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

Wednesday, December 9, 2009

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

I. Call To Order

Chairperson Goldman called the meeting to order at 9:13 a.m.

A. Members Present:

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

B. Members Absent:

Dorothy E. Deremo

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

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

II. Introductions

No introductions were made.

III. Review of Agenda

Motion by Commissioner Young, seconded by Commissioner Miller, to approve the agenda as presented. Motion Carried.

IV. Declaration of Conflicts of Interest

Commissioner Sandler identified a conflict of interest related to Bone Marrow Transplantation (BMT) Services and Heart/Lung and Liver (HLL) Transplantation Services.
Chairperson Goldman identified a conflict of interest related to BMT Services and HLL Transplantation Services.
Commissioner Falahee identified a potential conflict at the last meeting. It was determined that no conflict existed.

V. Review of Minutes – September 10, 2009

Motion by Commissioner Falahee, seconded by Vice-Chairperson Smith, to approve the minutes of September 10, 2009 as presented. Motion Carried.

VI. BMT Services

A. Standard Advisory Committee (SAC) Report:
Chairperson VeCasey gave a written and oral report on behalf of the BMT SAC. (Attachment A)

B. Review of Proposed Language:
Ms. Rogers gave an overview of the proposed language for BMT Services. (Attachment B).

C. Public Comment:

Karen Kippen, Henry Ford Health System
Sean Gehle, St. John's Health System
Patrick O'Donovan, Beaumont Hospital
Bob Meeker, Spectrum Health
Dennis McCafferty, Economic Alliance of Michigan (Attachment C)
Carol Kristner, Karmanos Cancer Institute
Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment D)

D. Commission Discussion:
Discussion followed.

E. Commission Proposed Action:
Motion by Commissioner Miller, seconded by Vice-Chairperson Smith, to approve the proposed language and move forward to Public Hearing and the Joint Legislative Committee (JLC) with the Department's recommended changes. Yes – 7, No – 1, Abstained – 2. Motion Carried.

VII. HLL Transplantation Services

A. SAC Report:

Chairperson Ball gave brief overview of the HLL SACs activity (Attachment E).

B. Review of Proposed Language:
Ms. Rogers gave an overview of the proposed language for HLL Transplantation Services (Attachment F).

C. Public Comment:

Karen Kippen, Henry Ford Health System
Dennis McCafferty, Economic Alliance of Michigan (Attachment C)
Bob Meeker, Spectrum Health

D. Commission Discussion:
Discussion followed.

E. Commission Proposed Action:
Motion by Commissioner Falahee, seconded by Commissioner Ajluni, to approve the proposed language and move forward to Public Hearing and the JLC. Yes – 7, No – 0, Abstained – 2. Motion Carried.

VIII. Magnetic Resonance Imaging (MRI) Services

A. Review of MRI Data Request:
Mr. Hart provided the MRI data report as requested. (Attachment G)

B. Review of Proposed Language:
Ms. Rogers gave an overview of the proposed language for MRI Services. (Attachment H).

Recessed at 11:05 a.m and reconvened at 11:17 a.m.

C. Public Comment:

Dennis McCafferty, Economic Alliance of Michigan (Attachment C)
Doug Rich, St. John's Health System
Terry Gerald, Detroit Medical Center
Dr. Basha, Basha Diagnostics
Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment D)

D. Commission Discussion:
Discussion followed.

E. Commission Proposed Action:
Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to approve the proposed language with amendments (Attachment I) and move forward to Public Hearing and JLC. Yes – 6, No – 4, Abstained – 0. Motion Carried.

IX. Hospital Beds

Mr. Hart gave a verbal report on Hospital Beds (Inpatient Rehabilitation).

X. Standing New Technology Advisory Committee (NEWTAC)

Commissioner Keshishian gave a brief update of the NEWTAC activity.

XI. Legislative Report

Mr. Lyon gave a brief update.

XII. Administrative Update

A. Mr. Hart gave the Administrative Update.

B. Health Policy Section Update:
Ms. Rogers gave a brief update on the Health Policy Section.

C. CON Evaluation Section Update:
Mr. Horvath gave an update on the CON Evaluation Section and provided an overview of the Compliance Report (Attachment J)

XIII. Legal Activity Report

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

XIV. Future Meeting Dates

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

XV. Public Comment

Terry Gerald, Detroit Medical Center
Jim Pomeroy, Select Medical
Amy Barkholz, MHA
Cheryl Miller, Trinity Health (Attachment L)
Susan Heck, Corazon Consulting (Attachment L)
Michael Yaeg, Hurley Medical Center
Dennis McCafferty, Economic Alliance of Michigan (Attachment C)
Barbara Jackson, Blue Cross Blue Shield of Michigan (Attachment D)
Bob Meeker, Spectrum Health
Karen Kippen, Henry Ford Health System

XVI. Review of Commission Work Plan

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

Motion by Commissioner Sandler, seconded by Commissioner Ajluni, to approve the Work Plan as presented including receipt of FY2009 CON Annual Activity Report. Motion Carried.

XXII. Adjournment

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

TO: THE CERTIFICATE OF NEED COMMISSION

FROM: BONE MARROW TRANSPLANTATION STANDARD ADVISORY COMMITTEE, Don VeCasey, Chairman

SUBJECT: DRAFT REPORT ON OUR ASSIGNED CHARGE

This SAC was given the following charges:

A. **Charge**: To review, consider and to recommend any necessary changes to the BMT Services Standards (along with the rationale for maintaining or changing each key provision) regarding the following specific issues;

1. **Issue - Whether continued regulation of BMT services is necessary**.

   Recommendation – Continue regulation.

   Rationale - The SAC heard formal presentations and much discussion, both among itself and from public comment, but after first denying a motion to remove BMT services from regulation, it then recommended that these services continue to be regulated. The majority, by a 10 to 2 vote, feels that these services are extremely complex and have high morbidity and mortality rates that justify continued regulation.

2. **Issue - Look at statewide access issues, with particular reference to access outside southeastern Michigan.** ***Note*****:** Attached to this report are copies of presentations given to the SAC by representatives from Beaumont Hospital (**Data Pertaining to Access, Quality & Cost on Bone Marrow Transplant**), Spectrum Hospital (**Need for Bone Marrow Transplant Services in Western Michigan**), and the Henry Ford Health System (**Challenges of Running "Small" BMT Programs**).

   We thank Dr. Akhtar and Dr. Wiemann from Beaumont Hospital, Mr. Richard Funnell from Spectrum Health Hospitals, and Dr. Janakiraman from the Henry Ford Health System for their respective presentations.

   Recommendation # 1, Regarding access outside southeastern Michigan – We recommend that a second statewide planning area be established, to mirror the second planning area now established for pediatric BMT services on the western side of the state. We further recommend that only one BMT service be established in the second planning area. This motion passed by a vote of 10 to 2.

   Rationale – Existing BMT services are all located within a relatively small area in southeastern Michigan, thus necessitating lengthy drives and hours in transit for the families of BMT recipients to maintain contact and provide the support so important to patients. We imagine that the same rationale applied when the

decision made previously to provide for pediatric BMT services in a second planning area applies equally for adults.

We realize that a second planning area in and of itself, given Michigan's unique configuration, does not overcome mere geography. We realize, too, that actual distances to existing BMT services within the first planning area can exceed, in many instances, the actual distance now required from points in southwestern and northern Michigan, especially from our U.P. We feel, however, that the precedence set for pediatric BMT services has merit and should be applied for adult BMT services, too.

Recommendation # 2, Regarding access within southeastern Michigan – The SAC then took a look at access within the present statewide planning area. We heard testimony and held many discussions about the availability of BMT within this part of the state. We recommend no expansion within southeastern Michigan at this time.

Rationale - What we learned is that there is no hard evidence of unmet need for BMT services in southeastern Michigan, and that in many respects the present BMT services are in fact, not used to capacity now. In other words, capacity exceeds demand at this time. We understand that at times patients will prefer to stay within their own provider network and with their own physician(s). The reality, however, is that when need for BMT services arise, the issue of convenience and preference cannot, in and of themselves, dictate free choice of where the service may be obtained. An adequate network of resources is now deemed present in southeastern Michigan, and no expansion of BMT services there is recommended. This motion carried by a 10 to 2 vote also.

These recommendations followed a great deal of discussion, over both the SAC meeting in which the presentations cited were heard and during subsequent SAC meetings. We believe that we provided advocates for expanded BMT services with ample opportunities to convince the SAC members of the validity of their arguments and requests. This did not occur.

Again, by a vote 10 to 2 the above two recommendations were what emerged from our deliberations

B. **Charge** – To report promptly on the first two charges. This initial report was submitted verbally by the SAC chairman Don VeCasey, at the September CON Commission meeting.

C. Charge – Depending on its report on the first two charges, the SAC was then to look at the following issues:

1. **Need and Recommendation** – The SAC looked at the issue of need and concluded that there is no need for expansion of BMT services beyond as

noted above. The testimony we heard and the discussions among the SAC lead us to conclude that adequate BMT services are now available, as described in the rationale provided earlier.

2. **Access and Recommendation** – Access is somewhat a problem for those living in the farther regions of the state, but we concluded that it is impractical to provide access for everyone within a limited travel distance, however that might be defined. This fact of life in Michigan is one that people accept as part of the consequences of their choice of locale in which to live. This essentially duplicates the "Need" rationale from earlier.

3. **Cost and Recommendation** – The testimony presented was that costs are not a particularly troublesome factor in terms of physical facilities, were a new service authorized. Most facilities could handle the physical plant changes required.

   What was raised, however, are the costs involved in recruiting and retaining the specialized staff needed to provide excellent BMT services. Testimony was given that spoke to the "cannibalism" involved in the competition for skilled staff, wherein programs compete among themselves for too few available "experts." This is particularly onerous in terms of physicians, but spills over into the supportive staff necessary to maintain a BMT program. Special skills are required to recruit donors for BMT transplants and for the lengthy and intensive follow-up services that BMT patients require.

   Support staff and skilled physicians to provide these services are not in over-supply, and adding more programs is likely to exacerbate the problems of maintaining sufficient staffing.

   We have no specific recommendations to make on controlling or impacting costs, <u>except</u> as noted in proposed changes in the Standards sections 3 and 6 as noted later in this report.

4. **Quality and Recommendation** – We have no specific recommendations to address issues of quality. The discussions we had focused on use the standards otherwise already in existence. We accept that facilities are concerned about standards and willingly adhere to FACT-JACIE (Foundation for the Accreditation of Cellular Therapy and Joint Accreditation Committee ISCT & EMBT) standards.

5. **Consortium Possibilities and Recommendations** – There was a sense of willingness to "collaborate" or "cooperate" with other facilities in the provision of BMT services expressed by several providers, now or potentially. As practical matter, however, a true consortium approach was deemed impractical. BMT services are complex and are not seen as being divisible

among multiple locations/institutions. They are provided in a single location, effectively negating consortium potential.

D. Charge: In addition, the SAC shall consider possible changes in:

1. **The planning areas and Recommendations –** The SAC has already recommended adding a second adult planning area, to mirror the pediatric planning areas now used.

2. **Comparative Review Criteria and Recommendations –** Changes recommended include those outlined in the attachment *Review Standards.*

3. **Need Methodology: Facility – specific or by appropriate maximum number of BMT programs in the planning area(s) and Recommendations –** The SAC made no recommendation to change the need methodology from number per planning area to facility specific. By default, the decision made by the SAC is to recommend retention of number per planning area, with limits of one in the new western planning area recommended by the SAC, and retention of three in the other (eastern) planning area.

E. Additional Consideration: Should separate standards be developed, one for allogeneic transplants and one for autologous transplants?

The SAC heard arguments for splitting the two procedures into separate standards, as found in the paper attached to this report titled *Rationale for Increasing Autologous Stem Cell Transplant Programs in Michigan,* and presented Dr. Wiemann. After discussion, a motion to separate these services and have two sets of standards was made. It failed to pass, by a vote of 10 to 2.

F. Proposed Revisions in Standards

The BMTSAC recommends several changes in the BMT CON Review Standards, as described in the attached proposed revisions. Specifically, the BMTSAC recommends that:

1. **Section 3 Requirements to Initiate a Service** be changed so that the written consultation requirements in (10) (a) (iv) (A) schedule of site visits by consulting staff be changed from **6** visits in the first 12 months to **3** visits and in (B) from **4** visits to **3** visits in each of the second and third 12-months of operation.

The BMTSAC believes the previous schedule is not warranted and is excessive.

2. Section 4 Comparative review requirements in (2) (a) should be changed to award points based on straight-line distance from the nearest BMT service (rather than on existing BMT programs in the HSA) as follows:

Less than 75 miles = 0 points
75-150 miles = 1 point
Over 150 miles = 2 points

3. **Section 6 Project Delivery Requirements** should be changed so that a projection of a minimum of 30 transplants per year is required in order to be to be certified to provide BMT services.

   The BMTSAC recognizes that 30 is as arbitrary as any other number. Further, we acknowledge that 30 do not necessarily provide greater assurance of quality than does 10. However, a minimum of less than one transplant per month can be reasonably arguably is much further from assuring quality than is 10, until and unless some other more creditable standard can be developed. Generally, it seems appropriate to us to assume better quality with greater volume.

   In essence, we felt strongly that it is imperative that the standards we adopt now need to assure that we are not eventually authorizing many small volume programs, as opposed to fewer programs with adequate volumes to assure a better level of quality. Also, cost containment is furthered when a few programs adequate to meet the total need are operating, as opposed to many smaller volume programs providing the service.

   Our belief is that these two purposes, quality and cost containment, are better served with a higher minimum in place than the present limit of 10.

   This proposed new limit was approved unanimously by those voting on the issue, although one member did abstain on this vote.

G. Chairman's Summary

This BMTSAC group was sharply divided into roughly one group of 2 or 3 and then the rest of the group. It was clear early on that there were two agendas involved. The smaller group really wanted to expand BMT services in the original planning area (including SE Michigan), but they could never convince the rest of the BMTSAC to support that idea.

A second issue was expanding into two planning areas. It was difficult for the BMTSAC to deny the need for another adult BMT program, given that approval for a pediatric program already exists. Many of the same arguments apparently presented as persuasive for a pediatric second planning area were argued again for the adult program. In the end, the BMTSAC was convinced that a second state planning area is also appropriate for adults, with the further stipulation that only one additional program should be approved.

While I have served on many SAC's previously, I have never been subjected to the intensity of "lobbying" as this SAC endured. It is my expectation that the CON Commission itself will be heavily pressured to increase the cap in the first state planning area, and that no decision will be accepted that does not allow another program in SE Michigan. It is likely any negative decision will be taken directly to the governor and/or the legislature in an attempt to override the BMTSAC and the CON Commission if our recommendations are accepted.

Thank you for the opportunity to serve on this BMTSAC.

Possible Alternative to Comparative Review Criterion (D) in the draft BMT CON Review Standards proposed by the SAC

(d) A qualifying project will have points awarded based on the number of necessary support services/personnel as identified in section 7 that the applicant has available on-site on the date the application is submitted to the department, as follows~~. the applicant shall earn one (1) point each, up to a maximum of eleven (11) points, for the following~~:

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

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

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

(iv) therapeutic drug monitoring.

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

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

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

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

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

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

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

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

Number of BMT Support Personnel/Services available	Points
Zero or one	0
Two to five	1
Six to nine	2
Ten or eleven	3

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

~~Sec. 1. (1) These standards are requirements for the approval and delivery of services for all projects approved and Certificates of Need issued under Part 222 of the Code which involve bone marrow transplantation services.~~ THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL AND DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE CODE, BONE MARROW TRANSPLANTATION IS A COVERED CLINICAL SERVICE. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION ~~2~~22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

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

~~(3) A bone marrow transplantation~~ BMT service listed on the Department inventory that is located at a hospital site and initially does not perform both allogeneic and autologous procedures shall not be required to obtain separate CON approval to begin performing both autologous and allogeneic ~~bone marrow transplant~~ BMT procedures.

~~(4)~~ (3) An existing ~~bone marrow transplantation~~ BMT service that performs only adult procedures shall require separate CON approval in order to perform pediatric procedures. An existing ~~bone marrow transplantation~~BMT 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~~ BMT service" means the acquisition (including purchase, lease, donation, or other arrangement) of an existing ~~bone marrow transplantation~~ BMT 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" OR "BMT SERVICE" means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source.

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

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

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

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

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

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

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

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

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

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

(~~r~~Q) "Licensed site" means ~~either:~~

~~(i) in the case of a single site hospital,~~ the location of the ~~facility~~HOSPITAL 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~~R) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.

(~~t~~S) "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~~BMT is a treatment.

(~~u~~T) "Planning area" means:

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

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

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

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

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

(~~w~~V) "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.

(W) "TUMOR REGISTRY" MEANS A MANUAL OR COMPUTERIZED DATA BASE CONTAINING INFORMATION ABOUT ALL MALIGNANCIES AND ONLY THOSE THAT ARE DIAGNOSED AND/OR TREATED AT THE APPLICANT'S FACILITY. THE MALIGNANCIES MUST BE REPORTABLE TO THE MICHIGAN CANCER SURVEILLANCE PROGRAM AS REQUIRED PURSUANT TO PUBLIC ACT 82 OF 1984, AS AMENDED.

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

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

Sec. 3. ~~(1)~~ An applicant proposing to initiate a ~~bone marrow transplantation~~ BMT service shall demonstrate the following requirements:

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

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

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

(a) operating rooms.

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

(c) dialysis.

(d) inpatient-outpatient social work.

(e) inpatient-outpatient psychiatry/psychology.

(f) clinical research.

(g) a microbiology and virology laboratory.

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

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

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

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

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

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

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

(i) anesthesiology.

(ii) cardiology.

(iii) critical care medicine.

(iv) gastroenterology.

(v) general surgery.

(vi) hematology.

(vii) infectious diseases.

(viii) nephrology.

(ix) neurology.

(x) oncology.

(xi) pathology, including blood banking experience.

(xii) pulmonary medicine.

(xiii) radiation oncology.

(xiv) radiology.

(xv) urology.

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

(i) dermatology.

(ii) immunology.

(iii) neurosurgery.

(iv) orthopedic surgery.

(4) An applicant must provide an implementation plan for the proposed ~~bone marrow transplantation~~BMT service. "IMPLEMENTATION PLAN" MEANS A PLAN THAT DOCUMENTS HOW A PROPOSED BMT SERVICE WILL BE INITIATED WITHIN THE TIME PERIOD SPECIFIED IN THESE

STANDARDS OR THE CON RULES. AT A MINIMUM, THE IMPLEMENTATION PLAN SHALL IDENTIFY:

(A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE PROPOSED BMT SERVICE INCLUDING, BUT NOT LIMITED TO, THE DEVELOPMENT OF PHYSICAL PLANT REQUIREMENTS, SUCH AS AN INTENSIVE CARE UNIT CAPABLE OF TREATING IMMUNO-SUPPRESSED PATIENTS, EQUIPMENT ACQUISITIONS, AND RECRUITMENT AND EMPLOYMENT OF ALL PHYSICIAN AND SUPPORT STAFF;

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

(C) IF THE APPLICANT PREVIOUSLY HAS BEEN APPROVED FOR A BMT SERVICE FOR WHICH EITHER THE CON EXPIRED OR THE SERVICE DID NOT PERFORM A TRANSPLANT PROCEDURE DURING ANY CONSECUTIVE 12-MONTH PERIOD, WHAT CHANGES HAVE OR WILL BE MADE TO ENSURE THAT THE PROPOSED SERVICE CAN BE INITIATED AND PROVIDED ON A REGULAR BASIS.

(5)(a) An applicant shall demonstrate that the number of existing adult ~~bone marrow transplantation~~ BMT services DOES NOT EXCEED THREE (3) ADULT BMT SERVICES IN PLANNING AREA ONE IDENTIFIED IN ~~in the planning area identified in~~ Section 2(1)(~~u~~T)(i) OR ONE (1) ADULT BMT SERVICE IN PLANNING AREA TWO IDENTIFIED IN SECTION 2(1)(T)(II) AND THAT APPROVAL OF THE PROPOSED APPLICATION WILL NOT RESULT IN THE TOTAL NUMBER OF ADULT BMT SERVICES EXCEEDING THE NEED FOR EACH SPECIFIC PLANNING AREA ~~does not exceed three (3) adult bone marrow transplantation BMT services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation BMT services exceeding three (3) in the planning area.~~

(b) An applicant shall demonstrate that the number of existing pediatric ~~bone marrow transplantation~~BMT services does not exceed two (2) pediatric ~~bone marrow transplantation~~BMT services in planning area one identified in Section 2(1)(~~u~~T)~~(iii)~~(AI) or one (1) pediatric ~~bone marrow transplantation~~BMT service in planning area two identified in Section 2(1)(~~u~~T)~~(ii)(B)~~ and that approval of the proposed application will not result in the total number of pediatric ~~bone marrow transplantation~~BMT services exceeding the need for each specific ~~pediatric~~ planning area.

(6)(a) An applicant proposing to initiate an adult ~~bone marrow transplantation~~BMT service ~~that will perform only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall project that at least ~~10~~30 TRANSPLANTS, OF WHICH AT LEAST 10 ARE allogeneic transplant procedures, will be performed in the third 12-months of operation. ~~An applicant proposing to initiate an adult bone marrow transplantationBMT 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~~BMT service ~~that will perform only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall project that at least 10 TRANSPLANTS, OF WHICH 5 ARE allogeneic transplant procedures, will be performed in the third 12-months of operation. ~~An applicant proposing to initiate a pediatric bone marrow transplantationBMT 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~~BMT service shall specify whether patients age 18-20 are included in the projection of adult procedures required pursuant to subsection (a) or the projection of pediatric procedures required pursuant to subsection (b). An applicant shall not include patients age 18-20 in both adult and pediatric projections required pursuant to subsections (a) and (b).

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

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

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

(a) a designated pediatric inpatient oncology unit.

(b) a pediatric inpatient intensive care unit.

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

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

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

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

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

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

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

(iv) pediatric psychologists.

(v) child life specialists.

(10)(a) An applicant proposing to initiate either a new adult or pediatric ~~bone marrow transplantation~~BMT service shall submit, in its application, a written consulting agreement with an existing ~~bone marrow transplantation~~BMT service~~, that meets each of the requirements in subsection (b)~~. THE WRITTEN CONSULTING AGREEMENT MUST BE WITH AN EXISTING IN-STATE OR OUT-OF-STATE FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ACCREDITED TRANSPLANT UNIT THAT PERFORMS BOTH ALLOGENIC AND AUTOLOGOUS TRANSPLANTS FOR EITHER ADULT AND/OR PEDIATRICS. ~~SHALL SPECIFY~~ THE TERMS OF THE AGREEMENT AND THE ROLES AND RESPONSIBLITIES OF BOTH THE EXISTING AND PROPOSED SERVICE~~,~~ SHALL INCLUD~~E~~ING AT LEAST THE FOLLOWING:

~~(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~~BMT procedures.

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

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

(A) nursing services.

(B) infection control.

(C) nutritional support.

(D) staff needs and training.

(E) inpatient and outpatient medical coverage.

(F) transfusion and blood bank policies.

(G) transplant treatment protocols.

(H) hematopoiesis laboratory services and personnel.

(I) data management.

(J) quality assurance program.

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

(A) ~~6~~3 visits during the first 12-months of operation of the proposed service.

(B) ~~4~~3 visits during each the second 12-months and third 12-months of operation of the proposed service.

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

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

(B) transplant outcomes.

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

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

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

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

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

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

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

(i) currently is performing and is ~~Foundation for Accreditation of Cell Therapy (~~FACT~~)~~ accredited in, the types of transplants (allogeneic AND~~or~~ autologous; adult or pediatric) proposed to be performed by the applicant;

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

(iii) is located in the United States.

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

~~SECTION 84~~. REQUIREMENTS FOR APPROVAL – ACQUISITION OF A BMT SERVICE BY A CANCER HOSPITAL

(1) AN APPLICANT PROPOSING TO ACQUIRE AN EXISTING BMT SERVICE SHALL DEMONSTRATE THAT IT MEETS ALL OF THE REQUIREMENTS OF THIS SUBSECTION AND SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SECTION 3(5) AND THE DEPARTMENT INVENTORY.

(A) THE TOTAL NUMBER OF BMT SERVICES IS NOT INCREASED IN THE PLANNING AREA AS THE RESULT OF THE ACQUISITION.

(B) AS PART OF THE ACQUISITION OF THE BMT SERVICE, THE ACQUISITION OR REPLACEMENT OF THE CANCER HOSPITAL, OR FOR ANY OTHER REASONS, THE LOCATION OF THE BMT SERVICE SHALL BE LOCATED AT ITS PRIOR LOCATION OR IN SPACE WITHIN THE LICENSED CANCER HOSPITAL SITE.

(C) THE APPLICANT IS A CANCER HOSPITAL AS DEFINED BY THESE STANDARDS. THE APPLICANT SHALL, TO THE SATISFACTION OF THE DEPARTMENT, PROVIDE VERIFICATION OF PPS-EXEMPTION AT THE TIME OF APPLICATION, OR SHALL DEMONSTRATE COMPLIANCE WITH THE FOLLOWING TO THE SATISFACTION OF THE DEPARTMENT:

(I) THE APPLICANT, OR AN AFFILIATE OF THE APPLICANT, OPERATES A COMPREHENSIVE CANCER CENTER RECOGNIZED BY THE NATIONAL CANCER INSTITUTE IN CONJUNCTION WITH A MICHIGAN UNIVERSITY THAT IS DESIGNATED AS A COMPREHENSIVE CANCER CENTER, OR THE APPLICANT IS THE MICHIGAN UNIVERSITY THAT IS DESIGNATED AS A COMPREHENSIVE CANCER CENTER.

(II) THE APPLICANT COMMITS TO PROVIDE EVIDENCE, SATISFACTORY TO THE DEPARTMENT, OF APPROVAL AS A PPS-EXEMPT HOSPITAL WITHIN THE TIME LIMITS SPECIFIED IN SUBSECTION (G).

(D) THE APPLICANT DEMONSTRATES THAT IT MEETS, DIRECTLY OR THROUGH ARRANGEMENTS WITH THE HOSPITAL FROM WHICH IT ACQUIRES THE BMT SERVICE, THE REQUIREMENTS SET FORTH UNDER SECTION 3(3), (6), (7), AND (8), AS APPLICABLE.

(E) THE APPLICANT AGREES TO EITHER HAVE A WRITTEN CONSULTING AGREEMENT AS REQUIRED BY SECTION 3(10) OR OBTAIN A DETERMINATION BY THE DEPARTMENT THAT SUCH AN AGREEMENT IS NOT REQUIRED BECAUSE THE EXISTING BMT STAFF, SERVICES, AND PROGRAM SUBSTANTIALLY WILL CONTINUE TO BE IN PLACE AFTER THE ACQUISITION.

(F) THE APPLICANT AGREES AND ASSURES TO COMPLY, EITHER DIRECTLY OR THROUGH ARRANGEMENTS WITH THE HOSPITAL FROM WHICH IT ACQUIRES THE BMT SERVICE, WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS.

(G) IF THE APPLICANT DESCRIBED IN THIS SUBSECTION 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 NEXT UNITED STATES CONGRESS IN SESSION AFTER THE EFFECTIVE DATE OF THESE STANDARDS. 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 DEPARTMENT MAY EXPIRE 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 BMT 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 BMT SERVICE UNDER THIS SECTION SHALL NOT BE SUBJECT TO COMPARATIVE REVIEW.

Section 54. REVIEW STANDARDS FOR ~~Additional requirements for applications included in~~ comparative reviews

Sec. 45. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or UNDER these standards, shall be grouped and reviewed COMPARATIVELY with other applications in accordance with the CON rules applicable~~. to comparative reviews.~~

(~~3~~2) EACH APPLICATION IN A COMPARATIVE GROUP SHALL BE INDIVIDUALLY REVIEWED TO DETERMINE WHETHER THE APPLICATION HAS SATISFIED ALL THE REQUIREMENTS OF SECTION 22225 OF THE CODE BEING SECTION 333.22225 OF THE MICHIGAN COMPILED LAWS AND ALL OTHER APPLICABLE REQUIREMENTS FOR APPROVAL IN THE CODE AND THESE STANDARDS. IF THE DEPARTMENT DETERMINES THAT TWO OR MORE COMPETING APPLICATIONS SATISFY ALL OF THE REQUIREMENTS FOR APPROVAL, THESE PROJECTS SHALL BE CONSIDERED QUALIFYING PROJECTS. THE DEPARTMENT SHALL APPROVE THOSE QUALIFYING PROJECTS WHICH, WHEN TAKEN TOGETHER, DO NOT EXCEED THE NEED, AS DEFINED IN SECTION 22225(1) BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWS, AND WHICH HAVE THE HIGHEST NUMBER OF POINTS WHEN THE RESULTS OF SUBSECTION (2) ARE TOTALED. IF TWO OR MORE QUALIFYING PROJECTS ARE DETERMINED

TO HAVE AN IDENTICAL NUMBER OF POINTS, THEN THE DEPARTMENT SHALL APPROVE THOSE QUALIFYING PROJECTS WHICH, TAKEN TOGETHER, DO NOT EXCEED THE NEED, AS DEFINED IN SECTION 22225(1) OF THE CODE, BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWS, IN THE ORDER IN WHICH THE APPLICATIONS WERE RECEIVED BY THE DEPARTMENT, BASED ON THE DATE AND TIME STAMP PLACED ON THE APPLICATIONS BY THE CON ADMINISTRATIVE UNIT OF THE DEPARTMENT RESPONSIBLE FOR ADMINISTERING THE CON PROGRAM WHEN AN APPLICATION IS SUBMITTED.

~~(23)(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~~

(2)(A)A QUALIFYING PROJECT WILL HAVE POINTS AWARDED BASED ON THE STRAIGHT-LINE DISTANCE TO THE NEAREST EXISTING BMT SERVICE OF THE TYPE APPLIED FOR (ADULT OR PEDIATRIC), AS SHOW IN THE FOLLOWING SCHEDULE:

STRAIGHT-LINE DISTANCE TO NEAREST BMT SERVICE	Points Awarded
<75 MILES	0
75 – 150 MILES	1
>150 MILES	2

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

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume~~, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantationBMT 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 ROUNDED TO THE NEAREST WHOLE NUMBER.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the NEAREST WHOLE NUMBER~~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 HOSPITAL charges expressed as a percentage, ROUNDED TO THE NEAREST WHOLE NUMBER, 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 IN THIS SUBSECTION~~for rates~~ IS THE DATA IN THE MOST CURRENT DCH-MSA DISPROPORTIONATE SHARE HOSPITAL (DSH) REPORT ~~in effect~~ at the time

the application(S) 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~~BMT procedures will be performed and were referred for and received a ~~bone marrow transplant~~ BMT at an existing ~~bone marrow transplantation~~BMT service, and submits documentation from the existing ~~bone marrow transplantation~~BMT service(s) of these referrals.

(D) A QUALIFYING PROJECT WILL HAVE POINTS AWARDED BASED ON THE NUMBER OF NECESSARY SUPPORT SERVICES/PERSONNEL AS IDENTIFIED IN SECTION 7 THAT THE APPLICANT HAS AVAILABLE ON-SITE ON THE DATE THE APPLICATION IS SUBMITTED TO THE DEPARTMENT. THE APPLICANT SHALL EARN ONE (1) POINT EACH, UP TO A MAXIMUM OF ELEVEN (11) POINTS, FOR THE FOLLOWING:

(I) 24-HOUR BLOOD BANK SUPPORT, INCLUDING PHERESIS CAPABILITY, IRRADIATED BLOOD, PRODUCTS SUITABLE FOR CYTOMEGALOVIRUS-NEGATIVE TRANSPLANTS, AND BLOOD COMPONENT THERAPY.

(II) A PROCESSING AND CRYOPRESERVATION LABORATORY THAT MEETS THE STANDARDS OF THE FACT OR AN EQUIVALENT ORGANIZATION.

(III) ANATOMIC AND CLINICAL PATHOLOGY WITH COMPETENCY IN INTERPRETING PATHOLOGIC FINDINGS RELATED TO GRAFT-V-HOST DISEASE AND OTHER OPPORTUNISTIC INFECTIONS IN IMMUNO-COMPROMISED HOSTS.

(IV) THERAPEUTIC DRUG MONITORING.

(V) ONE OR MORE ATTENDING PHYSICIANS WITH FELLOWSHIP TRAINING, AND/OR AT LEAST 2 YEARS OF EXPERIENCE, IN PEDIATRIC AND/OR ADULT BMT, AS APPROPRIATE.

(VI) BOARD-CERTIFIED OR BOARD-ELIGIBLE CONSULTING PHYSICIANS IN ALL OF THE FOLLOWING AREAS: ANATOMIC PATHOLOGY WITH COMPETENCE IN GRAFT VERSUS HOST DISEASE AND OTHER OPPORTUNISTIC DISEASES, INFECTIOUS DISEASES WITH EXPERIENCE IN IMMUNO-COMPROMISED HOSTS, AND RADIATION ONCOLOGY WITH EXPERIENCE IN TOTAL BODY IRRADIATION.

(VII) A TRANSPLANT TEAM COORDINATOR, WITH EXPERIENCE IN EVALUATING PRE AND POST BMT PATIENTS.

(VIII) NURSES WITH SPECIALIZED TRAINING IN PEDIATRIC AND/OR ADULT, AS APPROPRIATE, BMT, HEMATOLOGY/ONCOLOGY PATIENT CARE, ADMINISTRATION OF CYTOTOXIC THERAPIES, MANAGEMENT OF INFECTIOUS COMPLICATIONS ASSOCIATED WITH HOST-DEFENSE MECHANISMS, ADMINISTRATION OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT, AND MANAGING IMMUNO-SUPPRESSED PATIENTS.

(IX) A PHARMACIST EXPERIENCED WITH THE USE OF CYTOTOXIC THERAPIES, USE OF BLOOD COMPONENTS, THE HEMODYNAMIC SUPPORT OF THE TRANSPLANT PATIENT, AND THE MANAGEMENT OF IMMUNO-SUPPRESSED PATIENTS.

(X) AN ACTIVE, FORMAL MULTI-DISCIPLINARY RESEARCH PROGRAM RELATED TO BMT.

(XI) A PROTECTIVE ENVIRONMENTAL INPATIENT UNIT FOR IMMUNO-SUPPRESSED PATIENTS THAT HAS AN ISOLATION POLICY, AN INFECTION CONTROL PLAN SPECIFIC TO THAT UNIT, AND AIR HANDLING SYSTEM CAPABLE OF PREVENTING NOSOCOMIAL INFECTIONS DISSEMINATED FROM CENTRAL HEATING AND COOLING SYSTEMS AND AMBIENT AIR.

~~(3) Each application in a comparative group shall be individually reviewed to determine whether the application has satisfied all the requirements of Section 22225 of the Code being Section 333.22225 of the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these standards. If the Department determines that two or more competing applications satisfy all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section 22225(1) BEING SECTION 333. 22225(1) OF THE MICHIGAN COMPILED LAWSof the Code, 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 by the CON ADMINISTRATIVE UNIT OF THE DEPARTMENT RESPONSIBLE FOR ADMINISTERING THE CON PROGRAM WHEN AN APPLICATION IS SUBMITTED.Department in accordance with Rule 325.9123.~~

(4) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT AWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE AWARDED FROM THE CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED.~~No points will be awarded to an applicant under specific subsections of Section 4 if information presented is inconsistent with related information provided in other portions of the CON application.~~

Section ~~56~~. Requirements for approval -- all applicants

Sec. ~~56~~. An applicant shall provide verification of Medicaid participation~~, at the time the application is submitted to the Department~~. An applicant that is initiating a new service or is a new provider not currently enrolled in Medicaid shall ~~provide a signed affidavit stating~~ CERTIFY that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved. ~~If the required documentation is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.~~

Section ~~67~~. Project delivery requirements -- terms of approval ~~for all applicants~~

Sec. ~~67.~~ (1) An applicant shall agree that, if approved, the ~~bone marrow transplantation~~BMT service shall be delivered in compliance with the following terms of CON approval:

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

(b) Compliance with applicable safety and operating standards.

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

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

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

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

(C) a processing and cryopreservation laboratory that meets the standards of the ~~Foundation for Accreditation of Cell Therapy (~~FACT~~)~~ 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 AND~~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~~BMT inpatient unit for immuno-suppressed patients that has an isolation policy, an infection control plan specific to that unit, and an air handling system capable of preventing nosocomial infections disseminated from central heating and cooling systems and ambient air.

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

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

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

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

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

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

(A) a transplant team leader, who is a physician that is board-certified in at least one of the following specialties: hematology, medical oncology, immunology, or pediatric hematology/oncology, as appropriate, and has had either at least one year of specific clinical training or two years of experience, both inpatient and outpatient, as an attending physician principally responsible for the clinical management of patients treated with hematopoietic transplantation. ~~If the bone marrow transplantationBMT service performs allogeneic transplants, t~~The team leader's experience shall include the clinical management of patients receiving an allogeneic transplant. The responsibilities of the transplant team leader shall include overseeing the medical care provided by attending physicians, reporting required data to the Department, and responsibility for ensuring compliance with the all applicable project delivery requirements.

(B) one or more attending physicians with specialized training in pediatric and/or adult BMT, as appropriate~~, bone marrow transplantation~~. ~~If a service performs allogeneic transplants, a~~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 CRITICAL CARE MEDICINE~~.radiation oncology with experience in total body irradiation, and an intensivist who is board-certified in critical care.~~

(D) ON-SITE AVAILABILITY OF BOARD-CERTIFIED OR BOARD-ELIGIBLE CONSULTING PHYSICIANS IN THE FOLLOWING AREAS: ANATOMIC PATHOLOGY WITH COMPETENCE IN GRAFT VERSUS HOST DISEASE (SERVICES PERFORMING ALLOGENEIC TRANSPLANTS) AND OTHER OPPORTUNISTIC DISEASES (SERVICES PERFORMING ALLOGENEIC ~~OR~~AND AUTOLOGOUS TRANSPLANTS), INFECTIOUS DISEASES WITH EXPERIENCE IN IMMUNO-COMPROMISED HOSTS, AND RADIATION ONCOLOGY WITH EXPERIENCE IN TOTAL BODY IRRADIATION.

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

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

~~(F~~G) nurses with specialized training in pediatric and/or adult, as appropriate, ~~bone marrow transplantation~~BMT, hematology/oncology patient care, administration of cytotoxic therapies, management of infectious complications associated with compromised host-defense mechanisms, administration of blood

components, the hemodynamic support of the transplant patient, and managing immuno-suppressed patients.

(GH) 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.

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

(IJ) designated social services staff.

(JK) designated physical therapy staff.

(KL) data management personnel designated to the bone marrow transplantationBMT service.

(LM) for an applicant performing pediatric bone marrow transplantsBMT, 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 transplantationBMT 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 transplantationBMT, 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 transplantationBMT 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 transplantBMT patients.

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

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

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

(d) Compliance with the following terms of approval:

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

(A) An adult bone marrow transplantationBMT service that performs only allogeneic transplants, or both allogeneic and autologous transplants, shall perform at least 1030 TRANSPLANTS, OF WHICH AT LEAST 10 ARE allogeneic transplants, in the third 12-months of operation AND ANNUALLY THEREAFTER. 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~~BMT service ~~that performs only allogeneic transplants, or both allogeneic and autologous transplants,~~ shall perform at least 10 TRANSPLANTS, OF WHICH AT LEAST 5 ARE 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~~BMT service that performs both adult and pediatric ~~bone marrow transplants~~BMT shall specify whether each patient age 18-20 is included in the category of adult procedures or the category of pediatric procedures. An applicant shall determine for each patient age 18-20 whether to record that patient as an adult or a pediatric procedure, but an applicant shall record each patient age 18-20 in only 1 category.

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

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

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

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

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

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

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

(v) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules. An applicant that initially does not perform both allogeneic and autologous procedures also shall notify the Department when it begins to perform ~~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~~BMT service. The notification shall include a statement describing the reasons for the termination. An applicant shall have 30 days following termination of that agreement to enter into a written consulting agreement that meets the requirements of Section 3(10). An applicant shall provide the Department with a copy of that written consulting agreement.

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

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

Section ~~7~~8. Documentation of projections

Sec. ~~7~~8. An applicant required to project volumes of service under Section 3 shall specify how the volume projections were developed. THE APPLICANT SHALL USE RELEVANT AND UNDUPLICATED DATA FOR PATIENTS IN THE SAME PLANNING AREA AS THE PROPOSED BMT SERVICE, WHICH ARE VERIFIABLE FROM THE MOST RECENT STATEWIDE TUMOR REGISTRY. THE APPLICANT SHALL ONLY INCLUDE NEW CANCER CASES THAT ARE APPROPRIATE FOR REFERRAL FOR BONE MARROW TRANSPLANTATION SERVICES AND FROM THE AGE GROUPING OF PATIENTS BASED ON THE TYPE OF SERVICE TO BE OFFERED. This specification of projections shall include aN ~~description of the data source(s) used,~~ assessments of the accuracy of ~~these data~~PROJECTIONS, and OF the statistical method used to make the projections. Based on this documentation, the Department shall determine if the projections are reasonable.

~~**Section 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 next United States Congress in session after the effective date of these standards. 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~~BMT Services

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

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

Sec. 11. (1) These CON review standards supersede and replace the CON Review Standards for Extrarenal Transplantation Services pertaining to ~~bone marrow transplantation~~BMT services approved by the CON Commission on ~~December 12, 2006~~SEPTEMBER 16, 2008 and effective on ~~March 8, 2007~~NOVEMBER 13, 2008.

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

Attachment C

1. **Bone Marrow Transplant, Proposed Action:**

   a. Overall - The BMT-SAC is recommending that the current authorization of 3 adult programs meets the access, cost and quality needs of southeast Michigan and that no additional adult programs are needed in southeast Michigan. EAM strongly supports this recommendation. The SAC also is recommending dividing the state into two planning areas, east and west (same as already done for pediatric) and allowing for (1) new adult program in the west planning area. The overwhelming SAC vote in favor of this one additional adult program in west Michigan prompted EAM to say that all new programs needed to have a much higher annual minimum volume (currently just 10) and meaningful projection language.

   b. Minimum Volume - EAM supports the BMT SAC's recommendations to have a higher minimum volume (increase from 10 to 30) for all new adult BMT programs, applying to the one additional program in west Michigan, and possible for any other new programs should a CON become available under the current limit. This is not intended to be an assurance of higher quality but rather an assurance of greater operational efficiency. The cost of staffing a BMT program is significant. If a reasonable annual patient load for a BMT specialist is 20 cases per year and an effective BMT programs should have a minimum of 2 specialist, than 40 procedures BMT patients per year would be the minimum optimum operational efficiency for a new program. We found that SAC's recommended annual minimum of 30 adult, plus the Standard's current annual minimum of 10 pediatric transplants would achieve this operational efficiency.

      For similar reasons, we support the elimination from the Standards all provisions related to autologous-only or allogeneic only transplant programs to insure that every patient would be provided the most appropriate BMT alternative.

   c. Volume Projection Criteria - EAM would also support some process included in the Standards that specifies how each applicant is to project the annual minimum volume for new programs. Without specific language for projecting this minimum volume in the Standard, the Department must accept whatever process the applicant chooses to use. EAM supports changing this pre-1988 language in the BMT Standard to language that would be based upon verifiable date relevant to the planning area.

   d. SAC Process - The persons who volunteered to be on this BMT SAC included a fair mix of experts and non-experts from different perspectives from a broad cross-section of the state. The Department did the best job possible to achieve a balance of those who have this service, those seeking to have this service and neutral third parties from those who volunteered to participate. All parties were given a fair opportunity to present their case. The SAC's recommendations are a valid consensus of most SAC members.

2. **Heart/Lung and Liver Transplant, Proposed Action:**

The Heart/Lung and Liver Transplant (HLLT) SAC is recommending that the current authorization of 3 programs in Michigan meets the access, cost and quality needs of the community and that no additional programs are needed in Michigan. EAM strongly support this recommendation. We agree with the findings of the MDCH staff that there are only two CONs for Heart Transplant programs. The Henry Ford and Children's Hospital heart transplant programs are part of a single CON, according to specific action by this Commission just a few years ago designating adult and pediatric programs operating at two nearby locations to be just one CON program. The final interpretation of this finding from the AG is still pending but we think there is no doubt about the MDCH staff's finding because the language in the Standards is so clear and definite.

3. **Magnetic Resonance Imaging (MRI) Services, Final Action:**

EAM also does not support replacing a mobile MRI with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their services to patients with Medicaid. Additional, for-profit fixed MRI capacity in excess of this +25% will be in direct competition for the fully insured patients with the not-for-profit MRI facilities in these communities.

This also creates a two-tiered healthcare delivery system; one for patients with insurance and a second for patients with Medicaid or no-insurance. By allowing this CON exception for higher volume Medicaid providers, we are allowing the Not-for-Profit hospitals in a community to not shoulder their fair share of the indigent care. Rather than making this change in CON for the For-Profit higher volume Medicaid providers, the Not-for-Profit hospitals should be held more accountable for living up to their mission of providing services to all.

Blue Cross
Blue Shield
Of Michigan

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Detroit, Michigan 48226-2998

Testimony
Blue Cross Blue Shield of Michigan/Blue Care Network
CON Commission Meeting
December 9, 2009

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

Bone Marrow Transplantation (BMT) Services Standard Advisory Committee (SAC)

BCBSM and BCN commend the demanding and exacting work of BMT SAC members and MDCH staff during the challenging deliberations of this group. BCBSM/BCN has been actively engaged in this process as an open-minded participant, well represented by Dr. Tom Ruane BCBSM PPO.

Per Dr. Ruane's statement during one of the SAC meetings," BCBSM/BCN is not convinced that improved access that would occur...would outweigh the problems caused by decreased volume in the existing centers...." Thus, BCBSM and BCN remain unconvinced of the need for additional BMT programs in Michigan despite the extensive information presented during the course of this SAC including presentations, discussions, statistical analyses and clinician-specialists' input.

Magnetic Resonance Imaging Service Standards

BCBSM and BCN continue to oppose most proposed exemptions to these standards, since multiple exceptions weaken the standards as a whole and have the potential to increase costs of health care service delivery.

- BCBSM/BCN does not support the proposed language to that allows replacement of a mobile MRI with a fixed MRI for any hospital emergency room with more than 20,000 visits per year. Based on input of our clinicians, there appears to be no clinical or public policy rationale that supports this exemption. The majority of MRI services do not need to be completed immediately upon arrival in the emergency department, and/or there may be no capacity at such facilities to treat the findings of a positive MRI if immediate scanning is indicated.
- BCBSM/BCN does not support language that allows for the replacement of mobile MRI units with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their service to Medicaid–covered patients. Many questions are left to be addressed regarding the validity of this proposal from a public policy rationale. Also, this additional capacity would be in direct competition with existing hospital-based not for profit MRI units, including for patients having coverage other than Medicaid.
- However, BCBSM/BCN supports proposed language that exempts MRI units for the simulation of megavoltage radiation cancer treatment. BCBSM and BCN clinicians feel that this approach provides more accurate treatment planning, which in turn generates higher quality patient care services.

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Cardiac Services Standards:

Concerns have been expressed about the lack of comprehensive cardiovascular services across all areas of the state. BCBSM and BCN continue to actively promote competition among financially stable health care system providers; particularly where competitive and comprehensive programs provide member choice, along with cost savings and high quality services.

BCBSM and BCN support moving forward the review of the Open Heart Surgery and Cardiac Catheterization CON Standards based on our traditional position for open and transparent discussions of key issues. Accordingly, BCBSM and BCN recommend that the CON Commission convene two Standard advisory Committees to review both sets of cardiac standards during 2010.

Conclusion

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

TO: Edward B. Goldman
Chairperson
Michigan CON Commission

FROM: James F. Ball
Chairperson
Heart/Lung and Liver Transplantation Services (HLL) SAC

SUBJECT: Final Report

The following is the final report of our Committee on the items of the Charge. The timing of our assignment permitted us to hold seven meetings, comprising approximately 17 hours of testimony and discussion. As will be discussed further below, with the exception of discussion of whether there should be an increase in the number of authorized services and/or whether there should be a partitioning of the state into multiple planning areas, there was relatively little controversy.

1. **Consider and recommend whether continued regulation of these services is necessary. (If the recommendation is yes, then continue with items 2 through 6.)**

   The <u>unanimous</u> opinion of the SAC was that regulation of these services SHOULD continue. Unlike many other services that are subject to CON in Michigan, HLL services are constrained by the availability of organ donations. Testimony indicated that this situation is not likely to change in the near term, certainly not before the Standards would come up for review again. There is a direct relationship between quality and volume as is recognized by volume standards associated with various Federal approvals (e.g., CMS, OPTN). Additionally, financial and staffing requirements dictate concentration of the services to relatively few providers.

2. **Consider the establishment of a clear needs based methodology for the initiation of heart/lung transplantation services.**

   The <u>consensus</u> view of the SAC was that the current Standards represent appropriate allocation of services based on patient need and the practical ability to respond to it. The implication of the Charge element was that the current Standards are not based on need. In the discussions of other Standards, “needs-based” has tended to be a euphemism for “facility-based”, with the view that initiation of additional covered services should be associated with performance of a particular volume of other services and/or a particular volume of patients with designated conditions in a catchment area. Testimony revealed that the existing units have the capacity for additional services. There was no testimony that there is unmet need based on lack of capacity. There is a record of both importation and exportation of organs. Patients going out of state for transplants appear to be functions of insurer direction to network facilities, patient preference for use of out-of-state facilities (if approved by carriers), availability of family support systems, logistics and proximity issues (e.g., UP – Wisconsin link), failure to meet Center criteria and, to a lesser extent, a transplant type not being available in Michigan (e.g., liver and kidney at the same time). Simply increasing the number of facilities authorized would not respond to most of these issues.

3. Consider continuation and/or amendment of the CAP currently regulating the number of heart/lung transplant services in Michigan.

4. Recommend a methodology for regulating the number of heart/lung transplant services with rationale for the recommendation.

5. If the existing cap methodology is recommended then consider and make recommendations to the existing cap methodology for heart/lung transplantation services, including the following items: (a) Any modification of the number of approvable new programs; (b) Any changes in planning area designation; and (c) Any changes to the comparative review standards as defined in Section 6.

The consensus view of the SAC was that the number of approvable Programs, the single statewide planning area and the comparative review elements of the current Standards should be retained.

The members were not unaware that the timing of the impaneling of the SAC may have been, in large part, a function of the localized interest on the west side of the state in having a new center approved there. Dr Hooker, a member of the SAC, and representatives of Spectrum Health made presentations on the topic. In the end, however, no change was recommended.

On the issue of the number of approvable Programs, at one of our earlier meetings it was determined that because the DMC/Children's and the Henry Ford operations were, in fact, approved by the Department in 1996 as a single, joint sharing, adult/pediatric service contemplated under the existing Standards, there is an open slot for heart/lung transplant services. I understand that Spectrum now has an application pending.

Following the September meeting, it was suggested that failure to recommend expansion was based on the availability of an open slot. It also was suggested that regardless of the clear wording of the Standards and approval letter, the status of the arrangement might be challenged and overturned. If so, the argument went, the SAC would have opted for recommending an increase in numbers. We specifically addressed that issue in a separate meeting in October and voted (10 - 0 – 2 abstentions) to retain the current number. In fairness, it should be noted that had Dr. Hooker been able to attend, or to have an alternate, my presumption is that the vote would have been 10 – 1 – 2. I believe the vote reflected the discussion that took place over several meetings – that while approving additional capacity to permit a site in western Michigan would solve some patient preference and proximity issues, it would not solve others, would not necessarily mean that there would be an increase in services, would add cost without a concomitant increase in quality or access and could negatively impact volume of services elsewhere. The facts remain that the state both imports and exports organs, that there is existing capacity to perform additional services, that organs are not being exported because of lack of capacity and whether the lack of a facility in Grand Rapids is causing people to miss out on available heart transplants is somewhat conjectural.

On the issue of planning areas, we took a vote at the October meeting, with an identical outcome. I believe the consensus position reflects at least two primary thoughts. The first, and perhaps most obvious, is that it is not an issue of simply deciding to split the planning area to create new opportunity. You have the issue of the appropriate number and how the state should be split. Partitioning the state in 2

sections longitudinally, as the Grand Rapids-area contingent advocates, addresses a concern for people in that area. But it does not help people in other areas (e.g., the UP or the upper thumb), who would remain equally inconvenienced. Should the state be partitioned in thirds, quarters or whatever, in order to accommodate the potential interests of other areas? Secondly, while partitioning alone, without an increase in approvable services, would not solve the concern of the Grand Rapids contingent, the opposite is not true. If the Commission decides to increase the number of approvable services, the existing comparative review standards should result in the additional service(s) being located outside of southeast Michigan. It is not necessary to debate how the state should be partitioned.

6. Recommend potential changes in outdated and inconsistent language in sections 4, 8, 9 and 10 for Heart/Lung/and Liver transplant services.

The Staff will be presenting recommended updates at your December meeting. There are two items I would like to note specifically.

- We are recommending that the provisions for joint adult/pediatric heart/lung programs be extended to liver. It is not clear that there will be an interest in pediatric liver services, but it was felt that if there ever is, encouraging such sharing arrangements is consistent with the principles of CON.
- At the October meeting, the Department submitted proposed technical updates with respect to indigent and/or uncompensated care. We did not have sufficient notice to be able to discuss this and assess the potential impact of the changes. We opted to move them forward to you, with the understanding that the Department may withdraw them before your meeting or, if not, will explain them and provide the analysis of potential impact.

Respectfully submitted

James. F. Ball
December 2, 2009

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS
FOR HEART/LUNG AND LIVER 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 heart/lung or liver transplantation services.~~ THESE STANDARDS ARE REQUIREMENTS FOR THE APPROVAL AND DELIVERY OF SERVICES UNDER PART 222 OF THE CODE. PURSUANT TO PART 222 OF THE CODE, HEART/LUNG AND LIVER TRANSPLANTATION ~~IS A~~ARE COVERED CLINICAL SERVICES. THE DEPARTMENT SHALL USE THESE STANDARDS IN APPLYING SECTION 22225(1) OF THE CODE, BEING SECTION 333.22225(1) OF THE MICHIGAN COMPILED LAWS AND SECTION 22225(C) OF THE CODE, BEING SECTION 333.22225(2)(C) OF THE MICHIGAN COMPILED LAWS.

(2) ~~Heart/lung or liver transplantation is a covered clinical service for purposes of Part 222 of the Code.~~

~~(3) For~~ For purposes of Part 222 a separate CON is required for heart/lung or liver transplantation services. A CON issued for a heart/lung transplantation service includes a service that performs heart, heart/lung, or lung transplant procedures and a separate CON is not required to begin performing any of these procedures if one or more are not performed initially.

~~(4) The Department shall use sections 3, 4, 5, and 11, as applicable, in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws.~~

~~(5) The Department shall use sections 7, 8, 9, and 10, 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) "Certificate of Need Commission" or "CON Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(b) "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.

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

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

(e) "Health service area" or "HSA" means the geographic area set forth in Section ~~129~~.

~~(f) "Implementation plan" means a plan that documents how a proposed 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 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 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.

(gF) "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.

(hG) "Licensed site" means either (i) in the case of a single site hospital, the location of the facility HOSPITAL 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.

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

(jI) "OPO" or "Organ Procurement Organization" OR "OPO" means an organ procurement organization as defined by Title 42, Part 485.302. "ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK" OR "OPTN" MEANS THE ORGANIZATION CONTRACTED BY THE FEDERAL DEPARTMENT OF HEALTH AND HUMAN SERVICES TO OPERATE THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

(kJ) "OPTN" or "Organ Procurement and Transplantation Network" OR "OPTN" means the organization contracted by the federal Department of Health and Human Services to operate the organ procurement and transplantation network. "ORGAN PROCUREMENT ORGANIZATION" OR "OPO" MEANS AN ORGAN PROCUREMENT ORGANIZATION AS DEFINED BY CFR TITLE 42, PART 485.302.

(lK) "Pediatric" means, for purposes of these standards, any patient less than 15 years of age or any patient with congenital anomalies related to the proposed transplantation service.

(mL) "Planning area" means the state of Michigan.

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

(oN) "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.

(pO) "Transplant and Health Policy Center" means the statewide organization which studies issues regarding organ transplantation and other emerging health care technologies and operates the organ transplant registry.

(qP) "Transplant support program" means, for purposes of these standards, a program where a hospital providing a transplantation service has a written agreement with one or more hospitals to coordinate the care of transplant patients residing outside the HSA in which the hospital providing the transplantation service is located in order that patients may receive transplant-related services, to the

~~maximum extent practical, at the hospital with which the agreement is written. The program shall be active on the date an application is submitted to the Department having accepted potential transplant recipient(s) into the program.~~

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

Section 3. Requirements for ~~approval --~~ all applicants

Sec. 3. (1) An applicant proposing to perform either a heart, heart/lung, ~~or~~ lung or liver transplantation service shall demonstrate that it offers all of the following services or programs:

(a) operating rooms;
(b) anesthesiology;
(c) microbiology and virology laboratory;
(d) continuous availability, either on-site or on-call, of:
(i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear medicine; and
(ii) a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support; cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology.
(e) dialysis;
(f) infectious disease;
(g) inpatient-outpatient social work;
(h) inpatient-outpatient psychiatry/psychology;
(i) clinical research;
(j) a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization THAT IS AN APPROVED MEMBER OF THE OPTN, either on-site or through written agreement;
(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, immuno-suppressive drug monitoring and tissue typing;
(m) continuous availability of red cells, platelets, and other blood components;
(n) an established organ donation protocol, with brain death protocol, consistent with applicable Michigan law; and
(o) a written TRANSPLANT agreement with Michigan's federally designated ~~organ procurement organization (~~OPO~~)~~ to promote organ donation at the applicant hospital(s).

(2) An applicant must provide~~, at the time the CON application is submitted,~~ an implementation plan for the proposed transplantation service. IMPLEMENTATION PLAN MEANS A PLAN THAT DOCUMENTS HOW A PROPOSED 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~~A) EACH COMPONENT OR ACTIVITY NECESSARY TO BEGIN PERFORMING THE PROPOSED 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~~B) THE TIMETABLE FOR COMPLETING EACH COMPONENT OR ACTIVITY SPECIFIED IN SUBSECTION (I); AND
(~~iii~~C) IF THE APPLICANT PREVIOUSLY HAS BEEN APPROVED FOR A 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.

(3) An application which proposes a joint sharing arrangement for a transplantation service which involves more than one licensed site shall demonstrate all of the following:

(a) all licensed sites in the joint sharing arrangement are part of a single legal entity authorized to do business in Michigan;

(b) all licensed sites in the joint sharing arrangement are geographically close enough so as to facilitate cost-effective sharing of resources;

(c) an applicant has designated a single licensed site where the transplant surgical procedure(s) will be performed, except that where an applicant proposes a joint sharing arrangement which involves both adult and pediatric transplant procedures, the applicant may designate a single licensed site where all adult transplant procedures will be performed and a single licensed site where all pediatric transplant procedures will be performed, if:

(i) both licensed sites are part of the joint sharing arrangement;

(ii) the same transplant coordinator will serve patients at both licensed sites;

(iii) laboratory procedures related to the proposed transplantation service will be performed at a single common laboratory operated by the applicant;

(iv) all physicians performing the proposed transplantation procedures at either licensed site are part of a common organizational entity (i.e., partnership, professional corporation, or medical school faculty); and

(v) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification.

(4) An applicant shall provide verification of Medicaid participation. AN APPLICANT THAT IS A NEW PROVIDER NOT CURRENTY ENROLLED IN MEDICAID SHALL CERTIFY THAT PROOF OF MEDICAID PARTICIPATION WILL BE PROVIDED TO THE DEPARTMENT WITHIN SIX (6) MONTHS FROM THE OFFERING OF SERVICES IF A CON IS APPROVED. ~~at the time the application is submitted to the Department. 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.~~

(5) AN APPLICATION WHICH PROPOSES A JOINT SHARING ARRANGEMENT FOR A HEART, ~~OR~~ HEART/LUNG, ~~OR~~ LUNG OR LIVER TRANSPLANTATION SERVICE WHICH INVOLVES MORE THAN ONE LICENSED SITE, WHERE THE LICENSED SITES IN THE JOINT SHARING ARRANGEMENT ARE NOT PART OF A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN MICHIGAN, SHALL NOT BE REQUIRED TO MEET SECTION 4(1) OR 5(1) OF THESE STANDARDS, IF AN APPLICANT CAN DEMONSTRATE ALL OF THE FOLLOWING:

(I) EACH LICENSED SITE IN THE JOINT SHARING ARRANGEMENT IS PARTY TO A WRITTEN JOINT VENTURE AGREEMENT AND EACH LICENSED SITE HAS JOINTLY FILED AS THE APPLICANT FOR THE CON;

(II) ALL LICENSED SITES IN THE JOINT SHARING ARRANGEMENT ARE GEOGRAPHICALLY CLOSE ENOUGH SO AS TO FACILITATE COST-EFFECTIVE SHARING OF RESOURCES;

(III) THE APPLICATION CONTAINS A FORMAL PLAN FOR THE SHARING OF SERVICES, STAFF AND ADMINISTRATIVE FUNCTIONS RELATED TO THE TRANSPLANTATION SERVICE, INCLUDING BUT NOT LIMITED TO: PATIENT REVIEW, PATIENT SELECTION, DONOR ORGAN RETRIEVAL AND PATIENT CARE MANAGEMENT;

(IV) AN APPLICANT HAS DESIGNATED A SINGLE LICENSED SITE WHERE ALL OF THE ADULT TRANSPLANTATION PROCEDURES WILL BE PERFORMED AND A SINGLE LICENSED SITE WHERE ALL OF THE PEDIATRIC TRANSPLANTATION PROCEDURES WILL BE PERFORMED, PROVIDED THAT BOTH LICENSED SITES ARE PART OF THE JOINT SHARING ARRANGEMENT;

(V) THE LICENSED SITE AT WHICH THE PEDIATRIC TRANSPLANTATION SERVICE WILL BE PROVIDED SHALL HAVE ADMITTED OR DISCHARGED AT LEAST 7,000 PEDIATRIC PATIENTS DURING THE MOST RECENT 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE AVAILABLE

TO THE DEPARTMENT;

(VI) THE LICENSED SITE THAT IS DESIGNATED AS THE SITE AT WHICH ADULT PROCEDURES WILL BE PERFORMED IS AUTHORIZED UNDER FORMER PART 221 OR PART 222, AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT, TO PERFORM ADULT HEART OR HEART/LUNG OR LUNG OR LIVER TRANSPLANTATION SERVICES;

(VII) THE APPLICANT SHALL AGREE THAT THE TWO LICENSED SITES WILL JOINTLY APPLY TO PERFORM TRANSPLANTATION PROCEDURES UNDER THE SAME OPTN CERTIFICATION; AND

(VIII) THE APPLICANT PROJECTS A MINIMUM OF 12 ADULT AND 10 PEDIATRIC HEART, ~~OR~~ HEART/LUNG, ~~OR~~ LUNG OR LIVER TRANSPLANTATION PROCEDURES IN THE SECOND 12-MONTHS OF OPERATION FOLLOWING THE DATE ON WHICH THE FIRST HEART, ~~OR~~ HEART/LUNG, ~~OR~~ LUNG OR LIVER TRANSPLANT PROCEDURE IS PERFORMED, AND ANNUALLY THEREAFTER.

Section 4. Additional requirements for ~~applicants seeking approval to provide~~ heart, ~~or~~ heart/lung or lung transplantation services

Sec. 4. (1) Approval of an application proposing to provide heart, ~~or~~ heart/lung or lung transplantation services shall not result in more than three (3) heart, ~~or~~ heart/lung or lung transplantation services in the planning area. In evaluating compliance with this subsection, an application submitted or a certificate approved pursuant to Section 43(5) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 43(5) of these standards, an applicant for a heart, ~~or~~ heart/lung or lung transplantation service shall project a minimum of 12 heart, ~~or~~ heart/lung or lung transplantation procedures annually in the second 12-months of operation following the date on which the first heart, ~~or~~ heart/lung or lung transplant procedure is performed and annually thereafter.

(3) An applicant proposing to provide heart, ~~or~~ heart/lung or lung transplantation services shall demonstrate that it either operates an existing renal transplant service or has a written agreement with a renal transplant service in the same hospital subarea that ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service.

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

(a) a cardiovascular medical/surgical program that includes at least the following: (i) an open heart surgery service that performs at least 300 adult and/or 100 pediatric procedures annually, as applicable; and (ii) a cardiac catheterization service that performs at least 500 adult and/or 250 pediatric cardiac catheterizations and coronary arteriograms annually, as applicable, and has the capability to perform these procedures on an emergency basis.

(b) continuous availability, either on-site or on-call, of angiography services;

(c) an intensive care unit with 24-hour per day on-site physician coverage;

(d) continuously available coagulation laboratory services; and

(e) a blood bank capable of providing 20 units of blood, platelets, and fresh blood products on demand.

~~(5) An application which proposes a joint sharing arrangement for a heart or heart/lung or lung transplantation service which involves more than one licensed site, where the licensed sites in the joint sharing arrangement are not part of a single legal entity authorized to do business in Michigan, shall not be required to meet Section 4(1) of these standards, if an applicant can demonstrate all of the following:~~

~~(i) each licensed site in the joint sharing arrangement is party to a written joint venture agreement and each licensed site has jointly filed as the applicant for the CON;~~

~~(ii) all licensed sites in the joint sharing arrangement are geographically close enough so as to~~

~~facilitate cost-effective sharing of resources;~~

~~(iii) the application contains a formal plan for the sharing of services, staff and administrative functions related to the transplantation service, including but not limited to: patient review, patient selection, donor organ retrieval and patient care management;~~

~~(iv) an applicant has designated a single licensed site where all of the adult transplantation procedures will be performed and a single licensed site where all of the pediatric transplantation procedures will be performed, provided that both licensed sites are part of the joint sharing arrangement;~~

~~(v) the licensed site at which the pediatric transplantation service will be provided shall have admitted or discharged at least 7,000 pediatric patients during the most recent 12-month period for which verifiable data are available to the Department;~~

~~(vi) the licensed site that is designated as the site at which adult procedures will be performed is authorized under former Part 221 or Part 222, at the time the application is submitted to the Department, to perform adult heart or heart/lung or lung transplantation services;~~

~~(vii) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation procedures under the same OPTN certification; and~~

~~(viii) the applicant projects a minimum of 12 adult and 10 pediatric heart or heart/lung or lung transplantation procedures in the second 12-months of operation following the date on which the first heart or heart/lung or lung transplant procedure is performed, and annually thereafter.~~

Section 5. Additional requirements for ~~applicants seeking approval to provide~~ liver transplantation services

Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not result in more than three (3) liver transplantation services in the planning area. IN EVALUATING COMPLIANCE WITH THIS SUBSECTION, AN APPLICATION SUBMITTED OR A CERTIFICATE APPROVED PURSUANT TO SECTION 3(5) OF THESE STANDARDS SHALL BE CONSIDERED AS A SINGLE SERVICE.

(2) EXCEPT FOR AN APPLICATION PURSUANT TO SECTION 3(5) OF THESE STANDARDS, an applicant for a liver transplantation service shall project a minimum of 12 liver transplantation procedures annually in the second 12-months of operation following the date on which the first liver transplant procedure is performed, and annually thereafter.

(3) An applicant proposing to provide liver transplantation services shall demonstrate that it either operates an existing renal transplant service or has a written agreement with a renal transplant service in the same hospital subarea that ensures that the professional expertise of the renal transplant service is readily available to the proposed transplantation service.

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

(a) continuous availability, either on-site or on-call, of angiography services;
(b) an intensive care unit with 24-hour per day on-site physician coverage;
(c) endoscopic retrograde cholangiopancreatography (ERCP) availability;
(d) percutaneous cholangiogram availability;
(e) percutaneous liver biopsy capability;
(f) a rapid blood infusion system;
(g) hemoperfusion; and
(h) a rapid red blood cell (RBC) blood saver system.

Section 6. REVIEW STANDARDS FOR ~~Additional requirements for applications included in~~ comparative reviews

Sec. 6. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or UNDER these standards shall be grouped and reviewed COMPARATIVELY with other applications in accordance with the CON rules. ~~applicable to comparative reviews.~~

(2)(a) A qualifying project will be awarded points based on the percent of compliance with the Uniform Anatomical Gift Law, Act No. 186 of the Public Acts of 1986, being Section 333.10101 et seq. of the Michigan Compiled Laws. The number of points awarded shall be calculated by dividing the number of deaths reported to the OPO by the total number of eligible deaths reported to the Department and multiplying the product by 4. The maximum number of points that can be awarded under this subsection is 4. An applicant shall provide, in the application at the time it is submitted to the Department, documentation of the total number of eligible deaths at the licensed site at which the proposed transplantation service will be provided, for the most recent year for which the Department has verifiable data.

(b) A qualifying project will have points awarded based on the number of transplantation services of the type proposed, both operating and CON approved, but not yet operational, in the health service area in which the proposed program will be located, on the date the application is submitted to the Department, as shown in the following schedule:

Number of Transplant Programs in HSA	Points Awarded
Two or more programs	0
One program	2
No programs	4

(c) 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 heart/lung or liver 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 heart/lung or liver 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 ROUNDED TO THE NEAREST WHOLE NUMBER.

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

For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total HOSPITAL charges expressed as a percentage, ROUNDED TO THE NEAREST WHOLE NUMBER, as determined by the Michigan Department of Community Health Medical Services Administration ~~pursuant to Chapter VIII of the Medical Assistance Hospital Program Manual~~. The indigent volume data being used IN THIS SUBSECTION ~~for rates~~ IS THE DATA IN THE MOST CURRENT DCH-MSA DISPROPORTIONATE SHARE HOSPITAL (DSH) REPORT~~in effect~~ at the time the application(S) is deemed submitted ~~will be used~~ by the Department ~~in determining the number of points awarded to each qualifying project~~.

(d) 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 heart/lung or liver transplant procedures will be performed and were referred for and received a heart/lung or liver transplant at an existing heart/lung or liver transplantation service, and submits documentation from the existing

heart/lung or liver 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 or more of the competing applications satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have the highest number of points when the results of subsection (2) are totaled. If two or more qualifying projects are determined to have an identical number of points, the Department shall approve those qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications were received by the Department, based on the date and time stamp placed on the application ~~for~~ BY THE CON ~~form (form T-150-G-1.01 or any subsequent replacement form) by the Division of Health Facility Development (or the~~ administrative unit of the Department responsible for administering the CON program~~)~~ when an application is submitted.

(4) SUBMISSION OF CONFLICTING INFORMATION IN THIS SECTION MAY RESULT IN A LOWER POINT REWARD. IF AN APPLICATION CONTAINS CONFLICTING INFORMATION WHICH COULD RESULT IN A DIFFERENT POINT VALUE BEING AWARDED IN THIS SECTION, THE DEPARTMENT WILL AWARD POINTS BASED ON THE LOWER POINT VALUE THAT COULD BE AWARDED FROM CONFLICTING INFORMATION. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 6 POINTS BEING AWARDED, BUT OTHER CONFLICTING INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED, THEN 6 POINTS WILL BE AWARDED. IF THE CONFLICTING INFORMATION DOES NOT AFFECT THE POINT VALUE, THE DEPARTMENT WILL AWARD POINTS ACCORDINGLY. FOR EXAMPLE, IF SUBMITTED INFORMATION WOULD RESULT IN 12 POINTS BEING AWARDED AND OTHER CONFLICTING INFORMATION WOULD ALSO RESULT IN 12 POINTS BEING AWARDED, THEN 12 POINTS WILL BE AWARDED.~~No points will be awarded to an applicant under specific subsections of Section 6 if information presented in Section 6 is inconsistent with related information provided in other portions of the CON application.~~

Section 7. Project delivery requirements -- terms of approval ~~for all applicants~~

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

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

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards, as applicable:

(i) The applicant shall perform the applicable required volumes within the time periods specified in these standards, and annually thereafter.

(ii) The applicant shall comply AND REMAIN A FUNCTIONALLY ACTIVE PROGRAM with THE ~~applicable~~ OPTN AND ITS BY-LAWS AND POLICIES.

(A) THE APPLICANT SHALL COMPLY WITH THE~~and Medicare~~ CENTER FOR MEDICARE AND MEDICAID SERVICES (CMS) STANDARDS AND SHALL BECOME MEDICARE APPROVED WITHIN FIVE YEARS OF IMPLEMENTATION.~~requirements~~OF SERVICES.

(B) THE APPLICANT MUST BE IN GOOD STANDING WITH THE OPTN.

(iii) The transplantation service shall have a transplant team leader and coordinator.

(iv) The applicant shall have patient management plans and protocols that include the following: (A) therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the

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

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

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

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

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

(ix) 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 statewide transplantation registry operated by the Transplant and Health Policy Center and other national and international registries applicable to the transplantation service.~~ THE APPLICANT SHALL ALSO MAINTAIN A REGISTRY OF PATIENTS LISTED FOR A TRANSPLANT AND FOR TRANSPLANT RECIPIENTS AS REQUIRED BY THE FEDERAL OPTN.

(x) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, patient survival rates at both 12 and 24 months following the transplant procedure, primary and secondary diagnoses, whether the transplant procedure was a first or repeat transplant procedure, length of stay, the volume of care provided to patients from all payor sources, and other data requested by the Department and approved by the CON Commission. The applicant shall provide the required data on an individual basis for each designated licensed site; in a format established by the Department; and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.

(xi) The applicant, to assure that the 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.

(xii) The applicant shall provide the Department with a notice stating the date on which the first transplant procedure is performed and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.

(xiii) The transplantation service must operate, or have a written agreement with, a histocompatibility laboratory that meets the standards of the American Society for Histocompatibility and Immunogenetics or an equivalent organization.

(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 Uniform Anatomical Gift Law, ~~Act No. 186 of the Public Acts of 1986, being~~PURSUANT TO MCL Section 333.10101 et seq. of the Michigan Compiled Laws.

(2) The agreements and assurances required by this section, ~~and sections 8, 9, and 10,~~ as applicable, shall be in the form of a certification ~~authorized by the governing body of~~ AGREED TO BY the applicant or its authorized agent.

~~Section 8. Additional terms of approval -- applicants proposing heart, heart/lung, lung or liver transplantation services~~

Sec. 8. (1) An applicant shall agree to establish and maintain all of the following:
(a) a written agreement with the federally approved organ procurement organization whose designated service area includes the location of the proposed transplantation service;
(b) organ preservation capability;
(c) an organized 24-hour transport system for transportation of organs, donors, and blood serum;
(d) an organized 24-hour communication service capable of serving the transplant team and others, as appropriate;
(e) a cyclosporine assay laboratory with results available on the same day;
(f) an immunologic monitoring laboratory;
(g) a specialized inpatient transplantation unit;
(h) nurses with specialized training assigned to operating room(s) and intensive care unit(s) used in conjunction with the transplantation service, trained in the hemodynamic support of the transplant patient and managing immuno-suppressed patients.
(i) a medical staff and governing board policy that provides for the selection of candidates for organ transplantation procedures in accordance with the patient selection criteria approved by the Department;
(j) an ethics committee or human use committee to review and approve the institution's protocols related to organ transplantation, including protocols involving the selection of donors and recipients; and
(k) a multi-disciplinary transplant recipient evaluation committee.

(2) An applicant shall agree that the transplantation service shall be staffed with qualified adult and pediatric, as applicable, transplant surgeon(s) and transplant physician(s). For purposes of evaluating this subsection, the Department shall consider it prima facie evidence as to the training of the surgeon(s) and physician(s) if they meet the requirements for certification by Medicare or the OPTN. However, the applicant may submit and the Department may accept other evidence that the surgeon(s) and physician(s) are qualified.

Section 9. Additional terms of approval -- applicants proposing heart or heart/lung or lung transplantation services

Sec. 9. (1) An applicant shall agree that the heart or heart/lung or lung transplantation service will be staffed and provided by at least the following:
(a) cardiologists or surgeons trained in endocardial biopsy;
(b) cardiologists and surgeons trained in immunosuppression techniques;
(c) both adult and pediatric, as appropriate, cardiologists and surgeons;
(d) surgeons with demonstrated capability of successfully performing orthotopic cardiac transplants in animals in a setting simulating the human situation;
(e) two cardiac transplant surgical teams with a total of at least three trained cardiac surgeons, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing a recipient operation;
(f) a pathologist capable of diagnosing rejection on endocardial biopsies; and
(g)an anesthesiologist trained in open heart surgery.
(2) An applicant must demonstrate heart transplant patient survival rates at one year and two years after transplantation of 73% and 65%, respectively. For lung and heart/lung, an applicant must demonstrate patient survival rates at one and two years after transplantation of no less than the national average survival rate for the specific transplant type for the most recent year for which data is published by the OPTN.

Section 10. Additional terms of approval -- applicants proposing liver transplantation services

Sec. 10. (1) An applicant shall agree that the liver transplantation service will be staffed and provided by at least the following:
(a) surgeons with demonstrated capability of successfully performing hepatic transplants in animals in a setting simulating the human situation;

~~(b) surgeons with demonstrated proficiency in major hepatic surgery such as hepatic lobectomy, repair of biliary strictures, and Porto systemic shunts;~~
~~(c) adult and pediatric, as appropriate, gastroenterologists and hematologists on the active medical staff;~~
~~(d) a pathologist capable of diagnosing hepatic rejection;~~
~~(e) anesthesiologist(s) trained in liver transplantation;~~
~~(f) two liver transplant surgical teams, with one surgical team continuously available for organ retrieval thereby enabling a second team to simultaneously begin performing recipient hepatectomy in preparation for liver implantation; and~~
~~(g) cardiopulmonary bypass equipment and a cardiopulmonary bypass team immediately available for a liver transplant recipient operation, a requirement which may be satisfied by a written agreement which ensures that a cardiopulmonary bypass team will always be on-site throughout the entire liver transplant recipient operation; and, a veno-venous bypass system which does not require heparin.~~

~~(2) The applicant shall establish and maintain all of the following:~~
~~(a) nuclear HID biliary scan availability;~~
~~(b) a continuously available coagulation laboratory; and~~
~~(c) a blood bank system capable of providing 200 units of blood or packed cells and 100 units of plasma on demand.~~

~~(3) An applicant must demonstrate patient survival rates at one year and two years after transplantation of no less than the national average survival rate for the most recent year for which data is published by the OPTN.~~

Section ~~11~~8. Documentation of projections

Sec. ~~11~~8. An applicant required to project volumes of service under sections 4 or 5 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 ~~12~~9. Health Service Areas

Sec. ~~12~~9. Counties assigned to each of the health service areas are as follows:

HSA			
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 ~~13~~10. Effect on prior CON Review Standards; comparative reviews

Sec. ~~13~~10. (1) These CON review standards supersede and replace the CON Review Standards for ~~Extrarenal Transplantation~~ FOR HEART/LUNG AND LIVER TRANSPLANTATION Services approved by the CON Commission on ~~June 4, 1997~~MARCH 9, 2004 and effective on ~~July 26, 1997~~JUNE 4, 2004.

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

For MRI Visits during the period July 1, 2008 through June 30, 2009
Souce: Michigan Department of Community Health MRI Data System

December 9, 2009

	Insurance Type				
MRI Grouping Level*	**Medicaid**	**Other**	**No Charge**	**Uninsured**	**Total**
Hospitals Macomb/Oakland/Wayne	**6,375 4.3%**	**131,181 88.8%**	**1,594 1.1%**	**8,507 5.8%**	**147,657 100.0%**
County of Residents Macomb/Oakland/Wayne	**13,912 4.7%**	**249,628 83.8%**	**3,493 1.2%**	**31,007 10.4%**	**298,040 100.0%**
Basha Routes Macomb/Oakland/Wayne	**2,503 30.9%**	**4,414 54.5%**	**2 0%**	**1,179 14.6%**	**8,098 100.0%**
State of Michigan TOTALS	**52,844 7.4%**	**579,290 80.8%**	**5,809 .8%**	**79,002 11.0%**	**716,945 100.0%**

***Note: Categories are NOT mutually exclusive**

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

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

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

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

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

In the case of an MRI service that operates, or has a valid CON to operate, more than one fixed MRI unit at the same site, the term means the number of MRI adjusted procedures in excess of 8,000 multiplied by the number of fixed MRI units at the same site. For example, if an MRI service operates, or has a valid CON to operate, two fixed MRI units at the same site, the available number of MRI adjusted procedures is the number that is in excess of 16,000 (8,000 x 2) MRI adjusted procedures.

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

(d) "Central service coordinator" means the organizational unit that has operational responsibility for a mobile MRI unit(s).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ll) "Planning area" means

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(vv) "Site" means

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

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

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

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

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

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

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

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

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

Section 3. Requirements to initiate an MRI service

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

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

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

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

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

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

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

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

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

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

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

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

(IV) AT LEAST 2,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF THE FOLLOWING:

(A) AT LEAST 25% OF THE MRI ADJUSTED PROCEDURES HAVE A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE.

(B) THE APPLICANT IS A FOR-PROFIT, FREESTANDING FACILITY.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 4. Requirements to replace an existing MRI unit

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

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

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

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

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

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

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

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

Section 5. Requirements to expand an existing MRI service

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 8. Requirements to establish a dedicated research MRI unit

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

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

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

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

Section 9. Requirements to establish a dedicated pediatric MRI unit

Sec. 9. (1) An applicant proposing to establish dedicated pediatric MRI shall demonstrate all of the following:

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

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

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

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

(d) The applicant shall have in operation the following pediatric specialty programs:

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

(2) An applicant meeting the requirements of subsection (1) shall be exempt from meeting the requirements of Section 5 of these standards.

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

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

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

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

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

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

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

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

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

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

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

Section 11. Requirements for all applicants

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

Section 12. Project delivery requirements – terms of approval

Sec. 12. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:
(a) Compliance with these standards.
(b) Compliance with applicable safety and operating standards.
(c) Compliance with the following quality assurance standards:
(i) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.
(ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
(iii) An applicant shall provide documentation identifying the specific individuals that form the MRI team. At a minimum, the MRI team shall consist of the following professionals:
(A) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board-certified radiologist.
(B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
(C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.
(iv) An applicant shall document that the MRI team members have the following qualifications:
(A) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:
(1) The physician is licensed to practice medicine in the State of Michigan.

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

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

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

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

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

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

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

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

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

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

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

(i) MRI units shall be operating at a minimum average annual level of utilization during the second 12 months of operation, and annually thereafter, of 6,000 actual MRI adjusted procedures per unit for fixed MRI services, 5,500 actual MRI adjusted procedures per unit for mobile MRI services, and a total of 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI. Each mobile host site in a rural or micropolitan statistical area county shall have provided at least a total of 400 adjusted procedures during its second 12 months of operation, and annually thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during its second 12 months of operation and annually thereafter, from all mobile units providing services to the site. In meeting these requirements, an applicant shall not include any MRI adjusted procedures performed on an MRI unit used exclusively for research and approved pursuant to Section 8(1) or for an IMRI unit approved pursuant to Section 10.

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

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

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

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

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

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

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

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

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

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

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

(3) AN APPLICANT FOR AN MRI UNIT APPROVED UNDER SECTION 3(2)(B)(IV) SHALL AGREE TO CONTINUE TO PROVIDE AT LEAST 25% OF THE MRI VISITS WITH A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE DURING THE FIRST 12 MONTHS OF OPERATION AND ANNUALLY THEREAFTER FOR AT LEAST 10 YEARS.

(~~3~~4) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section 13. MRI procedure adjustments

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) Subsection (2) shall not apply to an application proposing a subsequent fixed MRI unit (second, third, etc.) at the same site.

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

Section 14. Documentation of actual utilization

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

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

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

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

(i) For purposes of computing actual MRI adjusted procedures, MRI adjusted procedures performed on MRI units used exclusively for research and approved pursuant to Section 8(1) and dedicated pediatric MRI approved pursuant to Section 9 shall be excluded.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed data commitment, on a form provided by the Department in response to the applicant's letter of intent for

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

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

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

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

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

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

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

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

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

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

(i) The approved CON is withdrawn or expires.

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 17. Lists published by the Department

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

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

(i) The number of actual MRI adjusted procedures;

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

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

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

(i) The number of available MRI adjusted procedures;

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

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

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

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

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

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

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

Sec. 18. (1) These CON review standards supersede and replace the CON Review Standards for Magnetic Resonance Imaging Services approved by the CON Commission on ~~September 16, 2008~~ SEPTEMBER 10, 2009 and effective ~~November 13, 2008~~ NOVEMBER 5, 2009.

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

Section 19. Health Service Areas

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

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

APPENDIX A

CON REVIEW STANDARDS FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

Amendment to MDCH Draft of Proposed MRI Standards

Section 2. Definitions

Add the following:

(jj) "NO CHARGE" MEANS AN MRI VISIT WHERE THE PATIENT IS NOT CHARGED A FEE FOR THE VISIT BY THE MRI SERVICE. THIS DOES NOT INCLUDE INPATIENT OR OTHER VISITS WHERE THE MRI VISIT IS INCLUDED IN A LARGER FEE BEING PAID BY A THIRD PARTY PAYER SUCH AS A DRG (DIAGNOSIS-RELATED GROUP) PAYMENT.

Section 3. Requirements to initiate an MRI service

Modify Section 3(2)(b)(iv)(A) to read as follows:

(A) AT LEAST 25% OF TOTAL MRI **VISITS** HAVE A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE.

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

Add the following to Section 7(1)

(C) FOR ANY APPLICATION PROPOSING TO ACQUIRE AN EXISTING FIXED MRI SERVICE AND ITS UNIT(S) THAT WAS INITIATED UNDER SECTION 3(2)(B)(IV) OF THESE STANDARDS, THE APPLICANT ALSO MUST MEET THE REQUIREMENTS OF SECTION 3(2)(B)(IV).

CERTIFICATE OF NEED

Quarterly Compliance Activity Report to the CON Commission

July1, 2009 through September 30, 2009 (FY 2009)

This quarterly report is designed to update the Commission on the Department's activity in monitoring compliance with all Certificates of Need issued as required by Section 22247 of the Public Health Code.

MCL 333.22247

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

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

(a) Revoke or suspend the certificate of need.

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

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

(d) Request enforcement action under section 22253.

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

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

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

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

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department performs follow up checks on approved CONs to determine if proposed projects have been implemented in accordance with Part 222. For this quarter, the following actions have occurred:

Activity	Recent Quarter	Year-to-Date
Letters mailed to verify progress approved projects	275	1,409
Projects deemed 100% complete and operational	46	417
CON approvals expired due to noncompliance with Part 222	28	155

Compliance: In accordance with MCL 333.22247, the Department has initiated compliance investigations on two open heart surgical services and one mobile MRI route, which are still ongoing. Of special note, the Department has posted a new position for a compliance officer. This person, once hired, will focus primarily on volume checks and other project delivery requirements.

CERTIFICATE OF NEED LEGAL ACTION

(11/23/09)

Case Name	**Date Opened**	**Case Description**	**Status**
Livingston County - Compare Group #950184 INCLUDES: Brighton Senior Care & Rehab Center #2009-5819-CON Heartland Healthcare Center II 2009-6457-CON Livingston Health Campus Livingston Care Center, LLC 2009-5815-CON Medilodge of Howell, Inc. 2009-32560-CON	12/30/08	Livingston County – Comparative Review of nursing home beds – Administrative Appeal. The five applicants are: (1) Brighton Senior Care & Rehab Center, LLC (successful applicant), (2) HCR ManorCare Services, LLC (petitioner), (3) Trilogy Healthcare of Livingston, LLC, (4) Livingston Care Center, LLC (petitioner), and (5) MediLodge of Howell, Inc. (petitioner).	On October 9, 2009, the Administrative Law Judge issued a 40-page Proposal for Decision to Grant the Department of Community Health's Motion for Summary Disposition (PFD). The ALJ found that DCH properly conducted the comparative review when it determined Brighton's application scored the highest and that DCH properly determined that Livingston's and Medilodge's CON applications did not demonstrate compliance with MCL 333.2225(1) by failing to comply with the applicable revised CON standards for nursing home beds. Two out of three petitioners filed exceptions to the PFD. On November 6, 2009, DCH filed responses to the exceptions. We are currently waiting for a final decision from the Director.

CERTIFICATE OF NEED LEGAL ACTION

(11/23/09)

Case Name	**Date Opened**	**Case Description**	**Status**
Livingston County - Compare Group # 950195 INCLUDES: Livingston Care Center 2009-5815-CON Livingston Health Campus Medilodge of Howell 2009-6458-CON	9/22/08	Livingston County – Comparative Review of nursing home beds – Administrative Appeal. The three applicants are: (1) Trilogy Healthcare of Livingston, LLC, (2) Livingston Care Center, LLC and (3) MediLodge of Howell, Inc. (petitioner).	The parties agreed to stay this matter until resolution of Compare Group 95-0184.
Macomb County - Compare Group # 950185 INCLUDES: FountainBleu-Shelby Township 2009-19036-CON Utica Health Campus 2009-19041-CON Medilodge of Richmond 2009-19039-CON Medilodge of Sterling Heights 2009-19040-CON Medilodge of Washington 2009-19042-CON Heartland Health Care Center – Macomb 2009-19038-CON Windemere Park Nursing Center 2009-19043-CON	4/30/09	Macomb County – Comparative Review of nursing home beds – Administrative Appeal. The seven applicants are: ,(1) Fountainbleu, LLC (petitioner) (2) HCR ManorCare Services, LLC (successful applicant) (3) MediLodge of Richmond, LLC (petitioner) (4) MediLodge of Sterling Heights, Inc. (petitioner) (5) Trilogy Healthcare of Macomb, LLC (successful applicant) (6) MediLodge of Washington, LLC (petitioner) and (7) VanDyke Partners, LLC (successful applicant).	On November 19, 2009, DCH filed a Motion for Summary Disposition. Appellants response briefs are due by December 3, 2009 and reply briefs are due by December 17, 2009. A hearing will be schedule once all briefs are submitted.
Macomb County INCLUDES: Heartland Health Care Center – III	10/15/09	Macomb County – nursing home beds – Administrative Appeal. There was only one applicant, Heartland Health Center – Macomb III.	The parties agreed to stay this matter until resolution of Compare Group 95-0185.

CERTIFICATE OF NEED LEGAL ACTION

(11/23/09)

Case Name	**Date Opened**	**Case Description**	**Status**
Oakland Count y- Compare Group # 950177 INCLUDES: Woodward at Bloomfield Hills 2009-19212-CON McAuley Center 2009-19215-CON Waltonwood at Twelve Oaks – 3 2009-19214-CON Waltonwood at Main – 2 2009-19213-CON The Manor of Farmington Hills 2009-19044-CON Bloomfield Orchard Villa 2009-19136-CON	4/30/09	Oakland County – Comparative Review of nursing home beds – Administrative Appeal. The six applicants are: ,(1) Manor of Farmington Hills (petitioner), (2) Bloomfield Orchard Villa (petitioner), (3) Woodward at Bloomfield Hills Health Center (approved applicant), (4) Waltonwood at Main (approved applicant), (5) Waltonwood at Twelve Oaks (approved applicant, and (6) McAuley Center (approved applicant).	On December 1, 2009, DCH filed a Motion for Summary Disposition. Appellants response briefs are due by December 15, 2009 and reply briefs are due by December 29, 2009. A hearing will be schedule once all briefs are submitted
Oakland County INCLUDES: West Winds Health Center	4/30/09	Oakland County – nursing home beds – Administrative Appeal. There was only one applicant, West Winds Health Center.	The parties agreed to stay this matter until resolution of Compare Group 95-0177.
Ottawa County - Compare Group #950189 INCLUDES: Park Place Inn of Hudsonville 2009-19216-CON Waterford Rehab 2009-19217-CON	04/27/09	Ottawa County - Comparative Review of nursing home beds – Administrative Appeal. The two applicants are: (1) Waterford Rehab (petitioner) and (2) Park Place (successful applicant).	Petitioner withdrew its appeal and the matter has been dismissed. We will close our file.

CERTIFICATE OF NEED LEGAL ACTION

(11/23/09)

Woodcare X (Caretel) v MDCH Genesee County Cir Docket No.: 08-89784 CZ	10/08/08	Complaint for Mandamus	Parties have stipulated to an order of dismissal which was submitted to the Court on 8/27/09. Order entered 9/24/09 and appealed. CA no 294480.
Woodcare X (Caretel) v MDCH Court of Claims Docket No.: 08-132-MK	12/03/08	Filed for damages and specific performance of a settlement agreement reached 20 years ago.	Court rescheduled trial to 11/10/09, then denied our motion based on government immunity. Appeal filed 10/27/09, and case stayed. No 294824; consolidated with 294480.
Woodcare X (Caretel) v MDCH	10/27/09	Appeal of Mandamus and Court of Claims.	Brief filed.
MDCH v Woodcare X (Caretel) and CMS U.S. District Court (Western)	08/27/09	Filed Complaint for Declaratory & Injunctive Relief	CMS filed motion to dismiss, and we responded. Anticipate a ruling or notice of hearing by end of year.

s: chd; assign control; special; CON Leg Action; report 11/23/09

Request to Advance the Reviews of the Open Heart Surgery and Cardiac Catheterization Standards

CON Commission Meeting
December 9, 2009

Coalition of Health Systems

MetroHealth

TRINITY HEALTH
Novi, Michigan

BOTSFORD
HOSPITAL

Henry Ford
HEALTH SYSTEM

SAINT MARY'S
HEALTH CARE

MERCY
HEALTH PARTNERS

GARDEN CITY
HOSPITAL

DMC
DETROIT MEDICAL CENTER

HURLEY
MEDICAL CENTER

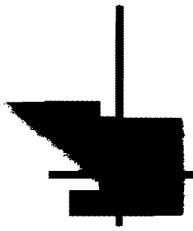
ST. MARY MERCY LIVONIA
SAINT JOSEPH MERCY HEALTH SYSTEM

Cheryl Miller - Testimony

- Director, Health Networks – Trinity Health, Novi MI,
- Introduction of Coalition member hospitals, health systems who prepared the document and testimony being presented today
  - Botsford Hospital
  - Detroit Medical Center
  - Garden City Osteopathic Hospital
  - Henry Ford Health System
  - Hurley Medical Center
  - Metropolitan Health
  - Trinity Health
- Overview of efforts to date with CON Commission, MDCH leadership
- Request: Advance the review of the Cardiac Cath and OHS standards to 2010 instead of 2011; please consider this matter at January 28th Commission Work Plan meeting
- Testimony today will focus on:
  - Why now? What's the urgency?
  - How these findings fit into 3 tenets of CON: Cost, Quality, Access
- Health care is in transition, shifts are already being seen
  - Pay for performance in lieu of fee for service
  - "Build it and they will come" to patient- centered medical homes
  - Variation in care to standardized evidence-based practices

Thank you for the opportunity to revisit this critical issue

- Represents hospital systems across the State
- Objectives of today's testimony
  - Highlight the issues supporting the acceleration of the review of the Cardiac Cath and Open Heart Standards
  - Request inclusion on January 28th agenda for Commission Work Plan meeting



In response to previous discussions with the Commission and MDCH leadership……

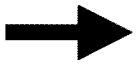
- Why the urgency to review these standards in 2010 instead of 2011 as scheduled?

- What has changed that would require an acceleration of the review schedule?

- How do these findings fit into the three tenets of CON?
  - ✓ Access
  - ✓ Quality
  - ✓ Cost

How can the CON program be flexible during the current health care transition?

- **Current reality:**
  - Fee for service (the more we do, the more we get paid)
  - Rewarded for high-tech
  - Specialty focus
  - "Build it and they will come" (brick and mortar)
  - Low accountability for outcomes
  - Extreme variation in care delivery



- **New reality:**
  - Pay for performance (at risk for managing cost, managing chronic conditions, and health outcomes)
  - Patient-centered medical homes
  - Primary care focus
  - Distributed model of care
  - Information-driven
  - Standardization to evidence-based practices

Shifts are already occurring

- **Example: Michigan Blue Cross/Blue Shield's Physician Group Incentive Program (PGIP)**
  - Primary care and select specialty physicians on risk/reward programs for:
    - Patient-centered medical home behavior (open access, patient navigators, disease registries, e-prescribing, continuous improvement initiatives, etc.)
    - Patient satisfaction
      Patient outcomes (e.g., chronic disease management)
    - Now includes gastro, ortho, rad oncology
  - Results:
    - 23% lower inpatient cost PMPM*, 20% lower admissions/1,000
    - 7% lower readmission cost PMPM*
    - 52% lower self-referral rate for low-tech imaging

* Per Member Per Month

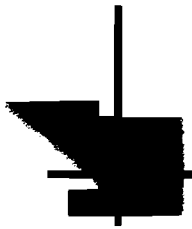
Other Important Considerations

- A recent informal NEWTAC meeting included discussion of a new procedure - percutaneous insertion of cardiac valves; concerns were expressed that current standards do not include this new clinical practice.
  - NEWTAC chairman, Dr. Marc Keshishian, doesn't seem interested in waiting until 2011 to review this issue. If a SAC is to be formed to look at this specific matter, a full evaluation of all issues might as well be done.

- The tentative schedule for the review of standards is even more onerous in 2011 than 2010 so it may be wise to move up the OHS and Cardiac Cath reviews to prevent an overload in 2011:

2010	2011
Air Ambulance	Cardiac Cath & OHS
CT	Hospital Beds
Lithotripsy	MRT
NICU	PET
Nursing Homes	Surgical Services

- Consider combining the review of the Cardiac Catheterization and Open Heart Surgery standards into a single Standard Advisory Committee (SAC).

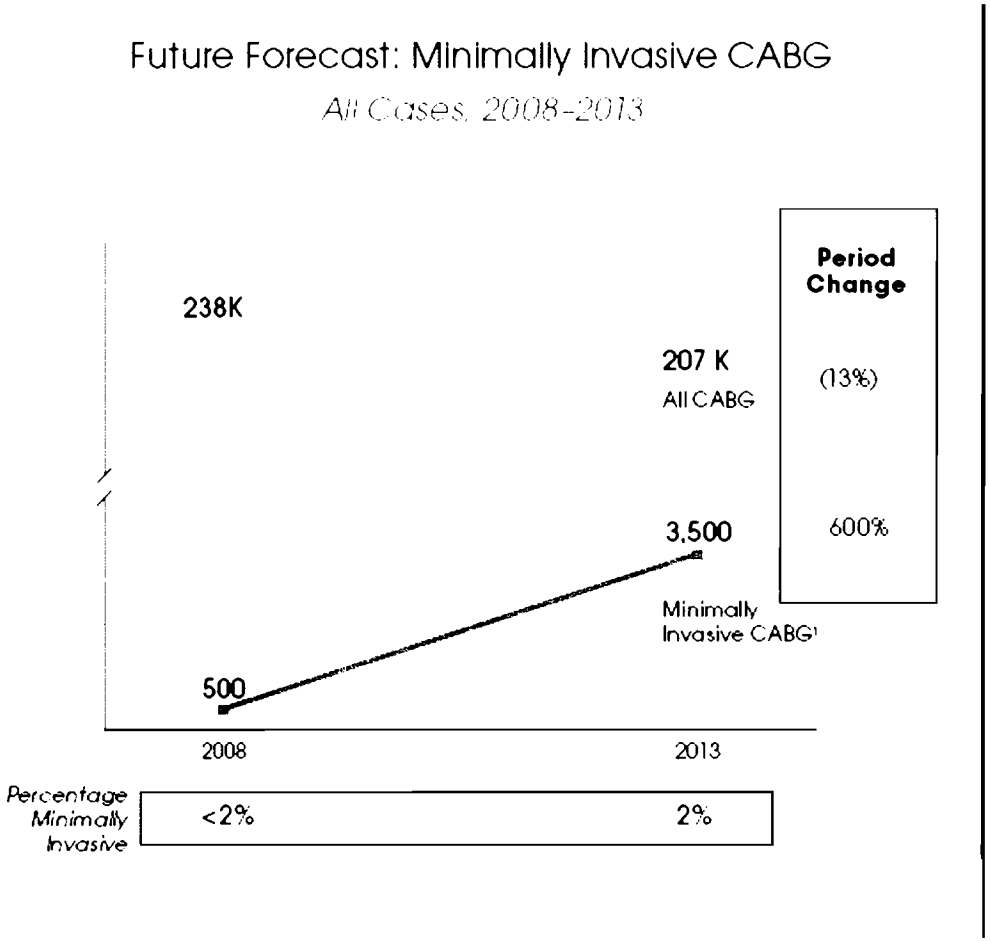


Other Important Considerations (con't)

- May help address OHS compliance issues as several of the current programs are having difficulty meeting and/or maintaining required volume levels/thresholds. If OHS was de-linked from therapeutic procedures, some providers might be willing to discontinue their OHS programs. This could lead to fewer OHS programs overall and higher volumes at remaining programs, while at the same time maintaining access to therapeutic procedures.

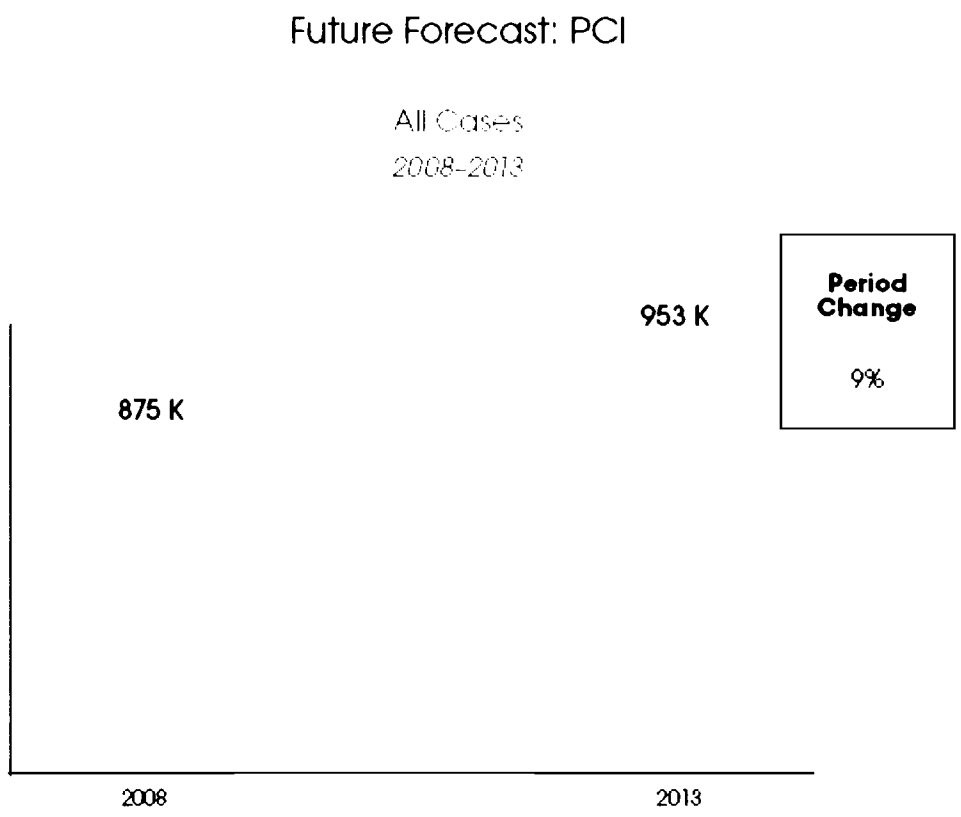
- Concerning OHS in the Grand Rapids market, the ratio of programs to population is a commonly used measure to determine whether access is sufficient.
  - Nationally: 1 OHS program: 280,964 population
  - Michigan: 1 OHS program: 321,889 population
  - Kent Co.: 1 OHS program: 599,524 population
  - Greater West Michigan region: 1 OHS program: 1,179,394 population

Demand for CABG is projected to continue to decline……



Source: Best Practice Profile, Cardiovascular Roundtable, Advisory Board April 15, 2009

While the demand for PCI is projected to increase

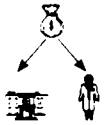


Source: Cardiovascular Roundtable, Advisory Board; July 31, 2009

Cardiovascular bundled payment pilots already in process

New Bundled Payment Demo Underway

Reimbursing for an Acute Care Episode



Bundled Payment

- Combined Parts A/B payment provided to PHO
- Bundled payment for inpatient stay only; potential to expand to post-discharge treatment after one year
- Distribute payment according to pre-determined methodology

Selected Inpatient Procedures

- 28 cardiac procedures including CABG, valves, defibrillator implants, pacemakers, PCI
- Nine orthopedic procedures
- High-volume, easily defined, associated quality measures

Specific Criteria

- Must establish PHO, meet minimum historical volume and quality thresholds
- Must maintain quality; monitoring incorporates 30-day readmission and mortality rates, CABG revision within six months

Additional Payouts

- Optional gainsharing with physicians for quality, cost, efficiency improvements not to exceed 25 percent of normal pay
- Rebate up to 50 percent of Medicare savings to beneficiaries' annual premium

Source: Health Care Policy Horizon Scan, Advisory Board; July 29, 2009

Susan Heck - Testimony

- Susan Heck, Senior Vice President, Corazon, Inc.
- Corazon is a national consulting firm that specializes in cardiac, vascular & neuroscience service development
- Overview of the national regulatory climate related to elective PCI –clinical practice outpacing ACC guidelines
  - Only 4 states do not allow Primary or Elective PCI
  - Only 5 states including Michigan restrict to Primary only
  - 23 have no regulations governing practice
  - 16 states allow Primary and Elective with only 7 of 16 requiring study or trial participation
- A review of the costs to payors for diagnostic cath & elective PCI being performed in staged settings:
  - The net difference between DX cath and Elective PCI in same care setting vs. a staged procedure is approximately $7,300 per case based on a Medicare rate
  - Duplicate testing and redundant costs for dye, catheters, trays
  - Increase length of stay
  - Ambulance transfer fees average $400 per case
  - Given the groups estimate of about 1000 procedures— currently **paying over $7.3 million for less than standard care**

More than 500 centers in U.S. offer PCI without Surgery on Site (SOS) 39 States Allow Elective PCI with varying requirements

RECENT REGULATORY CHANGES

- **California**
  - Allows primary PCI, in Jan '09 bill passed for a pilot to allow 6 hospitals to add elective PCI.
- **Florida**
  - In Jan '09 moved from CON to a 2-level licensure of adult cardiovascular services; Level 1 permits community hospitals meeting specific criteria to offer elective & emergent PCI services, Level 2 facilities provide open heart services.
- **Georgia**
  - In 2005, permitted 10 hospitals to participate in a national clinical trial to allow community hospitals to provide elective & emergent PCI without SOS. In July of '09 16 additional hospitals were granted approval to do primary & elective **without** participation in the C-PORT trial.
- **New York**
  - Engaged in project to allow 10 facilities to perform primary PCI. Regulatory changes signed in Nov of 09 that will allow elective PCI & prohibit the addition of diagnostic only labs.
- **Pennsylvania**
  - Beginning in 2001, 10 programs granted exceptions to pilot to provision of both primary and elective PCI without SOS. In '09 approved 5 new programs if they qualify to participate in the C-PORT trial.
- **West Virginia**
  - In August '08, implemented 3 tiers of service: Tier 1 --must demonstrate a minimum diagnostic cath volume threshold; after 1 year of diagnostic caths, can apply to offer primary PCI under Tier 2. Hospitals that offer primary PCI for at least 2 years may apply to offer elective PCI under Tier 3.

PCI Regulations – State by State

- Not permitted
- Primary only
- Primary & Elective
- Permitted, not regulated

Cost

- Failure to allow elective PCI without SOS (surgery on site) means:
  - Increase health care costs associated with the additional expenses of transportation
  - Duplicate testing as patients move from one acute care facility to another
  - Increase in overall length of stay (LOS) incumbent in the staged care process

Payor Cost Avoidance Scenario

Sample based on Medicare

Medicare Costs	Hospital Component	Physician Component (Pro-fee)	Transport Component	Total
DX Cath and Elective PCI in the same setting of Care	$ 11,452	$ 1,108	$ -	$ 12,560
DX cath with a Transfer to another facility for Elective PCI	$ 18,193	$ 1,282	$ 386	$ 19,861
Difference	**$ 6,742**	**$ 174**	**$ 386**	**$ 7,302**

Sample Cost Avoidance	
Sample PCI Case Volume	1,000
Payor Cost Differential	$ 7,302
Total Cost Avoidance	**$ 7,302,000**

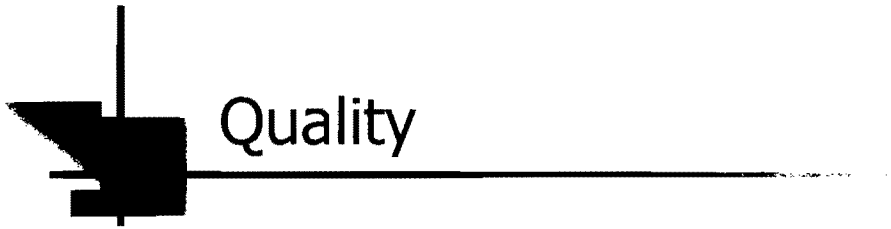
- Hospital component for PCI based on CMS split of case volume across DRGs 246-251
- Physician Pro-fee for dx cath based on CMS left heart cath & PCI blended payment rate based on 1.4 stents/case
- Transport based on Michigan ground rates + 10 miles & a blend of Advanced Life Support levels

Dr. Jaggi - Testimony

- Mike Jaggi, D.O. –Chief Medical Officer and Director of Emergency Medicine, Hurley Medical Center, Flint, Michigan
- American College of Cardiology (ACC)
  - Acute dissection related to all PCI >1% --actually **0.2%**
  - Practice outpacing ACC's **very conservative position** in their guidelines
  - ACC lead by **academic cardiologists** with vested interest in driving procedures to tertiary hubs
  - National (including ACC's own database) & international data points to safety in new practice
- Changing clinical practice is based on:
  - Technology advances—Improved catheters, wires and stents
  - Growing expertise of cardiologists to manage complications
  - Even tertiary centers no longer hold ORs open or keep staff on stand-by
- Practice of "coupling" diagnostic and PCI procedures in the same care setting is supported by quality and cost outcomes. When programs cannot provide elective PCI:
  - Greater dye, radiation, infection and bleeding complication exposure
  - Disconnect from their medical home
  - Change access to care for the economically disadvantaged populations

Access

- Changing clinical practice supports the"coupling" of diagnostic cath and PCI. Patients are forced to be transferred away from their medical home – which is the complete opposite approach of the current health care and payment reform efforts.
- Even highly regulated states such as New York are changing regulations to allow primary and elective PCI at centers without on-site surgery.
  - Further support to the changing clinical standards related to the coupling of diagnostic and interventional procedures, New York's new regulations prohibit the addition of any new diagnostic only cath labs.



Quality

- Current practice "couples" diagnostic caths with coronary intervention. Given prohibition to do elective caths without SOS (surgery on site), patients in Michigan experience:
  - Exposure to increased amount of blood thinners and increased x-ray dose;
  - Multiple invasive punctures which can lead to peripheral complications and increased chance of infections;
  - A disconnect from their medical home as their medical record and PCPs do not easily cross hospital boundaries at this time;
  - Dissatisfaction with transfer as the patient and family must navigate unfamiliar settings and meet new physicians.
  - Duplicate testing
  - Increased length of stay (LOS) due to transfer

Quality

- Senior author on the study, **Dr Ralph G Brindis** (Northern California Kaiser Permanente, San Francisco, CA), told **heart*wire*** that while there is now an important randomized clinical trial under way, known as **C-PORT Elective**, looking at the feasibility and outcomes of performing elective "off-site" PCI (angioplasty without on-site surgical backup), these new data, culled from the **National Cardiovascular Data Registry** (NCDR), may be persuasive enough to convince guideline-writing groups to reassess some of their advice.
  Source: *http://www.theheart.org/article/981347.do*

- A study in the June 30th issue of the Journal of the American College of Cardiology (JACC) showed patients who received elective percutaneous coronary intervention (PCI, aka angioplasty) at **hospitals without on-site cardiac surgery had no difference in mortality compared with patients receiving the same procedure at hospitals with surgical backup on site**. Some recent media reports have focused on the topic of performing elective PCI at hospitals where no cardiac surgery is performed to 'back up' the procedure should a complication arise. This new study provides additional information suggesting this can be done safely if such programs carefully monitor their results and follow rules about which patients are appropriate for PCI in facilities without on-site surgical backup.
  Sources: *http://www.seconds-count.org/Details.aspx?PAGE_ID=503; http://www.theheart.org/article/981347.do*

Quality (con't)

- SCAI* Statement On Percutaneous Coronary Intervention (PCI) In Facilities Without On-Site Cardiac Surgery (http://www.seconds-count.org/Details.aspx?PAGE_ID=503)
  - "The ability to perform PCI in community hospitals often translates into an overall improved level of cardiovascular care, enabling the hospital to recruit the most skilled health care providers and offer overall better care to the people they serve."
  - "Advances resulting from the development of stents and the effectiveness of PCI in treating heart attacks, as well as the success of door-to-balloon time programs have led to a decrease in the need for open-heart surgery in patients with blocked arteries. Therefore, cardiac surgery is available at fewer hospitals than in the past."

- The American College of Cardiology's own database (ACC-NCDR) supports that **primary and elective interventions can be performed as safely at programs without open heart surgery on site**. Actual clinical practice evident in their own database supports the fact that practice is outpacing the ACC's endorsement.

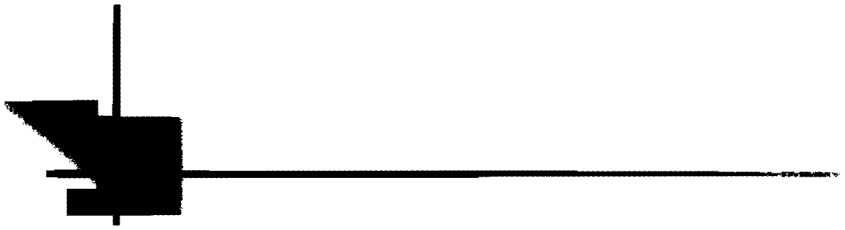
- "Optimal outcomes with PCI have been observed at community hospitals without on-site cardiac surgical programs with application of a prospective, standardized quality assurance protocol. The in-hospital mortality rate at Immanuel St. Joseph's Hospital and Franciscan Skemp Healthcare was comparable to that at Saint Mary's Hospital for both elective (0.3%, 0.1%, 0.4%; P=.24) and nonelective PCI (2.6%, 2.4%, 3.1%; P=.49). No patient undergoing elective PCI required transfer for emergency cardiac surgery." (http://www.mayoclinicproceedings.com/content/84/6/501.abstract)

* Society for Cardiovascular Angiography and Interventions

Request from the Coalition

- Please include our request, specifically *the acceleration of the review of both the cardiac cath and OHS standards by one year from 2011 to 2010*, at the January 28th CON Commission Work Plan meeting.

- Consider combining the review of the Cardiac Catheterization and Open Heart Surgery standards into a single Standard Advisory Committee (SAC).




THANK YOU

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

Attachment M

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2009												2010											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Air Ambulance Services										PH	•	•	• R F											
Bone Marrow Transplantation (BMT) Services**	• R	•	• R	•	•	▮	▮	▮	▮	▮	▮	• —	•	P •	• ▲ F									
Computed Tomography (CT) Scanner Services										PH •	•	•	• R											
Heart/Lung and Liver Transplantation Services**	• R	•	•	▮	▮	▮	▮	▮	▮	▮	•	• —	•	P •	• ▲ F									
Hospital Beds										•	•	• R												
Magnetic Resonance Imaging (MRI) Services	• R	•	•	•	•	• —	• P	•	• ▲ F R	•	•	• —	•	P •	• ▲ F									
Neonatal Intensive Care Services/Beds (NICU)										PH •	•	•	• R											
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups										PH •	•	•	• R											
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units										PH •	•	•	• R											
New Medical Technology Standing Committee	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M	• M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M R
Administrative Rules	•	•	• R	•	•	• R	•	•	• R	•	•	• R	•	•	• R D									

KEY

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

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

For Approval December 9, 2009

Updated November 19, 2009

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy, Regulation & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	November 13, 2008	2012
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	June 20, 2008	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2011
Magnetic Resonance Imaging (MRI) Services	November 5, 2009	2012
Megavoltage Radiation Therapy (MRT) Services/Units	November 13, 2008	2011
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	June 20, 2008	2010
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	November 5, 2009	2012
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2010

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.