BB) "PEDIATRIC PATIENT DAYS OF CARE" MEANS INPATIENT DAYS OF CARE FOR PATIENTS IN THE APPLICANT’S MICHIGAN INPATIENT DATABASE DATA AGES 0 THROUGH 14 EXCLUDING NORMAL NEWBORNS.

(~~aa~~CC) "Planning year" means five years beyond the base year, established by the CON Commission, for which hospital bed need is developed, unless a different year is determined to be more appropriate by the Commission.

(#) “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 OF THESE STANDARDS.

(~~bb~~DD) “Relevance index” or “market share factor” (%Z) means a mathematical computation where the numerator is the number of inpatient hospital patient days provided by a specified hospital subarea from a specific zip code and the denominator is the total number of inpatient hospital patient days provided by all hospitals to that specific zip code using MIDB data.

(~~cc~~EE) “Relocate existing licensed hospital beds" for purposes of sections 6(3) and 8 of these standards, means a change in the location of existing hospital beds from the existing licensed hospital site to a different existing licensed hospital site within the same hospital subarea or HSA. This definition does not apply to projects involving replacement beds in a hospital governed by Section 7 of these standards.

(FF) "REMAINING PATIENT DAYS OF CARE" MEANS TOTAL INPATIENT DAYS OF CARE IN THE APPLICANT'S MICHIGAN INPATIENT DATABASE DATA MINUS OBSTETRICS PATIENT DAYS OF CARE AND PEDIATRIC PATIENT DAYS OF CARE.

(~~dd~~GG) "Replacement beds in a hospital" means hospital beds that meet all of the following conditions; (i) an equal or greater number of hospital beds are currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently licensed; (ii) the hospital beds are proposed for replacement in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.); and (iii) the hospital beds to be replaced will be located in the replacement zone.

(~~ee~~HH) "Replacement zone" means a proposed licensed site that is (i) in the same subarea as the existing licensed site as determined by the Department in accord with Section 3 of these standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a population of less than 200,000.

(~~ff~~II) "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 B.

(#) “UNCOMPENSATED CARE VOLUME” MEANS THE HOSPITAL’S UNCOMPENSATED CARE VOLUME AS STATED ON THE MOST RECENT MEDICARE AND MICHIGAN MEDICAID FORMS FILED WITH THE MEDICAL SERVICES ADMINISTRATION WITHIN THE DEPARTMENT.

(~~gg~~JJ) "Utilization rate" or "use rate" means the number of days of inpatient care per 1,000 population during a one-year period.

(~~hh~~KK) "Zip code population" means the latest population estimates for the base year and projections for the planning year, by zip code.

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

Section 3. Hospital subareas

Sec. 3. (1)(a) Each existing hospital is assigned to a hospital subarea as set forth in Appendix A which is incorporated as part of these standards, until Appendix A is revised pursuant to this subsection.

(i) These hospital subareas, and the assignments of hospitals to subareas, shall be updated, at the direction of the Commission, starting in May 2003, to be completed no later than November 2003. Thereafter, at the direction of the Commission, the updates shall occur no later than two years after the official date of the federal decennial census, provided that:

(A) Population data at the federal zip code level, derived from the federal decennial census, are available; and final MIDB data are available to the Department for that same census year.

(b) For an application involving a proposed new licensed site for a hospital (whether new or replacement), the proposed new licensed site shall be assigned to an existing hospital subarea utilizing a market survey conducted by the applicant and submitted with the application. The market survey shall provide, at a minimum, forecasts of the number of inpatient discharges for each zip code that the proposed new licensed site shall provide service. The forecasted numbers must be for the same year as the base year MIDB data. The market survey shall be completed by the applicant using accepted standard statistical methods. The market survey must be submitted on a computer media and in a format

specified by the Department. The market survey, if determined by the Department to be reasonable pursuant to Section 15, shall be used by the Department to assign the proposed new site to an existing subarea based on the methodology described by "The Specification of Hospital Service Communities in a Large Metropolitan Area" by J. William Thomas, Ph.D., John R. Griffith, and Paul Durance, April 1979 as follows:

(i) For the proposed new site, a discharge relevance factor for each of the zip codes identified in the application will be computed. Zip codes with a market forecast factor of less than .05 will be deleted from consideration.

(ii) The base year MIDB data will be used to compute discharge relevance factors (%Rs) for each hospital subarea for each of the zip codes identified in step (i) above. Hospital subareas with a %R of less than .10 for all zip codes identified in step (i) will be deleted from the computation.

(iii) The third step in the methodology is to calculate a population-weighted average discharge relevance factor $\overline{R}_j$ for the proposed hospital and existing subareas. Letting:

P_i = Population of zip code i.

d_{ij} = Number of patients from zip code i treated at hospital j.

$D_i = \sum_j d_{ij}$ = Total patients from zip code i.

$I_j = \{i \mid (d_{ij}/D_i) \geq \alpha\}$, set of zip codes for which the individual relevance factor [%R from (i) and (ii) above) values (d_{ij}/D_i) of hospital j exceeds or equals α, where α is specified $0 \leq \alpha \geq 1$.

then $$\overline{R}_j = \frac{\sum_{i \varepsilon Ij} P_i (d_{ij}/D_i)}{\sum_{i \varepsilon Ij} P_i}$$

(iv) After $\overline{R}_j$ is calculated for the applicant(s) and the included existing subareas, the hospital/subarea with the smallest $\overline{R}_j$ ($S\overline{R}_j$) is grouped with the hospital/subarea having the greatest individual discharge relevance factor in the $S\overline{R}_j$'s home zip code. $S\overline{R}_j$'s home zip code is defined as the zip code from $S\overline{R}_j$'s with the greatest discharge relevance factor.

(v) If there is only a single applicant, then the assignment procedure is complete. If there are additional applicants, then steps (iii), and (iv) must be repeated until all applicants have been assigned to an existing subarea.

(2) The Commission shall amend Appendix A to reflect: (a) approved new licensed site(s) assigned to a specific hospital subarea; (b) hospital closures; and (c) licensure action(s) as appropriate.

(3) As directed by the Commission, new sub-area assignments established according to subsection (1)(a)(i) shall supersede Appendix A and shall be included as an amended appendix to these standards effective on the date determined by the Commission.

Section 4. Determination of the needed hospital bed supply

Sec. 4. (1) The determination of the needed hospital bed supply for a limited access area and a hospital subarea for a planning year shall be made using the MIDB and population estimates and projections by zip code in the following methodology:

(a) All hospital discharges for normal newborns (DRG 391) and psychiatric patients (ICD-9-CM codes 290 through 319 as a principal diagnosis) will be excluded.

(b) For each discharge from the selected zip codes for a limited access area or each hospital subarea discharge, as applicable, calculate the number of patient days (take the patient days for each discharge and accumulate it within the respective age group) for the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older. Data from non-Michigan residents are to be included for each specific age group. Data from

non-Michigan residents are to be included for each specific age group. For limited access areas, proceed to section 4(1)(e).

(c) For each hospital subarea, calculate the relevance index (%Z) for each zip code and for each of the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 THROUGH 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older.

(d) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective base year zip code and age group specific year population. The result will be the zip code allocations by age group for each subarea.

(e) For each limited access area or hospital subarea, as applicable, calculate the subarea base year population by age group by adding together all zip code population allocations calculated in (d) for each specific age group in that subarea. For a limited access area, add together the age groups identified for the limited access area. The result will be six population age groups for each limited access area or subarea, as applicable.

(f) For each limited access area or hospital subarea, as applicable, calculate the patient day use rates for ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75 and older by dividing the results of (b) by the results of (e).

(g) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective planning year zip code and age group specific year population. The results will be the projected zip code allocations by age group for each subarea. For a limited access area, multiply the population projection for the plan year by the proportion of the zip code that is contained within the limited access area for each zip code age group. The results will be the projected zip code allocations by age group for each zip code within the limited access area.

(h) For each hospital subarea, calculate the subarea projected year population by age group by adding together all projected zip code population allocations calculated in (g) for each specific age group. For a limited access area, add together the zip code allocations calculated in (g) by age group identified for the limited access area. The result will be six population age groups for each limited access area or subarea, as applicable.

(i) For each limited access area or hospital subarea, as applicable, calculate the limited access area or hospital subarea, as applicable, projected patient days for each age group by multiplying the six projected populations by age group calculated in step (h) by the age specific use rates identified in step (f).

(j) For each limited access area or hospital subarea, as applicable, calculate the adult medical/surgical limited access area or hospital subarea, as applicable, projected patient days by adding together the following age group specific projected patient days calculated in (i): ages 15 through 44, ages 45 through 64, ages 65 through 74, and ages 75 and older. The 0 (excluding normal newborns) through 14 (pediatric) and female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges) age groups remain unchanged as calculated in (i).

(k) For each limited access area or hospital subarea, as applicable, calculate the limited access area or hospital subarea, as applicable, projected average daily census (ADC) for three age groups: Ages 0 (excluding normal newborns) through 14 (pediatric), female ages 15 through 44 (DRGs 370 through 375 – obstetrical discharges), and adult medical surgical by dividing the results calculated in (j) by 365 (or 366 if the planning year is a leap year). Round each ADC to a whole number. This will give three ADC computations per limited access area or subarea, as applicable.

(l) For each limited access area or hospital subarea, as applicable, and age group, select the appropriate occupancy rate from the occupancy rate table in Appendix D.

(m) For each limited access area or hospital subarea, as applicable, and age group, calculate the limited access area or subarea, as applicable, projected bed need number of hospital beds for the limited access area or subarea, as applicable, by age group by dividing the ADC calculated in (k) by the appropriate occupancy rate determined in (l). To obtain the total limited access area or hospital, as applicable, bed need, add the three age group bed projections together. Round any part of a bed up to a whole bed.

Section 5. Bed Need

Sec. 5. (1) The bed-need numbers incorporated as part of these standards as Appendix C shall apply to projects subject to review under these standards, except where a specific CON review standard states otherwise.

(2) The Commission shall direct the Department, effective November 2004 and every two years thereafter, to re-calculate the acute care bed need methodology in Section 4, within a specified time frame.

(3) The Commission shall designate the base year and the future planning year which shall be utilized in applying the methodology pursuant to subsection (2).

(4) When the Department is directed by the Commission to apply the methodology pursuant to subsection (2), the effective date of the bed-need numbers shall be established by the Commission.

(5) As directed by the Commission, new bed-need numbers established by subsections (2) and (3) shall supersede the bed-need numbers shown in Appendix C and shall be included as an amended appendix to these standards.

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

Sec. 6. (1) An applicant proposing new beds in a hospital, except an applicant meeting the requirements of subsection 2, 3, 4, or 5 shall demonstrate that it meets all of the following:

(a) The new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(b) The total number of existing hospital beds in the subarea to which the new beds will be assigned does not currently exceed the needed hospital bed supply as set forth in Appendix C. The Department shall determine the subarea to which the beds will be assigned in accord with Section 3 of these standards.

(c) Approval of the proposed new beds in a hospital shall not result in the total number of existing hospital beds, in the subarea to which the new beds will be assigned, exceeding the needed hospital bed supply as set forth in Appendix C. The Department shall determine the subarea to which the beds will be assigned in accord with Section 3 of these standards.

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

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

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

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital.

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

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

of the new hospital must be disposed of by one of the following means:

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

(B) Delicensure of the hospital beds; or

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

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

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

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

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

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

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

(3) An applicant proposing to add new hospital beds, as the receiving licensed hospital under Section 8, shall demonstrate that it meets all of the requirements of this subsection and shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(a) The approval of the proposed new hospital beds shall not result in an increase in the number of licensed hospital beds as follows:

(i) In the subarea, or

(ii) in the HSA pursuant to Section 8(2)(b).

(A) The receiving hospital shall meet the requirements of section 6(4)(b) of these standards.

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

(c) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(4) An applicant may apply for the addition of new beds if all of the following subsections are met. Further, an applicant proposing new beds at an existing licensed hospital site shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

(a) The beds are being added at the existing licensed hospital site.

(b) The hospital at the existing licensed hospital site has operated ~~as follows~~ AT AN ADJUSTED OCCUPANCY RATE OF 80% OR ABOVE for the previous, consecutive ~~12~~ 24 months based on its ~~existing~~ licensed AND APPROVED hospital bed capacity. ~~as documented on the most recent reports of the "Annual Hospital Statistical Questionnaire" or more current verifiable data:~~ THE ADJUSTED OCCUPANCY RATE SHALL BE CALCULATED AS FOLLOWS:

~~Number of Licensed Hospital Beds~~	~~Average Occupancy~~
~~Fewer than 300~~	~~80% and above~~
~~300 or more~~	~~85% and above~~

(I) COMBINE ALL PEDIATRIC PATIENT DAYS OF CARE AND OBSTETRICS PATIENT DAYS OF CARE PROVIDED DURING THE MOST RECENT, CONSECUTIVE 24-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT AND MULTIPLY THAT NUMBER BY 1.1.

(II) ADD REMAINING PATIENT DAYS OF CARE PROVIDED DURING THE MOST RECENT, CONSECUTIVE 24-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT TO THE NUMBER CALCULATED IN (I) ABOVE. THIS IS THE ADJUSTED PATIENT DAYS.

(III) DIVIDE THE NUMBER CALCULATED IN (II) ABOVE BY THE TOTAL POSSIBLE PATIENT DAYS [LICENSED AND APPROVED HOSPITAL BEDS MULTIPLIED BY 730 (OR 731 IF INCLUDING A LEAP YEAR)]. THIS IS THE ADJUSTED OCCUPANCY RATE.

(c) The number of beds that may be approved pursuant to this subsection shall be the number of beds necessary to reduce the ADJUSTED occupancy rate for the hospital to ~~80~~ 75 percent ~~for hospitals with licensed beds of 300 or more and to 75 percent for hospitals with licensed beds of fewer than 300~~. The number of beds shall be calculated as follows:

(i) Divide the ~~actual~~ number of ADJUSTED patient days CALCULATED IN SUBSECTION (B)(II) ~~of care provided during the most recent, consecutive 12-month period for which verifiable data are available to the department by .80 for hospitals with licensed beds of 300 or more and~~ by .75 f~~or hospitals with licensed beds of fewer than 300~~ to determine licensed bed days at ~~80 percent occupancy or~~ 75 percent occupancy ~~as applicable~~;

(ii) Divide the result of step (i) by ~~365~~ 730 (or ~~366~~ 731 ~~for~~ IF INCLUDING A leap year~~s~~) and round the result up to the next whole number;

(iii) Subtract the number of licensed AND APPROVED HOSPITAL beds as documented on the "Department Inventory of Beds" from the result of step (ii) and round the result up to the next whole number to determine the maximum number of beds that may be approved pursuant to this subsection.

(d) A licensed acute care hospital that has relocated its beds, after the effective date of these standards, shall not be approved for hospital beds under this subsection for five years from the effective date of the relocation of beds.

(e) Applicants proposing to add new hospital beds under this subsection shall not be subject to comparative review.

(f) Applicants proposing to add new hospital beds under this subsection shall demonstrate to the Department that they have pursued a good faith effort to relocate acute care beds from other licensed acute care hospitals within the HSA. At the time an application is submitted to the Department, the applicant shall demonstrate that contact was made by one certified mail return receipt for each organization contacted.

(5) An applicant proposing a new hospital in a limited access area shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards, agrees and assures to comply with all applicable project delivery requirements, and all of the following subsections are met.

(a) The proposed new hospital, unless a critical access hospital, shall have 24 hour/7 days a week emergency services, obstetrical services, surgical services, and licensed acute care beds.

(b) The Department shall assign the proposed new hospital to an existing subarea based on the current market use patterns of existing subareas.

(c) Approval of the proposed new beds in a hospital in a limited access area shall not exceed the bed need for the limited access area as determined by the bed need methodology in Section 4 and as set forth in Appendix E.

(d) The new beds in a hospital in a limited access area shall result in a hospital of at least 100 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. If the bed need for a limited access area, as shown in Appendix E, is less, then that will be the minimum number of beds for a new hospital under this provision. If an applicant for new beds in a hospital under this provision simultaneously applies for status as a critical access hospital, the minimum hospital size

shall be that number allowed under state/federal critical access hospital designation.

(e) Applicants proposing to create a new hospital under this subsection shall not be approved, for a period of five years after beginning operation of the facility, of the following covered clinical services: (i) open heart surgery, (ii) therapeutic cardiac catheterization, (iii) fixed positron emission tomography (PET) services, (iv) all transplant services, (v) neonatal intensive care services/beds, and (vi) fixed urinary extracorporeal shock wave lithotripsy (UESWL) services.

(f) Applicants proposing to add new hospital beds under this subsection shall be prohibited from relocating the new hospital beds for a period of 10 years after beginning operation of the facility.

(g) An applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital as follows:

(i) In a metropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and serve a population of 50,000 or more inside the limited access area and within 30 minutes drive time from the proposed new hospital.

(ii) In a rural or micropolitan statistical area county, an applicant proposing to add a new hospital pursuant to this subsection shall locate the new hospital within the limited access area and serve a population of 50,000 or more inside the limited access area and within 60 minutes drive time from the proposed new hospital.

Section 7. Requirements for approval -- replacement beds in a hospital in a replacement zone

Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing replacement beds in a hospital in the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

(2) In order to be approved, the applicant shall propose to (i) replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are located, and (ii) that the proposed new licensed site is in the replacement zone.

(3) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

Section 8. Requirements for approval of an applicant proposing to relocate existing licensed hospital beds

Sec 8. (1) The proposed project to relocate beds, under this section, shall constitute a change in bed capacity under Section 1(4) of these standards.

(2) Any existing licensed acute care hospital may relocate all or a portion of its beds to another existing licensed acute care hospital as follows:

(a) The licensed acute care hospitals are located within the same subarea, or

(b) the licensed acute care hospitals are located within the same HSA if the receiving hospital meets the requirements of Section 6(4)(b) of these standards.

(3) The hospital from which the beds are being relocated, and the hospital receiving the beds, shall not require any ownership relationship.

(4) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory for the applicable subarea.

(5) The relocation of beds under this section shall not be subject to a mileage limitation.

Section 9. Project delivery requirements -- terms of approval for all applicants

Sec. 9. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

(a) Compliance with these standards

(b) Compliance with applicable operating standards

(I) AN APPLICANT APPROVED PURSUANT TO SECTION 6(4) MUST ACHIEVE A MINIMUM OCCUPANCY OF 75 PERCENT OVER THE LAST 12-MONTH PERIOD IN THE THREE YEARS AFTER THE NEW BEDS ARE PUT INTO OPERATION, AND FOR EACH SUBSEQUENT CALENDAR YEAR, OR THE NUMBER OF NEW LICENSED BEDS SHALL BE REDUCED TO ACHIEVE A MINIMUM OF 75 PERCENT AVERAGE ANNUAL OCCUPANCY FOR THE REVISED LICENSED BED COMPLEMENT.

(II) THE APPLICANT MUST SUBMIT DOCUMENTATION ACCEPTABLE AND REASONABLE TO THE DEPARTMENT, WITHIN 30 DAYS AFTER THE COMPLETION OF THE 3-YEAR PERIOD, TO SUBSTANTIATE THE OCCUPANCY RATE FOR THE LAST 12-MONTH PERIOD AFTER THE NEW BEDS ARE PUT INTO OPERATION AND FOR EACH SUBSEQUENT CALENDAR YEAR, WITHIN 30 DAYS AFTER THE END OF THE YEAR.

(c) Compliance with the following quality assurance standards:

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

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

(A) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The data shall be submitted to the Department or its designee.

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

(i) Not deny services to any individual based on ability to pay or source of payment.

(ii) Maintain information by source of payment to indicate the volume of care from each payor and non-payor source provided annually.

(iii) Provide services to any individual based on clinical indications of need for the services.

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

Section 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties

Sec. 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties, for purposes of these standards, are incorporated as part of these standards as Appendix B. The Department may amend Appendix B as appropriate to reflect changes by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget.

Section 11. Department inventory of beds

Sec. 11. The Department shall maintain and provide on request a listing of the Department inventory of beds for each subarea. ~~***Hospitals that have state/federal critical access hospital designation are excluded from the bed inventory***~~.

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on March ~~98~~, ~~2004~~ 2005 and effective ~~June 4, 2004~~MAY 27, 2005.

(2) Projects reviewed under these standards shall be subject to comparative review except those projects meeting the requirements of Section 7 involving the replacement of beds in a hospital within the replacement zone and projects involving acquisition (including purchase, lease, donation or comparable arrangements) of a hospital.

Section 13. Additional requirements for applications included in comparative reviews

Sec. 13. (1) EXCEPT FOR THOSE APPLICATIONS FOR LIMITED ACCESS AREAS, ~~Any~~ ANY application FOR HOSPITAL BEDS~~, OTHER THAN EXISTING HOSPITAL BEDS~~, THAT ~~ARE~~ IS 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) Each application in a comparative review group shall be individually reviewed to determine whether the application IS A QUALIFYING PROJECT. ~~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 ~~one~~ TWO or more ~~of the~~ competing applications ~~satisfies~~ satisfyARE QUALIFYING PROJECTS, IT SHALL CONDUCT A COMPARATIVE REVIEW. ~~all of the requirements for approval, these projects shall be considered qualifying projects.~~ The Department shall approve those qualifying projects which, WHEN taken together, do not exceed the need, as defined in Section 22225(1) OF THE CODE, AND WHICH HAVE THE HIGHEST NUMBER OF POINTS WHEN THE RESULTS OF SUBSECTION (3) ARE TOTALED. IF TWO OR MORE QUALIFYING PROJECTS ARE DETERMINED TO HAVE AN IDENTICAL NUMBER OF POINTS, THEN THE DEPARTMENT SHALL APPROVE THOSE QUALIFYING PROJECTS THAT, WHEN TAKEN TOGETHER, THAT DO NOT EXCEED THE NEED in the order IN WHICH THE APPLICATIONS WERE RECEIVED BY the Department ~~determines the projects most fully promote the availability of quality health services at reasonable cost~~BASED ON THE DATE AND TIME STAMP PLACED ON THE APPLICATIONS BY THE DEPARTMENT IN ACCORDANCE WITH RULE 325.9123.

(3)(A) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE PERCENTILE RANKING OF THE APPLICANT'S UNCOMPENSATED CARE VOLUME~~, AS DEFINED BY THE DEPARTMENT,~~ AND AS MEASURED BY PERCENTAGE OF GROSS HOSPITAL REVENUES AS SET FORTH IN THE FOLLOWING TABLE. ~~FOR PURPOSES OF SCORING,~~ THE APPLICANT'S UNCOMPENSATED CARE VOLUME WILL BE THE CUMULATIVE OF ALL CURRENTLY LICENSED MICHIGAN HOSPITALS UNDER COMMON OWNERSHIP OR CONTROL ~~OWNED BY, UNDER COMMON CONTROL OF, OR HAVING AS A COMMON PARENT~~ WITH THE APPLICANT ~~WHICH~~THAT ARE LOCATED IN THE SAME HEALTH SERVICE AREA AS THE PROPOSED ~~ADDITIONAL~~HOSPITAL BEDS. ~~THE SOURCE DOCUMENT FOR THE CALCULATION SHALL BE THE MOST RECENT COST REPORT SUBMITTED TO THE DEPARTMENT FOR PURPOSES OF CALCULATING DISPROPORTIONATE SHARE HOSPITAL PAYMENTS.~~ IF A HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL ~~OWNED BY, UNDER COMMON CONTROL OF, OR HAVING A COMMON PARENT~~ WITH THE APPLICANT HAS NOT FILED A COST REPORT, THEN THE RELATED APPLICANT SHALL RECEIVE A SCORE OF ZERO. THE SOURCE DOCUMENT FOR THE CALCULATION SHALL BE THE MOST RECENT COST REPORT FILED WITH THE DEPARTMENT

FOR PURPOSES OF CALCULATING DISPROPORTIONATE SHARE HOSPITAL PAYMENTS.

PERCENTILE RANKING	POINTS AWARDED
90.0 – 100	25 PTS
80.0 – 89.9	20 PTS
70.0 – 79.9	15 PTS
60.0 – 69.9	10 PTS
50.0 – 59.9	5 PTS

WHERE AN APPLICANT PROPOSES TO CLOSE A HOSPITAL(S) AS PART OF ITS APPLICATION, DATA FROM THE ~~CLOSED~~ HOSPITAL(S) TO BE CLOSED SHALL BE EXCLUDED FROM THIS CALCULATION.

(B) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE ~~STATEWIDE~~HEALTH SERVICE AREA PERCENTILE RANK OF THE APPLICANT'S MEDICAID VOLUME AS MEASURED BY PERCENTAGE OF GROSS HOSPITAL REVENUES AS SET FORTH IN THE FOLLOWING TABLE. FOR PURPOSES OF SCORING, THE APPLICANT'S MEDICAID VOLUME WILL BE THE CUMULATIVE OF ALL CURRENTLY LICENSED MICHIGAN HOSPITALS UNDER COMMON OWNERSHIP OR CONTROL ~~OWNED BY, UNDER COMMON CONTROL OF, OR HAVING A COMMON PARENT~~ WITH THE APPLICANT, ~~WHICH~~THAT ARE LOCATED IN THE SAME HEALTH SERVICE AREA AS ~~TO~~ THE PROPOSED HOSPITAL~~ADDITIONAL~~ BEDS. ~~THE SOURCE DOCUMENTS FOR THE CALCULATION SHALL BE THE COST REPORT SUBMITTED TO THE DEPARTMENT FOR PURPOSES OF CALCULATING DISPROPORTIONATE SHARE HOSPITAL PAYMENTS.~~ IF A HOSPITAL UNDER COMMON OWNERSHIP OR CONTROL ~~OWNED BY, UNDER COMMON CONTROL OF, OR HAVING A COMMON PARENT~~ WITH THE APPLICANT HAS NOT FILED A COST REPORT, THEN THE RELATED APPLICANT SHALL RECEIVE A SCORE OF ZERO. THE SOURCE DOCUMENT FOR THE CALCULATION SHALL BE THE MOST RECENT COST REPORT FILED WITH THE DEPARTMENT FOR PURPOSES OF CALCULATING DISPROPORTIONATE SHARE HOSPITAL PAYMENTS.

PERCENTILE RANK	POINTS AWARDED
87.5 – 100	20 PTS
75.0 – 87.4	15 PTS
62.5 – 74.9	10 PTS
50.0 – 61.9	5 PTS
LESS THAN 50.0	0 PTS

WHERE AN APPLICANT PROPOSES TO CLOSE A HOSPITAL(S) AS PART OF ITS APPLICATION, DATA FROM THE ~~CLOSED~~ HOSPITAL(S) TO BE CLOSED SHALL BE EXCLUDED FROM THIS CALCULATION.

(C) A QUALIFYING PROJECT SHALL BE AWARDED POINTS AS SET FORTH IN THE FOLLOWING TABLE IN ACCORDANCE WITH ITS IMPACT ON INPATIENT CAPACITY ~~IN THE HEALTH SERVICE AREA OF THE PROPOSED HOSPITAL SITE. FURTHER, A QUALIFYING PROJECT SHALL BE AWARDED THE 25 POINTS FOR ANY SITUATION IN WHICH IT IS GUARANTEEING TO COMPLETELY CLOSE A HOSPITAL (AT WHICH AT LEAST 80% OF THE AVERAGE DAILY CENSUS FOR THE PRIOR 24 MONTHS WERE UTILIZED FOR REGULAR ACUTE CARE PATIENTS). IN ORDER TO QUALIFY FOR THESE POINTS, THE HOSPITAL THAT IS BEING CLOSED MUST BE FULLY DELICENSED AND CEASE TO OPERATE, AND THIS ACTION MUST NOT CREATE A BED NEED IN ANY AREA OR SUB-AREA AS A RESULT OF ITS CLOSING. THE HOSPITAL BEDS MAY NOT BE TRANSFERRED TO ANOTHER LOCATION OR FACILITY IF THE CLOSING IS TO QUALIFY FOR THESE POINTS, AND THE UTILIZATION (AS DEFINED BY THE AVERAGE DAILY CENSUS OVER THE PREVIOUS 24 MONTH PERIOD PRIOR TO THE DATE THAT THE APPLICATION IS SUBMITTED) OF THE HOSPITAL TO BE CLOSED MUST BE AT LEAST EQUAL~~

~~TO 50% OF THE SIZE OF THE HOSPITAL UNDER CONSIDERATION IN THE APPLICATION PROCESS (AS DEFINED BY THE NUMBER OF PROPOSED NEW LICENSED BEDS).~~ IF AN APPLICANT PROPOSES TO CLOSE A HOSPITAL(S), POINTS SHALL ONLY BE AWARDED IF (I) CLOSURE OF THAT HOSPITAL(S) DOES NOT CREATE A BED NEED IN ANY SUBAREA AS A RESULT OF ITS CLOSING; (II) THE APPLICANT STIPULATES THAT THE HOSPITAL BEDS TO BE CLOSED SHALL NOT BE TRANSFERRED TO ANOTHER LOCATION OR FACILITY; AND (III) THE UTILIZATION (AS DEFINED BY THE AVERAGE DAILY CENSUS OVER THE PREVIOUS 24 MONTH PERIOD PRIOR TO THE DATE THAT THE APPLICATION IS SUBMITTED) OF THE HOSPITAL TO BE CLOSED IS AT LEAST EQUAL TO 50% OF THE SIZE OF THE PROPOSED HOSPITAL (AS DEFINED BY THE NUMBER OF PROPOSED NEW LICENSED BEDS).

IMPACT ON CAPACITY	POINTS AWARDED
CLOSURE OF HOSPITAL(S)	25 PTS
~~MOVE BEDS~~	~~0 PTS~~
~~ADDS BEDS (NET)~~	~~-15 PTS~~
~~OR~~	
CLOSURE OF HOSPITAL(S) ~~OR DELICENSURE OF BEDS~~ WHICH CREATES A BED NEED	-15 PTS

~~WHERE AN APPLICANT PROPOSES TO CLOSE A HOSPITAL AS PART OF ITS APPLICATION, DATA FROM THE CLOSED HOSPITAL SHALL BE EXCLUDED FROM ANY CALCULATION RELATED TO OTHER FACTORS IN THE COMPARATIVE REVIEW PROCESS.~~

(D) A QUALIFYING PROJECT WILL BE AWARDED POINTS BASED ON THE PERCENTAGE OF THE APPLICANT'S HISTORICAL MARKET SHARE OF INPATIENT DISCHARGES OF THE POPULATION IN AN AREA WHICH WILL BE DEFINED AS THAT AREA CIRCUMSCRIBED BY THE PROPOSED HOSPITAL LOCATIONS DEFINED BY ALL OF THE APPLICANTS IN THE COMPARATIVE REVIEW PROCESS UNDER CONSIDERATION. THIS AREA WILL INCLUDE ANY ZIP CODE COMPLETELY WITHIN THE AREA AS WELL AS ANY ZIP CODE WHICH TOUCHES, OR IS TOUCHED BY, THE LINES THAT DEFINE THE AREA INCLUDED WITHIN THE FIGURE THAT IS DEFINED BY THE GEOMETRIC AREA RESULTING FROM CONNECTING THE PROPOSED LOCATIONS. IN THE CASE OF TWO LOCATIONS OR ONE LOCATION OR IF THE EXERCISE IN GEOMETRIC DEFINITION DOES NOT INCLUDE AT LEAST TEN ZIP CODES, THE MARKET AREA WILL BE DEFINED BY THE ZIP CODES WITHIN THE COUNTY (OR COUNTIES) THAT INCLUDES THE PROPOSED SITE (OR SITES). MARKET SHARE USED FOR THE CALCULATION SHALL BE THE CUMULATIVE MARKET SHARE OF THE POPULATION RESIDING IN THE SET OF ABOVE-DEFINED ZIP CODES OF ALL CURRENTLY LICENSED MICHIGAN HOSPITALS UNDER COMMON OWNERSHIP OR CONTROL~~OWNED BY, UNDER COMMON CONTROL OF, OR HAVING A COMMON PARENT~~ WITH THE APPLICANT, WHICH ARE IN THE SAME HEALTH SERVICE AREA.

PERCENT	POINTS AWARDED
% OF MARKET SHARE	% OF MARKET SHARE SERVED X 30 (TOTAL PTS. AWARDED)

THE SOURCE FOR CALCULATIONS UNDER THIS CRITERION IS THE MIDB.

Section 14. Review standards for comparative review of a limited access area

Sec. 14. (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) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects, when taken together, that 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 placed on the application by the Department when the application is filed.

(3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all currently licensed Michigan hospitals owned by, under common control of, or having as a common parent the applicant. The source document for the calculation shall be the most recent Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital owned by, under common control of, or having a common parent with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Ranking	Points Awarded
90.0 – 100	25 pts
80.0 – 89.9	20 pts
70.0 – 79.9	15 pts
60.0 – 69.9	10 pts
50.0 – 59.9	5 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(b) A qualifying project will be awarded points based on the statewide percentile rank of the applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all currently licensed Michigan hospitals owned by, under common control of, or having a common parent with the applicant. The source documents for the calculation shall be the Cost Report submitted to MDCH for purposes of calculating disproportionate share hospital payments. If a hospital owned by, under common control of, or having a common parent with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

Percentile Rank	Points Awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
Less than 50.0	0 pts

Where an applicant proposes to close a hospital as part of its application, data from the closed hospital shall be excluded from this calculation.

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity in the health service area of the proposed hospital site.

Impact on Capacity	Points Awarded
Closure of hospital(s)	15 pts
Move beds	0 pts
Adds beds (net)	-15 pts
or	
Closure of hospital(s) or delicensure of beds which creates a bed need	
or	
Closure of a hospital which creates a new Limited Access Area	

(d) A qualifying project will be awarded points based on the percentage of the applicant's market share of inpatient discharges of the population in the limited access area as set forth in the following table. Market share used for the calculation shall be the cumulative market share of Michigan hospitals owned by, under common control of, or having a common parent with the applicant.

Percent	Points Awarded
% of market share	% of market share served x 15 (total pts awarded)

The source for calculations under this criterion is the MIDB.

(e) A qualifying project will be awarded points based on the percentage of the limited access area's population within a 30 minute travel time of the proposed hospital site if in a metropolitan statistical area county, or within 60 minutes travel time if in a rural or micropolitan statistical area county as set forth in the following table.

Percent	Points Awarded
% of population within 30 (or 60) minute travel time of proposed site	% of population covered x 15 (total pts awarded)

(f) All applicants will be ranked in order according to their total project costs as stated in the CON application divided by its proposed number of beds in accordance with the following table.

Cost Per Bed	Points Awarded
Lowest cost	10 pts
2nd Lowest cost	5 pts
All other applicants	0 pts

Section 15. Documentation of market survey

Sec. 15. An applicant required to conduct a market survey under Section 3 shall specify how the market survey was developed. This specification shall include a description of the data source(s) used, assessments of the accuracy of these data, and the statistical method(s) used. Based on this documentation, the Department shall determine if the market survey is reasonable.

Section 16. Requirements for approval -- acquisition of a hospital

Sec. 16. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance with the needed hospital bed supply set forth in Appendix C for the subarea in which the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the following are met:

(a) the acquisition will not result in a change in bed capacity,

(b) the licensed site does not change as a result of the acquisition,

(c) the project is limited solely to the acquisition of a hospital with a valid license, and

(d) if the application is to acquire a hospital, which was proposed in a prior application to be

established as a long-term (acute) care hospital (LTAC) and which received CON approval, the applicant also must meet the requirements of Section 6(2). Those hospitals that received such prior approval are so identified in Appendix A.

Section 17. Requirements for approval – all applicants

Sec. 17. An applicant shall provide verification of Medicaid participation at the time the application is submitted to the Department. An applicant that is a new provider not currently enrolled in Medicaid shall provide a signed affidavit stating that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

Section 18. Health service areas

Sec. 18. Counties assigned to each of the health service areas are as follows:

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

919	Dickinson	Luce	Schoolcraft
920			
921			
922			

CON REVIEW STANDARDS FOR HOSPITAL BEDS

HOSPITAL SUBAREA ASSIGNMENTS

Health Service Area	Sub Area	Hospital Name	City
1 - Southeast			
	1A	North Oakland Med Centers (Fac #63-0110)	Pontiac
	1A	Pontiac Osteopathic Hospital (Fac #63-0120)	Pontiac
	1A	St. Joseph Mercy – Oakland (Fac #63-0140)	Pontiac
	1A	Select Specialty Hospital - Pontiac (LTAC - FAC #63-0172)*	Pontiac
	1A	Crittenton Hospital (Fac #63-0070)	Rochester
	1A	Huron Valley – Sinai Hospital (Fac #63-0014)	Commerce Township
	1A	Wm Beaumont Hospital (Fac #63-0030)	Royal Oak
	1A	Wm Beaumont Hospital – Troy (Fac #63-0160)	Troy
	1A	Providence Hospital (Fac #63-0130)	Southfield
	1A	Great Lakes Rehabilitation Hospital (Fac #63-0013)	Southfield
	1A	Straith Hospital for Special Surg (Fac #63-0150)	Southfield
	1A	The Orthopaedic Specialty Hospital (Fac #63-0060)	Madison Heights
	1A	St. John Oakland Hospital (Fac #63-0080)	Madison Heights
	1A	Southeast Michigan Surgical Hospital (Fac #50-0100)	Warren
	1B	Bi-County Community Hospital (Fac #50-0020)	Warren
	1B	St. John Macomb Hospital (Fac #50-0070)	Warren
	1C	Oakwood Hosp And Medical Center (Fac #82-0120)	Dearborn
	1C	Garden City Hospital (Fac #82-0070)	Garden City
	1C	Henry Ford –Wyandotte Hospital (Fac #82-0230)	Wyandotte
	1C	Select Specialty Hosp Wyandotte (LTAC - Fac #82-0272)*	Wyandotte
	1C	Oakwood Annapolis Hospital (Fac #82-0010)	Wayne
	1C	Oakwood Heritage Hospital (Fac #82-0250)	Taylor
	1C	Riverside Osteopathic Hospital (Fac #82-0160)	Trenton
	1C	Oakwood Southshore Medical Center (Fac #82-0170)	Trenton
	1C	Kindred Hospital – Detroit (Fac #82-0130)	Lincoln Park
	1D	Sinai-Grace Hospital (Fac #83-0450)	Detroit
	1D	Rehabilitation Institute of Michigan (Fac #83-0410)	Detroit
	1D	Harper University Hospital (Fac #/83-0220)	Detroit
	1D	St. John Detroit Riverview Hospital (Fac #83-0034)	Detroit
	1D	Henry Ford Hospital (Fac #83-0190)	Detroit
	1D	St. John Hospital & Medical Center (Fac #83-0420)	Detroit
	1D	Children's Hospital of Michigan (Fac #83-0080)	Detroit
	1D	Detroit Receiving Hospital & Univ Hlth (Fac #83-0500)	Detroit
	1D	St. John Northeast Community Hosp (Fac #83-0230)	Detroit
	1D	Kindred Hospital–Metro Detroit (Fac #83-0520)	Detroit
	1D	SCCI Hospital-Detroit (LTAC - Fac #83-0521)*	Detroit
	1D	Greater Detroit Hosp–Medical Center (Fac #83-0350)	Detroit
	1D	Renaissance Hosp & Medical Centers (Fac #83-0390)	Detroit
	1D	United Community Hospital (Fac #83-0490)	Detroit

*This is a hospital that must meet the requirement(s) of Section ~~15~~16(1)(d) - LTAC.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
1 – Southeast (continued)			
	1D	Harper-Hutzel Hospital (Fac #83-0240)	Detroit
	1D	Select Specialty Hosp–NW Detroit (LTAC - Fac #83-0523)*	Detroit
	1D	Bon Secours Hospital (Fac #82-0030)	Grosse Pointe
	1D	Cottage Hospital (Fac #82-0040)	Grosse Pointe Farm
	1E	Botsford General Hospital (Fac #63-0050)	Farmington Hills
	1E	St. Mary Mercy Hospital (Fac #82-0190)	Livonia
	1F	Mount Clemens General Hospital (Fac #50-0060)	Mt. Clemens
	1F	Select Specialty Hosp – Macomb Co. (FAC #50-0111)*	Mt. Clemens
	1F	St. John North Shores Hospital (Fac #50-0030)	Harrison Twp.
	1F	St. Joseph's Mercy Hosp & Hlth Serv (Fac #50-0110)	Clinton Township
	1F	St. Joseph's Mercy Hospital & Health (Fac #50-0080)	Mt. Clemens
	1G	Mercy Hospital (Fac #74-0010)	Port Huron
	1G	Port Huron Hospital (Fac #74-0020)	Port Huron
	1H	St. Joseph Mercy Hospital (Fac #81-0030)	Ann Arbor
	1H	University Of Michigan Health System (Fac #81-0060)	Ann Arbor
	1H	Select Specialty Hosp–Ann Arbor (Ltac - Fac #81-0081)*	Ann Arbor
	1H	Chelsea Community Hospital (Fac #81-0080)	Chelsea
	1H	Saint Joseph Mercy Livingston Hosp (Fac #47-0020)	Howell
	1H	Saint Joseph Mercy Saline Hospital (Fac #81-0040)	Saline
	1H	Forest Health Medical Center (Fac #81-0010)	Ypsilanti
	1H	Brighton Hospital (Fac #47-0010)	Brighton
	1I	St. John River District Hospital (Fac #74-0030)	East China
	1J	Mercy Memorial Hospital (Fac #58-0030)	Monroe
2 - Mid-Southern			
	2A	Clinton Memorial Hospital (Fac #19-0010)	St. Johns
	2A	Eaton Rapids Medical Center (Fac #23-0010)	Eaton Rapids
	2A	Hayes Green Beach Memorial Hosp (Fac #23-0020)	Charlotte
	2A	Ingham Reg Med Cntr (Greenlawn) (Fac #33-0020)	Lansing
	2A	Ingham Reg Med Cntr (Pennsylvania) (Fac #33-0010)	Lansing
	2A	Edward W. Sparrow Hospital (Fac #33-0060)	Lansing
	2A	Sparrow – St. Lawrence Campus (Fac #33-0050)	Lansing
	2B	Carelink of Jackson (Ltac Fac #38-0030)*	Jackson
	2B	W. A. Foote Memorial Hospital (Fac #38-0010)	Jackson
	2C	Hillsdale Community Health Center (Fac #30-0010)	Hillsdale
	2D	Emma L. Bixby Medical Center (Fac #46-0020)	Adrian
	2D	Herrick Memorial Hospital (Fac #46-0030)	Tecumseh

*This is a hospital that must meet the requirement(s) of Section ~~15~~16(1)(d) - LTAC.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
3 – Southwest			
	3A	Borgess Medical Center (Fac #39-0010)	Kalamazoo
	3A	Bronson Methodist Hospital (Fac #39-0020)	Kalamazoo
	3A	Borgess-Pipp Health Center (Fac #03-0031)	Plainwell
	3A	Lakeview Community Hospital (Fac #80-0030)	Paw Paw
	3A	Bronson – Vicksburg Hospital (Fac #39-0030)	Vicksburg
	3A	Pennock Hospital (Fac #08-0010)	Hastings
	3A	Three Rivers Area Hospital (Fac #75-0020)	Three Rivers
	3A	Sturgis Hospital (Fac #75-0010)	Sturgis
	3A	Sempercare Hospital at Bronson (LTAC - Fac #39-0032)*	Kalamazoo
	3B	Fieldstone Ctr of Battle Crk. Health (Fac #13-0030)	Battle Creek
	3B	Battle Creek Health System (Fac #13-0031)	Battle Creek
	3B	Select Spec Hosp–Battle Creek (Ltac - Fac #13-0111)*	Battle Creek
	3B	SW Michigan Rehab. Hosp. (Fac #13-0100)	Battle Creek
	3B	Oaklawn Hospital (Fac #13-0080)	Marshall
	3C	Community Hospital (Fac #11-0040)	Watervliet
	3C	Lakeland Hospital, St. Joseph (Fac #11-0050)	St. Joseph
	3C	Lakeland Specialty Hospital (LTAC - Fac #11-0080)*	Berrien Center
	3C	South Haven Community Hospital (Fac #80-0020)	South Haven
	3D	Lakeland Hospital, Niles (Fac #11-0070)	Niles
	3D	Lee Memorial Hospital (A) (Fac #14-0010)	Dowagiac
	3E	Community Hlth Ctr Of Branch Co (Fac #12-0010)	Coldwater
4 – WEST			
	4A	Memorial Medical Center Of West MI (Fac #53-0010)	Ludington
	4B	Kelsey Memorial Hospital (Fac #59-0050)	Lakeview
	4B	Mecosta County General Hospital (Fac #54-0030)	Big Rapids
	4C	Spectrum Hlth-Reed City Campus (Fac #67-0020)	Reed City
	4D	Lakeshore Community Hospital (Fac #64-0020)	Shelby
	4E	Gerber Memorial Hospital (Fac #62-0010)	Fremont
	4F	Carson City Hospital (Fac #59-0010)	Carson City
	4F	Gratiot Community Hospital (Fac #29-0010)	Alma

*This is a hospital that must meet the requirement(s) of Section ~~15~~16(1)(d) - LTAC.

(A) This is a hospital that has state/federal critical access hospital designation ~~(see Section 11)~~.

Health Service Area	Sub Area	Hospital Name	City
4 – West (continued)			
	4G	Hackley Hospital (Fac #61-0010)	Muskegon
	4G	Mercy Gen Hlth Partners–(Sherman) (Fac #61-0020)	Muskegon
	4G	Mercy Gen Hlth Partners–(Oak) (Fac #61-0030)	Muskegon
	4G	Lifecare Hospitals of Western MI (LTAC - Fac #61-0052)*	Muskegon
	4G	Select Spec Hosp–Western MI (LTAC - Fac #61-0051)*	Muskegon
	4G	North Ottawa Community Hospital (Fac #70-0010)	Grand Haven
	4H	Spectrum Hlth–Blodgett Campus (Fac #41-0010)	E. Grand Rapids
	4H	Spectrum Hlth–Butterworth Campus (Fac #41-0040)	Grand Rapids
	4H	Spectrum Hlth–Kent Comm Campus (Fac #41-0090)	Grand Rapids
	4H	Mary Free Bed Hospital & Rehab Ctr (Fac #41-0070)	Grand Rapids
	4H	Metropolitan Hospital (Fac #41-0060)	Grand Rapids
	4H	Saint Mary's Mercy Medical Center (Fac #41-0080)	Grand Rapids
	4I	Sheridan Community Hospital (A) (Fac #59-0030)	Sheridan
	4I	United Memorial Hospital & LTCU (Fac #59-0060)	Greenville
	4J	Holland Community Hospital (Fac #70-0020)	Holland
	4J	Zeeland Community Hospital (Fac #70-0030)	Zeeland
	4K	Ionia County Memorial Hospital (Fac #34-0020)	Ionia
	4L	Allegan General Hospital (Fac #03-0010)	Allegan
5 – GLS			
	5A	Memorial Healthcare (Fac #78-0010)	Owosso
	5B	Genesys Reg Med Ctr–Hlth Park (Fac #25-0072)	Grand Blanc
	5B	Hurley Medical Center (Fac #25-0040)	Flint
	5B	Mclaren Regional Medical Center (Fac #25-0050)	Flint
	5B	Select Specialty Hospital-Flint (LTAC - Fac #25-0071)*	Flint
	5C	Lapeer Regional Hospital (Fac #44-0010)	Lapeer
6 – East			
	6A	West Branch Regional Medical Cntr (Fac #65-0010)	West Branch
	6A	Tawas St Joseph Hospital (Fac #35-0010)	Tawas City
	6B	Central Michigan Community Hosp (Fac #37-0010)	Mt. Pleasant
	6C	Mid-Michigan Medical Center-Clare (Fac #18-0010)	Clare

*This is a hospital that must meet the requirement(s) of Section ~~15~~16(1)(d) - LTAC.

(A) This is a hospital that has state/federal critical access hospital designation ~~(see Section 11)~~.

Health Service Area	Sub Area	Hospital Name	City
6 – East (continued)			
	6D	Mid-Michigan Medical Cntr - Gladwin (Fac #26-0010)	Gladwin
	6D	Mid-Michigan Medical Cntr - Midland (Fac #56-0020)	Midland
	6E	Bay Regional Medical Center (Fac #09-0050)	Bay City
	6E	Bay Regional Medical Ctr-West (Fac #09-0020)	Bay City
	6E	Samaritan Health Center (Fac #09-0051)	Bay City
	6E	Bay Special Care (LTAC - Fac #09-0010)*	Bay City
	6E	Standish Community Hospital (A) (Fac #06-0020)	Standish
	6F	Select Specialty Hosp–Saginaw (LTAC - Fac #73-0062)*	Saginaw
	6F	Covenant Medical Centers, Inc (Fac #73-0061)	Saginaw
	6F	Covenant Medical Cntr–N Michigan (Fac #73-0030)	Saginaw
	6F	Covenant Medical Cntr–N Harrison (Fac #73-0020)	Saginaw
	6F	Healthsource Saginaw (Fac #73-0060)	Saginaw
	6F	St. Mary's Medical Center (Fac #73-0050)	Saginaw
	6F	Caro Community Hospital (Fac #79-0010)	Caro
	6F	Hills And Dales General Hospital (Fac #79-0030)	Cass City
	6G	Harbor Beach Community Hosp (A) (Fac #32-0040)	Harbor Beach
	6G	Huron Medical Center (Fac #32-0020)	Bad Axe
	6G	Scheurer Hospital (A) (Fac #32-0030)	Pigeon
	6H	Deckerville Community Hospital (A) (Fac #76-0010)	Deckerville
	6H	Mckenzie Memorial Hospital (A) (Fac #76-0030)	Sandusky
	6I	Marlette Community Hospital (Fac #76-0040)	Marlette
7 - Northern Lower			
	7A	Cheboygan Memorial Hospital (Fac #16-0020)	Cheboygan
	7B	Charlevoix Area Hospital (Fac #15-0020)	Charlevoix
	7B	Mackinac Straits Hospital (A) (Fac #49-0030)	St. Ignace
	7B	Northern Michigan Hospital (Fac #24-0030)	Petoskey
	7C	Rogers City Rehabilitation Hospital (Fac #71-0030)	Rogers City
	7D	Otsego Memorial Hospital (Fac #69-0020)	Gaylord
	7E	Alpena General Hospital (Fac #04-0010)	Alpena
	7F	Kalkaska Memorial Health Center (A) (Fac #40-0020)	Kalkaska
	7F	Leelanau Memorial Health Center (A) (Fac #45-0020)	Northport
	7F	Munson Medical Center (Fac #28-0010)	Traverse City
	7F	Paul Oliver Memorial Hospital (A) (Fac #10-0020)	Frankfort

*This is a hospital that must meet the requirement(s) of Section 15(1)(d) - LTAC.

(A) This is a hospital that has state/federal critical access hospital designation ~~(see Section 11)~~.

Health Service Area	Sub Area	Hospital Name	City
7 - Northern Lower (continued)			
	7G	Mercy Hospital - Cadillac (Fac #84-0010)	Cadillac
	7H	Mercy Hospital - Grayling (Fac #20-0020)	Grayling
	7I	West Shore Medical Center (Fac #51-0020)	Manistee
8 - Upper Peninsula			
	8A	Grand View Hospital (Fac #27-0020)	Ironwood
	8B	Ontonagon Memorial Hospital (A) (Fac #66-0020)	Ontonagon
	8C	Iron County General Hospital (Fac #36-0020)	Iron River
	8D	Baraga County Memorial Hospital (A) (Fac #07-0020)	L'anse
	8E	Keweenaw Memorial Medical Center (Fac #31-0010)	Laurium
	8E	Portage Health System (Fac #31-0020)	Hancock
	8F	Dickinson County Memorial Hospital (Fac #22-0020)	Iron Mountain
	8G	Bell Memorial Hospital (Fac #52-0010)	Ishpeming
	8G	Marquette General Hospital (Fac #52-0050)	Marquette
	8H	St. Francis Hospital (Fac #21-0010)	Escanaba
	8I	Munising Memorial Hospital (A) (Fac #02-0010)	Munising
	8J	Schoolcraft Memorial Hospital (A) (Fac #77-0010)	Manistique
	8K	Helen Newberry Joy Hospital (A) (Fac #48-0020)	Newberry
	8L	Chippewa Co. War Memorial Hosp (Fac #17-0020)	Sault Ste Marie

(A) This is a hospital that has state/federal critical access hospital designation ~~(see Section 11)~~.

APPENDIX B

CON REVIEW STANDARDS FOR HOSPITAL 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 C

CON REVIEW STANDARDS FOR HOSPITAL BEDS

The hospital bed need for purposes of these standards, effective September 19, 2006, and until otherwise changed by the Commission are as follows:

Health Service Area	SA No.	Bed Need
1 - SOUTHEAST		
	1A	2732
	1B	465
	1C	1497
	1D	2966
	1E	452
	1F	673
	1G	257
	1H	1571
	1I	50
	1J	150
2 - MID-SOUTHERN		
	2A	841
	2B	375
	2C	50
	2D	90
3 – SOUTHWEST		
	3A	853
	3B	270
	3C	233
	3D	67
	3E	61
4 – WEST		
	4A	59
	4B	51
	4C	19
	4D	13
	4E	38
	4F	145
	4G	376
	4H	1340
	4I	42
	4J	147
	4K	18
	4L	24
5 - GLS		
	5A	81
	5B	1126
	5C	117

APPENDIX C (Continued)

Health Service Area	SA No.	Bed Need
6 - EAST		
	6A	93
	6B	56
	6C	50
	6D	174
	6E	285
	6F	764
	6G	38
	6H	14
	6I	26
7 - NORTHERN LOWER		
	7A	38
	7B	188
	7C	24
	7D	32
	7E	84
	7F	374
	7G	63
	7H	57
	7I	36
8 - UPPER PENINSULA		
	8A	21
	8B	7
	8C	19
	8D	9
	8E	54
	8F	71
	8G	211
	8H	59
	8I	6
	8J	7
	8K	7
	8L	52

APPENDIX D

OCCUPANCY RATE TABLE

Adult Medical/Surgical

ADC >=	ADC<	Occup	Beds Start	Beds Stop
	30	0.60		<=50
31	32	0.60	52	52
32	34	0.61	53	56
35	37	0.62	57	60
38	41	0.63	61	65
42	46	0.64	66	72
47	50	0.65	73	77
51	56	0.66	78	85
57	63	0.67	86	94
64	70	0.68	95	103
71	79	0.69	104	114
80	89	0.70	115	126
90	100	0.71	127	140
101	114	0.72	141	157
115	130	0.73	158	177
131	149	0.74	178	200
150	172	0.75	201	227
173	200	0.76	228	261
201	234	0.77	262	301
235	276	0.78	302	350
277	327	0.79	351	410
328	391	0.80	411	484
392	473	0.81	485	578
474	577	0.82	579	696
578	713	0.83	697	850
714	894	0.84	851	894
895		0.85	>=1054	

Pediatric Beds

ADC >	ADC<=	Occup	Beds Start	Beds Stop
	30	0.50		<=50
30	33	0.50	61	66
34	40	0.51	67	79
41	46	0.52	80	88
47	53	0.53	89	100
54	60	0.54	101	111
61	67	0.55	112	121
68	74	0.56	122	131
75	80	0.57	132	139
81	87	0.58	140	149
88	94	0.59	150	158
95	101	0.60	159	167
102	108	0.61	168	175
109	114	0.62	176	182
115	121	0.63	183	190
122	128	0.64	191	198
129	135	0.65	199	206
136	142	0.66	207	213
143	149	0.67	214	220
150	155	0.68	221	226
156	162	0.69	227	232
163	169	0.70	233	239
170	176	0.71	240	245
177	183	0.72	246	252
184	189	0.73	253	256
190	196	0.74	257	262
197		0.75	>=263	

Obstetric Beds

ADC >	ADC<=	Occup	Beds Start	Beds Stop
	30	0.50		<=50
30	33	0.50	61	66
34	40	0.51	67	79
41	46	0.52	80	88
47	53	0.53	89	100
54	60	0.54	101	111
61	67	0.55	112	121
68	74	0.56	122	131
75	80	0.57	132	139
81	87	0.58	140	149
88	94	0.59	150	158
95	101	0.60	159	167

Obstetric Beds cont.

ADC >	ADC<=	Occup	Beds Start	Beds Stop
122	128	0.64	191	198
129	135	0.65	199	206
136	142	0.66	207	213
143	149	0.67	214	220
150	155	0.68	221	226
156	162	0.69	227	232
163	169	0.70	233	239
170	176	0.71	240	245
177	183	0.72	246	252
184	189	0.73	253	256
190	196	0.74	257	262
197		0.75	>=263	

102	108	0.61	168	175
109	114	0.62	176	182
115	121	0.63	183	190

APPENDIX E

LIMITED ACCESS AREAS

Limited access areas and the hospital bed need, EFFECTIVE MAY 27, 2005, for each of those areas are identified below. The hospital bed need for limited access areas shall be changed by the department in accordance with section 2(1)(q) of these standards, and this appendix shall be updated accordingly.

HEALTH SERVICE AREA	LIMITED ACCESS AREA	BED NEED	POPULATION FOR PLANNING YEAR
7	Alpena/Plus 1204	135	59,422
8	Upper Peninsula 1204	179	108,917

Sources:

1) Michigan State University
Department of Geography
Hospital Site Selection Final Report
November 3, 2004, as amended

2) Section 4 of these standards

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH AND MEDICAL AFFAIRS

CON REVIEW STANDARDS FOR HOSPITAL BEDS
-- ADDENDUM FOR PROJECTS FOR HIV INFECTED INDIVIDUALS --

(By authority conferred on the CON Commission by sections 22215 and 22217 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, 333.2217, 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 Hospital Beds and may be used for determining the need for projects established to meet the needs of HIV infected individuals.

(2) Except as provided by sections 2 and 3 below, these standards supplement and do not supercede the requirements and terms of approval required by the CON Review Standards for Hospital Beds.

(3) The definitions that apply to the CON Review Standards for Hospital Beds apply to these standards.

(4) "HIV infected" means that term as defined in Section 5101 of the Code.

(5) Planning area for projects for HIV infected individuals means the State of Michigan.

Section 2. Requirements for approval; change in bed capacity

Sec. 2. (1) A project which, if approved, will increase the number of licensed hospital beds in an overbedded subarea or will result in the total number of existing hospital beds in a subarea exceeding the needed hospital bed supply as determined under the CON Review Standards for Hospital Beds may, nevertheless, be approved pursuant to subsection (3) of this addendum.

(2) Hospital beds approved as a result of this addendum shall be included in the Department inventory of existing beds in the subarea in which the hospital beds will be located. Increases in hospital beds approved under this addendum shall cause subareas currently showing a current surplus of beds to have that surplus increased.

(3) In order to be approved under this addendum, an applicant shall demonstrate all of the following:
(a) The Director of the Department has determined that action is necessary and appropriate to meet the needs of HIV infected individuals for quality, accessible and efficient health care.
(b) The hospital will provide services only to HIV infected individuals.
(c) The applicant has obtained an obligation, enforceable by the Department, from existing licensed hospital(s) in any subarea of this state to voluntarily delicense a number of hospital beds equal to the number proposed in the application. The effective date of the delicensure action will be the date the beds approved pursuant to this addendum are licensed. The beds delicensed shall not be beds already subject to delicensure under a bed reduction plan.
(d) The application does not result in more than 20 beds approved under this addendum in the State.

(4) In making determinations under Section 22225(2)(a) of the Code, for projects under this addendum, the Department shall consider the total cost and quality outcomes for overall community health systems for services in a dedicated portion of an existing facility compared to a separate aids facility and has determined that there exists a special need, and the justification of any cost increases in terms of important quality/access improvements or the likelihood of future cost reductions, or both.

Section 3. Project delivery requirements--additional terms of approval for projects involving HIV infected individuals approved under this addendum.

Sec. 3. (1) An applicant shall agree that, if approved, the services provided by the beds for HIV infected individuals shall be delivered in compliance with the following terms of CON approval:

(a) The license to operate the hospital will be limited to serving the needs of patients with the clinical spectrum of HIV infection and any other limitations established by the Department to meet the purposes of this addendum.

(b) The hospital shall be subject to the general license requirements of Part 215 of the Code except as waived by the Department to meet the purposes of this addendum.

(c) The applicant agrees that the Department shall revoke the license of the hospital if the hospital provides services to inpatients other than HIV infected individuals.

Section 4. Comparative reviews

Sec. 4. (1) Projects proposed under Section 3 shall be subject to comparative review.

STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
LANSING

JENNIFER M. GRANHOLM
GOVERNOR

JANET OLSZEWSKI
DIRECTOR

CERTIFICATE OF NEED COMMISSION

December 12, 2006

TO: Governor Jennifer M. Granholm
Members of the Joint Legislative Committee on Certificate of Need
Representative Edward Gaffney, Co-Chairperson
Senator Beverly S. Hammerstrom, Co-Chairperson
Representative Stephen Adamini, Member
Senator Gretchen Whitmer, Member
Representative Gary Newell, Member
Senator Bruce Patterson, Member

FROM: Norma Hagenow, Chairperson
Certificate of Need Commission (CON)

SUBJECT: CON Review Standards for Bone Marrow Transplant (BMT)
Clarification of Review Process by CON Commission

On behalf of the Certificate of Need (CON) Commission, I am writing in response to the recent letters received by the CON Commission regarding its proposed final action for proposed Bone Marrow Transplantation (BMT) standards at its December 12, 2006 meeting. The letters requested the Commission to undertake a further review of the BMT standards in light of emerging science, evolving practice patterns and the desire to allow additional BMT programs in Michigan. The Commission, at its December 12, 2006 meeting, did in fact receive some additional input and undertook additional deliberations regarding the proposed BMT standard. The Commission elected to affirm its previous decision and by a unanimous vote (with two abstentions due to conflict of interest) approved the proposed standards.

During its deliberations, the Commission carefully considered all available information and expert testimony presented to it and, of course, is more than willing to consider any new additional supportable data or scientific information that would compel re-reviewing the BMT standards prior to their next review that is scheduled for 2008. This includes any emerging information related to embryonic or cord blood stem cell research.

At its December 12, 2006 meeting, however, it also became clear to Commission members that a significant amount of inaccurate information about the Commission's actual BMT review process and the BMT standards themselves was, unfortunately, being provided to some legislative members and other concerned decision makers. In response, I have provided the following clarification of the Commission's BMT review process and Michigan's BMT Program:

The Commission pursued a thorough process on BMT that involved considerable testimony and Commission discussion at four Commission meetings (Dec. '05, March '06, June '06, and Sept.

'06). The Commission again at its December 12, meeting heard extensive pro-and-con testimony from BMT medical experts with widely divergent opinions.

The Commission established a Work Group to further consider this issue between Commission meetings. It did not reach a consensus for action. A majority of the Work Group (partially comprised of multiple people from the hospitals advocating more programs) recommended that the Commission establish a more formal BMT Standards Advisory Committee (SAC), one option authorized by the Legislature for us to use. The Commission, however, concluded not to proceed with a SAC, in part, because all available information had been already reviewed and no consensus recommendation emerged.

Adding more programs in southeast Michigan would not improve BMT "affordability, accessibility or quality" and could have an adverse effect on costs and the volume numbers and practice proficiency of the three existing Southeastern Michigan BMT programs. The Commission, of course, is always open to substantive new information about why those three criteria would indicate there should be more adult programs in southeast Michigan. We have asked any possible new data or medical research studies be provided in writing so that MDCH staff can analyze and report that to us.

The Commission believes that there may be an access problem for adult BMT in West Michigan and Northern Michigan. At the Commission's September meeting, various Commissioners indicated openness to the proposal to divide the state into two planning areas (east - west) for adult BMT services, as was previously done by the predecessor Commission for pediatric BMT programs. At the September 2006 meeting, the Commission requested clear evidence of enough patients for either a northern or western Michigan program to assure safety and quality of those services.

Finally, the CON Commission has been getting a number of persistent questions about BMT that reflect a misunderstanding about the CON BMT review process and standard.

Why is BMT the only CON program with a statewide numeric limit on the number of programs? It's not. Other programs with statewide numeric limits are transplants of hearts, transplants of lungs, and heart-lung combination transplants. In addition, there are separate numeric limits for the many local planning areas on the number in each area of acute-care, long-term care/nursing home, and psychiatric beds.

Why hasn't the BMT CON Standard been updated in 20 years? It has. The BMT standard was reviewed in 1989, 1993, and 1997. Minor technical revisions were made in March 2004, and June 2005. One of those occasions was when the limit of three programs in the state was modified to allow for a pediatric program in western Michigan. There are now six bone marrow transplant programs in Michigan, three pediatric and three adult and the Commission is exploring the need for an additional adult program in west Michigan.

Shouldn't Commissioners employed by one of the three hospitals (U of M, Henry Ford, or Karmanos) with existing BMT programs not vote on the issue? They didn't. The two affected Commissioners themselves indicated that they had a conflict of interest and would not vote on this matter. At the December 12 meeting, both of these individuals again abstained from voting on this issue. The Commission has carefully followed advice received from the State Ethics Board and as advised by their assigned Assistant Attorney General.

Simply put, adequate regional BMT capacity exists in Southeastern Michigan. Quality and patient outcome is related to the number of procedures a team will do in a given year. Increasing the number of programs serving a stable number of cases within a region will by definition lesson the number of procedures each team will perform.

Hopefully, this information will help to clarify the Commission's actions related to its most recent review of BMT standards. The Commission greatly appreciates the Legislature's active interest and support for Michigan's CON program as we try to help control rising health care costs, improve quality and provide appropriate access for Michigan citizens.

Please feel free to contact me at, 810.606.6601, or Brenda Rogers, Special Assistant to the Commission, at 517.241.3349 if you have any further questions.

Sincerely,

Norma Hagenow, Chairperson

cc: Members of the Senate
Members of the House of Representatives
Janet Olszewski, Director Michigan Department of Health
Jan Christensen, Health Policy, Regulation and Professions, MDCH
William J. Hart, Jr., Health Policy, Regulation and & Professions Administration, MDCH
Irma Lopez, Health Policy Section, MDCH
Brenda Rogers, Special Assistant to the Certificate of Need Commission, MDCH

Sincerely,

Peter Ajluni, D.O. Orthopedic Surgical Phy P.C.	Roger G, Andrejewski Lacks Enterprises	Bradley N. Cory
Dorothy E. Deremo Hospice of Michigan	Edward B. Goldman University of Michigan	Marc D. Keshishian, M.D. Blue Care Network
Adam A. Miller UAW	Michael A. Sandler, M.D. Henry Ford Hospital	Michael W. Young D.O. Genesys Integrated Group

Kathie L. VanderPloeg-Hoekstra
Ship-Pac Inc.

Dated: December 12, 2006

Magnetic Resonance Imaging (MRI) Services Workgroup 2006

Discussion Items – Working Document

Prepared by: MDCH

1. Review Section 13(2)(e) – consider whether or not a rural multiplier should be allowed for expansion. Note: Consideration from 1/31/06 Public Hearing.	
Current Standards: Sec. 13. (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, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), 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, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), 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, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), 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.	Status: 5/16/06: The workgroup agreed that the multiplier would be allowed for the second unit only. Subsection 13(2)(e) would be changed to read as follows: (e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (~~second,~~ third, FOURTH, etc.) at the same site. 9/19/06: Dr. Sandler reported to the CON Commission that this item needed further discussion – another workgroup meeting will be scheduled. *Policy Perspective*: The creation of a rural multiplier (currently 1.4) was designed to be used to calculate the adjusted procedures required to obtain an initial fixed MRI unit in rural and micropolitan statistical areas. It recognizes the disadvantages associated with low population densities found in such areas. The multiplier addresses the density barrier that denies a fixed service for these communities. However, once the initial magnet is obtained and the rural or micropolitan area has a fixed service available, that fixed MRI unit must perform at the levels proscribed for all other fixed units when expansion is contemplated. There is not a sufficient rationale to support this change to the current use of the rural multiplier from its current use on only the first MRI. 10/23/06: Workgroup meeting held. Based on limited discussion, no consensus was reached. Dr. Sandler will report to the Commission at its December 12, 2006 meeting.

2. Consider partial use of a clinical MRI for research and consider weights for partial use of a clinical MRI visit for research. Note: Consideration from 1/31/06 Public Hearing.	
Current Standards: 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 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. (f) 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. (g) For each MRI procedure performed at a teaching facility, 0.15 shall be added to the base value. (h) The results of subsections (a) through (g) shall be summed, and that sum shall represent an MRI adjusted procedure. Note: The current standards allow for research scans to be done on a clinical MRI unit and for those scans to be counted.	Status: 5/16/06: The concept would allow for clinical use during the research unit's "downtime," which could help the institution defray the cost of the research unit. The current standards allow for clinical scans to be done on a research, but they are not billable scans. Joan Lowes, representing University Physican's Group, will draft language and work with the Department. Lynn Bosscher, Spectrum Health, will draft language for the weight. 9/19/06: The CON Commission approved & moved forward language for Public Hearing that would allow 0.25 to be added to the base value for each MRI visit that involves both a clinical and research scan on a single patient in a single visit. 9/19/06: Dr. Sandler reported to the CON Commission that the partial use of a clinical MRI for research needed further discussion – another workgroup meeting will be scheduled. *Policy Perspective*: DCH has concerns that dual purpose research/clinical MRI units could, over time, be subject to inappropriate utilization. The typically time-limited nature of research projects could make meaningful compliance activities difficult. The potential "extra" capacity available via a research/clinical machine could provide the owner with a built-in procedure generation to support subsequent service expansions. Similar concerns were shared with the CON Commission during the discussion on dual purpose research/clinical PET units on September 19, 2006. At that time, the Commission did not approve the dual purpose services. The Department sees little difference in these discussions. Finally, there is no compelling evidence that the existing review standards governing fully dedicated research MRI units are inadequate. 10/23/06: Workgroup meeting held. Joan Lowes, representing University Physician's Group, stated that they were withdrawing their request to consider this issue at this time. Dr. Sandler will report to the Commission at its December 12, 2006 meeting.

3. Consider elimination of Sec. 3(4)(c)(ii)(A) for conversion from a mobile unit to a fixed MRI unit for rural hospitals. Note: Consideration from 1/31/06 Public Hearing.	
Current Standards: Sec. 3. (4) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1): (a) The applicant is proposing to initiate a fixed MRI service. (b) The applicant is currently a host site being served by one or more mobile MRI units. (c) The applicant has received, in aggregate, the following: (i) at least 6,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available or (ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, and the applicant meets all of the following: (A) is located in a county that has no fixed MRI machines that are pending, approved by the Department, or operational at the time the application is deemed submitted; (B) the nearest fixed MRI machine is located more than 15 radius miles from the application site; (C) the applicant is a nonprofit licensed hospital site; (D) the applicant certifies in its CON application, by providing a governing body resolution, that the board of trustees of the facility has performed a due diligence investigation and has determined that the fixed MRI service will be economically viable to ensure provision of safe and appropriate patient access within the community hospital setting. (d) All of the MRI adjusted procedures provided at the applicant's approved site in the most recent 12-month period, referenced in (c) above, by each mobile MRI service/units from which any of the MRI adjusted procedures are being utilized to meet the minimum 6,000 or 4,000 MRI adjusted procedures shall be utilized to meet the requirements of (c). [For example: If mobile network 19 provided 4,000 adjusted procedures, network 21 provided 2,100, and network 18 provided 1,000, all of the adjusted procedures from network 19 and 21 must be used (i.e., 6,100) but the 1,000 adjusted procedures from network 18 do not need to be used to meet the 6,000 minimum.] (e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site.	Status: 5/16/06: Eliminate Section 3(4)(c)(ii)(A) for rural and micropolitan statistical area counties. Lynne Bosscher, Spectrum Health, will draft language. 9/19/06: Dr. Sandler reported to the CON Commission that this item needed further discussion – another workgroup meeting will be scheduled. *Policy Perspective*: Applying the CON principles of cost, quality, and access to the issue of additional fixed MRIs in counties currently served by a fixed unit, the Department has not identified a quality issue since the quality of a magnetically resonanced image is not dependent on whether the machine producing the image is movable or not. Further, the availability of a fixed service in the county insures that any perceived quality issue can be resolved by using the fixed magnet. Access can be addressed by the availability of mobile as well as fixed service in the county. If the mobile site requires additional time, the service provider in most cases can make such time available. The final issue, cost, speaks against allowing the use of 4,000 MRI adjusted procedures and in favor of 6,000. The greater procedure level insures that a machine, acquired at a fixed cost, will be functioning at a more cost effective level per procedure. At the current time, there does not appear to be sufficient rationale to support the suggested change. 10/23/06: Workgroup meeting held. No consensus was reached. However, Dr. Sandler asked the parties involved (Walt Wheeler, Carey Kalmowitz, and Bob Meeker) to draft language and submit it to the Department for their review. The Department agreed to review the language but does not support the policy change. Dr. Sandler will report to the Commission at its December 12, 2006 meeting.

4. A proposed change to Section 13(2)(a) that would allow certain Michigan hospitals currently treated as located in “metropolitan” counties to be treated as “rural” counties for purposes of calculating their actual adjusted MRI procedures. The eligible hospitals are the only hospitals in their counties and qualify under the Public Health Code to be designated as “critical providers” for purposes of the federal Critical Access Hospital program. Note: This proposal was received prior to the 9/19/06 CON Commission meeting and has not been reviewed by the workgroup.	
Current Standards: Sec. 13. (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, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), 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, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), 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, or for the November 1, 2005 MRI Service Utilization List, a county designated as "rural" as that term was defined under the "standards for defining metropolitan areas in the 1990s" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p 12154 (March 30, 1990), 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.	Status: 9/19/06: Dr. Sandler reported to the CON Commission that this item needed discussion – another workgroup meeting will be scheduled. *Policy Perspective*: As background, the Department supported the original language allowing counties designated as rural by the Statistical Policy Office of the Office of Information and Regulatory Affairs of the United States, Office of Management and Budget to be considered rural for the purpose of allowing them to complete fixed MRI service applications. The change in designations caught several counties unawares, and the CON Commission felt it fair to allow them to continue to be considered rural in this limited situation. While the language being proposed is somewhat similar to the earlier waiver, the Department has not had sufficient time to thoroughly review this newly suggested language but notes that language governing the November 1, 2005 MRI list has expired. 10/23/06: Workgroup meeting held. No consensus was reached. There appear to be 4 counties that would be impacted should the language be changed: Clinton, Newaygo, Cass, and Ionia. Only 3 of these counties were previously designated as rural counties: Newaygo, Cass, and Ionia. Dr. Sandler asked Brian Kaser, representing Clinton Memorial, to draft language and submit it to the Department for their review. The Department agreed to review the language but does not support the policy change. Dr. Sandler will report to the Commission at its December 12, 2006 meeting.

5. A proposed change to Section 3(4)(e) that would allow for the fixed MRI unit, after converting from mobile to fixed, to be placed within the relocation zone rather than at the applicant's current, approved host site. Note: This proposal was received after the 9/19/06 CON Commission meeting and has not been reviewed by the workgroup.

Current Standards:

Sec. 3. (4) An applicant that meets all of the following requirements shall not be required to be in compliance with subsection (1):

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

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

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

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

(ii) at least 4,000 MRI adjusted procedures within the most recent 12-month period for which data, verifiable by the Department, are available, and the applicant meets all of the following:

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

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

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

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

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

(e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site.

Status:

Background

12/9/03: CON Commission agreed to have the Department along with Dr. Sandler as the Commission Liaison to put together a group to look at a lower threshold for conversion (the resulting 4,000).

2/4/04: Workgroup meeting held.

3/9/04: Language presented to the Commission, including the requirement that the fixed unit be placed at the same site as the current, approved host site. Commission took Proposed Action.

4/1/04: Public Hearing held.

5/11/04: Commission took Final Action.

Policy Perspective: Subsection (e) has been written and rewritten as permissive and restrictive at different times over the last several years. Since an MRI unit can be relocated within the relocation zone already, approving this language would allow the unit to be converted and placed within the relocation zone all at the same time, saving the provider and the Department the additional expense and paperwork associated with two (2) applications. This change could be supported by the Department.

10/23/06: Workgroup meeting held. Consensus was reached to support the recommended change. Language for Section 3(4)(e) and technical changes for the definition of "licensed hospital site," Section 2(v), will be written as shown below. Dr. Sandler will report to the Commission at its December 12, 2006 meeting.

Section 3(4)(e):

(e) The applicant shall install the fixed MRI unit at the same site as the existing approved host site OR AT THE APPLICANT'S LICENSED HOSPITAL SITE AS DEFINED IN THESE STANDARDS.

Section 2(v):

	(v) "Licensed hospital site" means a health facility licensed under Part 215 of the Code. In the case of a single site hospital, it is ~~either (i)~~ the location of the facility authorized by license and listed on that licensee's certificate of licensure or ~~(ii)~~ in the case of a hospital with multiple sites, the location of each separate and distinct inpatient unit of the health facility as authorized by the licensee's certificate of licensure.

Psychiatric Beds and Services Workgroup 2006

Report to the Certificate of Need Commission

December 12, 2006

The Psychiatric Beds and Services Workgroup was established at the March 21, 2006 Certificate of Need (CON) Commission Meeting. The Commission assigned the Workgroup to follow up on the comments received regarding these Standards at the Public Hearing, held on January 31, 2006. The Workgroup has met on three (3) occasions and the next meeting is scheduled for January.

The Workgroup has reached a proposed consensus package consisting of modifying the following: the adult planning areas, the replacement zone and the minimum number of beds per unit. In addition a pilot program which allows the number of licensed beds per facility to fluctuate with the facility's occupancy rate for the previous 24 months under a renewing license concept. This would eliminate both underutilized beds at some facilities and high occupancy at other facilities.

This innovative approach uses concepts of quality improvement so that normal fluctuations in bed need within a reasonable range (common cause variation) will be handled via this automatic process. The advantage of this approach is the freeing up of the Department of Community and the CON Commission to focus their valuable time and attention on unusual (special cause variation) requests that require significant study and deliberation.

The Workgroup has worked through several implementation issues and continues to move forward. The proposed package and draft language will be reviewed by the Workgroup and is expected to be presented at the March 13, 2007 Commission meeting.

Respectfully submitted,

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

MEMORANDUM

Date: December 12, 2006

To: Joint Legislative Committee (JLC)

From: Certificate of Need (CON) Commission

RE: Recommendations Pertaining to the CON Program

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

Accordingly, the Commission respectfully submits the following:

Based on our ongoing review of the program, the Commission believes and unanimously recommends that the program is serving a valuable need and should be fully supported. In our bipartisan judgment, we have found that CON provides ongoing and significant benefits to assuring affordability, accessibility, and quality of health care in Michigan, thus meeting the three statutory objectives for the program. Also, we would recommend that the JLC not eliminate any further items from the list of covered services.

In addition to the responsibility of submitting the 2-year report on whether the program should be continued, subsection, MCL 333.22215(1)(e) of the CON law requires the Commission to "Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission." A copy of the 2005 CON Program Activity Report is being provided. The 2006 CON Program Activity Report will be sent under separate cover. Along with the annual report, the Department now provides quarterly program section performance reports to the Commission demonstrating the effectiveness of the CON program in processing letters of intent, applications, emergency applications, and amendments as well as issuing decisions within the specified time frames set forth in the Administrative Rules.

Finally, we would like to provide the JLC a brief summary of our activities and accomplishments since the March 2005 report. A summary of the approved changes to various CON Review Standards is attached. In addition, administrative changes, which were undertaken, are identified below.

- MCL 333.22215(1)(m) states, in part, "…review and, if necessary, revise each set of certificate of need review standards at least every 3 years." To comply with this statutory requirement, a rotating schedule has been adopted to review/update 5 – 6 sets of review standards each year, thus completely reviewing the 16 separate review standards over the 3 year time period. A Public Hearing is held each January to receive comments regarding the standards scheduled for review in that year.

- In support of the Commission, the Department has instituted the use of on-line submission of Public Hearing written testimony, on-line submission of nominations for Standard Advisory Committees (SACs), and web posting of audio transcripts of CON Commission meetings and SAC meetings.

- In support of administering the program, the Department has instituted the use of on-line submission of letters of intent. The on-line letter of intent module was made available to

applicants in January 2006, while the on-line management information module became available in July providing statewide public access to more than 8,000 CON records. Additional modules, under development and to be released in 2007, include on-line applications, amendments and emergency CONs with the ability to pay application fees on-line. As part of the on-line development, the Department conducted an extensive review of the application process and forms used eliminating numerous unnecessary forms and merging duplicative forms to create a more efficient process for CON applicants.

- In March 2006, the Department instituted publishing the bed need inventories on-line allowing potential applicants greater access to identify bed need areas throughout the State for hospital, neonatal intensive care unit, adult and adolescent psychiatric, nursing home, and special population nursing home beds.

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

Respectfully yours,

Norma Hagenow, Chairperson

Edward B. Goldman, Vice-Chairperson

Peter Ajluni, DO

Roger G. Andrzejewski

Bradley N. Cory

Dorothy E. Deremo

Marc D. Keshishian, MD

Adam A. Miller

Michael A. Sandler, MD

Kathie L. VanderPloeg-Hoekstra

Michael W. Young, DO

cc: Janet Olszewski. Director, MDCH
Dave McLaury, Chief Deputy Director, MDCH
Jan Christensen, Deputy Director, Health Policy, Regulation & Professions Administration, MDCH
Ron Styka, Division Chief, Attorney General's Office

bc: William J. Hart, Interim Bureau Director, Bureau of Health Policy, Planning & Access, MDCH
Mike Dankert, Director, Bureau of Health Systems, MDCH
Larry Horvath, Manager, CON Program Section, MDCH
John Hubinger, Director, Division of Community Health Policy, MDCH
Irma Lopez, Manager, CON Policy Section, MDCH
Brenda Rogers, Special Assistant to the Commission, CON Policy Section, MDCH

SUMMARY OF CON REVIEW STANDARDS CHANGES
(2005 – 2006)

- Revised the CON Review Standards for Nursing Home and Hospital Long-Term-Care Unit Beds. A statewide pilot (four years from the effective date of the addendum) program was established to study the potential benefit of new designs in the new construction, renovation, and/or replacement of existing nursing home and hospital long-term-care facilities throughout Michigan. The changes allow for projects that will enhance privacy, promote greater dignity, and increase the quality of life for residents. Pilot projects are established according to the current bed need methodology and do not add new beds to the existing statewide inventory. In addition, there is language that will assure recent investments made by nursing home operators to improve existing facilities, within five years prior to the effective date of the addendum, are not adversely impacted by the pilot program. Finally, the 450 gross square feet per bed maximum has been removed to allow for greater design flexibility for all new nursing homes statewide (not part of pilot program, but applicable to future nursing home development).

- Revised the CON Review Standards for Hospital Beds. Modifications, summarized below, were designed to improve the standards for acute care hospitals and their beds.

  - "Limited access areas" are defined as areas with significant population more than 30 minutes drive time from an acute care hospital with an emergency room. This is in response to major shifts in population within a subarea. The standards have provisions regarding the number of beds that may be available to a potential additional hospital and outlines what services they shall provide. Two areas have been identified as likely meeting the criteria for "limited access areas" and thus potentially eligible for the establishment of new hospitals: 1) Alpena area, and 2) the Upper Peninsula. Since there may be multiple applicants to start new hospitals in these areas, six comparative review criteria have been established in the standards to determine which applicants would receive the CONs for "limited access areas."

  - The prior pilot program for "high occupancy hospitals" which allows qualifying hospitals to add licensed hospital beds even in an overbedded subarea has been made permanent. High occupancy has been defined as 80% and above for smaller hospitals (less than 300 beds) and 85% and above for larger hospitals (300 beds and above).

- Revised the CON Review Standards for Psychiatric Beds and Services. The average occupancy rate for adult beds has been reduced from "90 percent" to "85 percent" in Section 6(2)(d) of the standards and several other technical changes have been made. Language has been added that would allow an applicant to apply for up to a maximum 20 beds in a Planning area that has a bed need of 1 or more but less than 20. The bed need methodology has been re-run and the bed need numbers have been updated accordingly. Further, the requirement that all existing adult or child/adolescent beds in a planning area must have an average occupancy rate of 85% for adults and 75% for child/adolescent has been restricted to existing facilities.

- Revised the CON Review Standards for Bone Marrow Transplantation Services. Acquisition of an existing bone marrow transplantation service has been approved.

- Revised the CON Review Standards for Magnetic Resonance Imaging (MRI) Services. Metropolitan counties (based on the 2000 census) that were previously identified as rural counties (based on the 1990 census) are allowed to receive the rural factor as calculated under

Section 13(2)(a), (b), and (c) and pursuant to Section 3(4)(c)(ii) for a limited period of time. The changes impacted the November 1, 2005 MRI Service Utilization List, and applicants had until April 1, 2006 to use the list.

- Revised the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units. The following modifications, summarized below, have been implemented:

  - Definitions refined.
  - Need methodology updated based on current available data (i.e., duplication rates/factors, etc.).
  - Key terms incorporated in accordance with P.A. 619 of 2002 (i.e., definition of rural, Medicaid participation requirements, etc.).
  - Requirement for demonstration of qualified staff for applicants proposing to begin operation of an MRT service.
  - Volume requirements modified for applicants proposing to replace/upgrade an existing MRT unit.
  - Addition of provisions to acquire and relocate existing MRT units under certain conditions.
  - Weights modified for treatment equivalents methodology, including IMRT.

- Revised the CON Review Standards for Surgical Services. The following modifications, summarized below, have been implemented:

  - Requirement that all volume projections justifying need for additional operating rooms are developed and documented based only on surgical cases performed in an existing operating room.
  - New definitions as well as technical revisions for improved clarity.
  - Qualified burn and trauma centers to receive an adjustment of .5 as part of the operating room inventory, as applicable, without any adjustment in their case/hours count.
  - Separate determinations of need for inpatient and outpatient surgical services, regardless of setting.
  - Separate requirements for maintenance of current surgical capacity and for expansion of new surgical capacity.
  - Revised volume requirements.
  - A ”blended method” of determining hospital-based operating room need, whereby a hospital could employ the hours-based standard for inpatient surgical capacity and the cases-based standard for outpatient surgical capacity.
  - A separate need standard developed for hospitals with surgical services in rural, micropolitan, and like areas.
  - The status of dedicated cystoscopy and endoscopy rooms clarified and the CON review process for those specialized operating rooms specified.
  - Requirements for Medicaid participation added as a result of PA 619 of 2002.

CERTIFICATE OF NEED

Quarterly Program Section Activity Report to the CON Commission

FY 2006 Year End Report

(July 1, 2006 through September 30, 2006)

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

Measures

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

Activity	Most Recent Quarter	Year-to-Date
Letters of Intent Received	139	561
Letters of Intent Processed within 15 days	139	548

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

Activity	Most Recent Quarter	Year-to-Date
Applications Received	92	383
Applications Processed within 15 Days	92	383
Applications Incomplete/More Information Needed	83	365

Administrative rules 325.9206 and 325.9207 requires the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Nonsubstantive Applications	42	0	162	0
Substantive Applications	30	0	173	2
Comparative Review Applications	0	0	3	0

Administrative Rule 325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	Most Recent Quarter	Year-to-Date
Emergency Applications Received	0	3
Decisions Issued within 10 workings Days	0	3

Measures – continued

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

Activity	Most Recent Quarter		Year-to-Date	
	Issued on Time	Not Issued on Time	Issued on Time	Not Issued on Time
Amendments	18	2	84	13

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

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

Other

Activity	Most Recent Quarter	Year-to-Date
FOIA Requests Received	59	333
FOIA Requests Processed on Time	59	333
Number of Applications Viewed Onsite	18	220

FOIA – Freedom of Information Act. Processing on time includes extension requests.

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

Attachment M

December 11, 2006

Norma Hagenow
Chairperson
Certificate of Need Commission
Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street, 7th Floor
Lansing, Michigan 48913

Dear Chairperson Hagenow,

I am writing as the Owner/Operator of Josephson Nursing Home, a 47 bed skilled nursing facility in Ironwood, Michigan, Gogebic County.

Our family owned corporation (CC&S) bought the facility August 29, 2003. At the time of purchase all of the beds were Medicaid certified only. On July 20, 2005, we became dually certified for all 47 beds. The original Josephson Nursing Home was built about 109 years ago with the adjacent resident structure completed in 1984. The new Life Safety Code Regulations deem it necessary that we abandon the original structure for all resident use. As new owner/operators, we had anticipated moving forward at a rapid pace but are not afforded the luxury of available assets to fund a remodel of this size without the additional income your 22 rural beds could provide.

If you are not familiar, Gogebic County is a rural county in the Upper Peninsula. There are three nursing homes in the county for a total of 221 beds. According to the nursing home bed need methodology, the county only requires 195 beds, but all of the nursing homes in the county run at very high occupancy, in excess of 96% occupancy for the past several years. Gogebic County borders Hurley, Wisconsin. Our local DHS reports that 15 Michigan Medicaid residents are currently housed in Nursing Facilities in Hurley. Year to date, our facility has had to turn away a minimum of 38 residents due to our bed capacity being at it's maximum. For some of these residents, the only option would be to move from their home state, creating a loss of census population and Michigan tax dollars. For others, it meant having to live at a different facility away from their spouse of many years.

At the March CON Commission meeting, you redistributed beds for nursing homes special population groups. That redistribution left zero beds in the pool for Health Needs for Special Nursing Care Services (aka Rural Beds). At that same meeting 22 beds were left unassigned until the Commission determined that a need existed in one of the special pool categories. I am writing today to request that the Commission allocate the remaining 22 special pool beds to the Health Needs for Special Nursing Care Services pool. This will allow us at least the opportunity to compete for those beds and provide relief to the citizens of Gogebic County and the surrounding UP area. Josephson Nursing Home has been an established landmark in the Gogebic Range since 1963.

By considering our request, you will allow 47 residents to remain an intrical part of this community. I appreciate your time in considering this request. If you have any questions, please feel free to contact me at (906) 932-2006.

Cordially,

Priscilla L. Cross, RN, DON, Owner/Operator

C.O.N. COMMISSION
PUBLIC COMMENT
12-19-2006

My name is Paul Ver Lee and with me today is my business partner Jeffery Pries. We are here today on behalf of Fair Acres Care Center. Thank you for allowing us to make this presentation

I have owned Fair Acres for over 20 years. In recent years we have expanded Fair Acres into a continuum of care community including a 20 resident Alzheimer's unit.

Fair Acres Care Center has applied for 18 Alzheimer's beds to add to our existing 49 bed SNF. This application is in comparative review with one other facility. We are here today to formally request the commission to release 18 additional of the remaining 22 special beds to the Alzheimer's special use category.

We submitted in advance statistics showing that nationwide the current 4.5 million individuals suffering from Alzheimer's disease is expected to increase to over 16 million by the year 2050. The state of Michigan Alzheimer's statistics breaks down as follows:

Alzheimer's Population		**SNF Beds**	**SNF Beds to Alzheimer's ratio**
Current	179,665	48,857	1 to 3.67
2030 estimate -	306,000		1 to 6.26
2050 estimate -	540,000		1 to 11.05

When we look at these projections from the standpoint of current available Skilled Nursing Services it is obvious that we are facing an issue that must be addressed. We are all aware of the staggering demographics based on our aging population. So I am sure that we do not need to convince you of the need for Alzheimer's care in Michigan.

The question most likely facing the commission today is which specialty group available poses the greatest need. We do not question the need for Hospice or religious use beds, we do however strongly feel the demand for dedicated Alzheimer's care is by far the most pressing. The need for special Alzheimer's units in Michigan is also evident by the number of beds applied for after the release of 60 beds in March, 2006. We are one of several facilities who applied for a total of 78 beds. Other specialty bed areas did not have an excess of applications. Hospice had 2 of 30 beds applied for and Religious beds had 20 of 20.

I would like to stress the need for *dedicated* Alzheimer's care. Individuals with Alzheimer's typically are integrated with other frail seniors when they reach the stage where they require 24 hour assistance. The well intended care givers often struggle with giving the most appropriate care.

- The resident populations are not compatible; therefore create significant conflict and quality of life issues for all long term care residents involved.

- The physical plants are not purpose built; therefore do not offer the best environment to meet the unique needs of the Alzheimer's resident.

- The staff has not received the dedicated intensive training necessary to give the best possible care to Alzheimer's residents.

In the late 1990's I proceeded with the development of assisted living unit that specialized in Alzheimer's care. It was at this same time that my mother was diagnosed with Alzheimer's. She eventually passed away at Fair Acres. I have seen the frustration of the Alzheimer's resident and their families, and I have experienced it personally. Our goal and passion is to become the premium continuum of care provider for Alzheimer's services in Macomb County.

The need for Alzheimer's services is not just about available beds, but also about meeting this unique need in *dedicated* fashion. It is our goal to provide a continuum of services for the Alzheimer's residents that will:

- Provide the care at the most appropriate level, from assisted living to skilled and/or hospice. This will assure the highest level of independence and quality of life for the resident.

- To provide these services in purpose built environments delivered by staff intensely trained in the unique needs and behaviors of Alzheimer's residents and their families.

Fair Acres Care Center, our skilled nursing facility, runs at a 99% occupancy. Fair Acres has not been able to meet the constant pressure for skilled beds from our assisted living Alzheimer's community. We see the need for Alzheimer's care every day in our own community.

The current demand for Alzheimer's care is significant throughout the state of Michigan. The statistical projections for growth are overwhelming. Therefore we strongly urge the commission to consider dedicating more beds to the specialty of Alzheimer's.

Thank you

Prevalence of Alzheimer's Disease by Chapter

GREATER MICHIGAN		Current			Current
Total		**135,562**			
Detroit Area		**76,682**	Northeastern Region		**5,835**
Huron	1,051		*Alcona*	390	
Macomb	16,244		*Alpena*	788	
Oakland	20,218		*Cheboygan*	662	
St. Clair	3,000		*Crawford*	324	
Sanilac	1,035		*Iosco*	829	
Wayne	35,134		*Montmorency*	333	
East Central Region		**9,493**	*Ogemaw*	540	
Genesee	7,065		*Oscoda*	250	
Lapeer	1,186		*Otsego*	447	
Shiawassee	1,242		*Presque Isle*	460	
Marquette/Alger Region		**8,130**	*Roscommon*	812	
Alger	255		West Michigan Region		**15,714**
Baraga	231		*Ionia*	885	
Chippewa	717		*Kent*	9,098	
Delta	1,016		*Mecosta*	719	
Dickinson	803		*Montcalm*	1,094	
Gogebic	652		*Ottawa*	3,918	
Houghton	910		Northwest Region		**6,829**
Iron	546		*Antrim*	554	
Keweenaw	72		*Benzie*	407	
Luce	154		*Charlevoix*	573	
Mackinac	303		*Emmet*	740	
Marquette	1,325		*Grand Traverse*	1,657	
Menominee	640		*Kalkaska*	301	
Ontonagon	257		*Leelanau*	526	
Schoolcraft	249		*Manistee*	670	
Mid-Michigan Region		**12,879**	*Missaukee*	316	
Arenac	373		*Osceola*	447	
Bay	2,496		*Wexford*	638	
Clare	714				
Gladwin	627				
Gratiot	881				
Isabella	868				
Midland	1,546				
Saginaw	4,263				
Tuscola	1,111				

MICHIGAN GREAT LAKES		Current
Total		**44,103**
South Central Region		**14,083**
Hillsdale	867	
Jackson	3,036	
Lenawee	1,867	
Livingston	1,998	
Monroe	2,370	
Washtenaw	3,945	
Capital Area Region		7,791
Barry	*947*	
Clinton	*1,054*	
Eaton	*1,767*	
Ingham	*4,023*	
Southwest Region		**16,513**
Allegan	1,729	
Berrien	3,461	
Branch	878	
Calhoun	2,745	
Cass	1,003	
Kalamazoo	4,082	
St. Joseph	1,210	
Van Buren	1,405	
West Shore Region		**5,716**
Lake	288	
Mason	737	
Muskegon	3,289	
Newaygo	857	
Oceana	545	

MICHIGAN TOTAL	179,665

2030 - 70% increase
2050 - 300% increase

Attachment N