

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

Thursday March 29, 2012

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

APPROVED MINUTES

I. Call to Order

Chairperson Falahee called the meeting to order @ 9:37 a.m.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Charles Gayney
Robert Hughes
Marc Keshishian, MD
Brian Klott
Gay L. Landstrom, RN
Suresh Mukherji, MD
Michael A. Sandler, MD
Kathleen Cowling, DO

B. Members Absent

Edward B. Goldman, Vice-Chairperson
Bradley Cory

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Tulika Bhattacharya
Scott Blakeney
Natalie Kellogg
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

Motion by Commissioner Mukherji, seconded by Commissioner Gayney, to approve the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interests

Commissioner Sandler stated he might have a potential conflict of interest with regards to the tabled discussion of the Bone Marrow Transplantation (BMT) standards.

IV. Review of Minutes of January 31, 2012

Motion by Commissioner Cowling, seconded by Commissioner Klott, to approve the minutes of January 31, 2012 as presented. Motion Carried.

Chairperson Falahee announced the two new Commissioners: Gail J. Clarkson, RN and Luis A. Tomatis, MD. In addition, he thanked Commissioners Sandler and Cory for their time served on the Commission.

Commissioner Sandler will continue to chair the Psychiatric Beds and Services workgroup.

V. BMT Services (Tabled from 1/31/12)

Motion by Commissioner Keshishian, seconded by Commissioner Cowling, to remove BMT services from the table. Motion carried in a vote of 9- Yes, 0- No, 0- Abstained.

Ms. Rogers gave a brief history of the BMT Services (see Attachment A).

A. Public Comment:

Patrick O'Donovan, Beaumont
Sean Gehle, St. John Providence
Karen Kippen, Henry Ford
Dr. Joe Uberti, Karmanos Cancer Institute (see Attachment B)
Dr. Gregory Yanik, University of Michigan (see Attachment C)

B. Commission Discussion

Commissioner Sandler and Commissioner Mukherji recused themselves from discussion.

Motion by Commissioner Landstrom, seconded by Commissioner Cowling, to continue regulation of BMT services. Motion carried in a vote of 7- Yes, 0- No, 2- Abstained.

C. Commission Action

Motion by Commissioner Klott, seconded by Commissioner Keshishian, to delegate to the Department to make technical edits of the BMT standards to be consistent with other CON review standards and bring back to a future meeting. Motion carried in a vote of 7- Yes, 0- No, and 0- Abstained.

VI. Hospital Bed Standards - February 9, 2012 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the public hearing and proposed changes to the Hospital Bed Standards (see Attachment D).

A. Public Comment:

Keith Crowell, Oaklawn Hospital (see Attachment E)
Jane Schelberg, Henry Ford Health System (see Attachment F)
Dennis McCafferty, Economic Alliance for Michigan (EAM)

B. Commission Discussion

Discussion followed.

C. Commission Action:

Motion by Commissioner Sandler, seconded by Commissioner Cowling, to accept the language with the Department's proposed amendments and move the language forward to a second public hearing and the Joint Legislative Committee (JLC). Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

Motion by Commissioner Sandler, seconded by Commissioner Klott, to accept the proposed amended language as presented by Jane Schelberg and move it forward to public hearing and the JLC. Motion carried in a vote of 9- Yes, 0- No, and 0- Abstained.

Motion by Commissioner Sandler, seconded by Commissioner Landstrom, to include Oaklawn Hospital's proposed amendment. Motion failed in a vote of 2-Yes, 5- No, and 1- Abstained.

Break @ 11:22 a.m. - 11:46 a.m.

VII. Heart/Lung, and Liver (HLL) Transplantation Services

A. Review of Proposed Language

Ms. Rogers gave a brief overview of the proposed language (See attachment G).

B. Public Comment

None

C. Commission Discussion

Discussion followed.

D. Commission Proposed Action

Motion by Commissioner Gayney, seconded by Commissioner Hughes, to approve the proposed language as presented by the Department to go to public hearing and the. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

VIII. Magnetic Resonance Imaging (MRI) Services - Status Update

A. Review of Proposed Language

Ms. Rogers gave an overview of the proposed language (see Attachments H and I).

Commissioner Keshishian gave a verbal report of the proposed PET/MRI & MRI-Guided EPI language.

B. Public Comment

None

C. Commission Discussion

None

D. Commission Proposed Action

Motion by Commissioner Keshishian, seconded by Commissioner Sandler, to approve the proposed language as presented and move it forward to public hearing and the JLC. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

IX. Positron Emission Tomography (PET) Scanner Service- Workgroup Update

A. Review of Proposed Language

Ms. Rogers gave an overview of the proposed language (see Attachments J and K).

Commissioner Keshishian gave a verbal report of the PET/MRI language.

B. Public Comment

None

C. Commission Discussion

None

D. Commission Proposed Action

Motion by Commissioner Klott, seconded by Commissioner Cowling, to approve the proposed language as presented and move it forward to public hearing and the JLC. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

X. Legislative Report

Mr. Blakeney stated there is nothing new to report.

XI. Administrative Update

A. Planning & Access to Care Section Update

Mr. Blakeney introduced Beth Nagel as the new manager for the Planning & Access to Care Section.

B. CON Evaluation Section Update

1. Compliance Report: Ms. Bhattacharya gave a brief summary of the compliance action taken by the Department (see Attachment L).
2. Quarterly Performance Measures (see Attachment M)
3. CON Annual Activity Report FY2011 (see Attachment N)
4. MRT Issue: Ms. Bhattacharya clarified the Department's interpretation of the technical amendment to Section 12(3) of the MRT Standards which was approved at the September 22, 2011 CON Commission Meeting and became effective November 21, 2011.

XII. Legal Activity Report

Mr. Potchen gave a brief overview of the CON legal action (see Attachment (O)).

XIII. Future Meeting Dates

- A. June 14, 2012
- B. September 27, 2012
- C. December 13, 2012

XIV. Public Comment

Melissa Cupp, Weiner Associates
Robert Meeker, Spectrum Health

XV. Review of Commission Work Plan

Ms. Rogers gave a brief overview of the work plan (see Attachment P).

A. Commission Discussion

Discussion followed.

B. Commission Action

Motion by Commissioner Sandler, seconded by Commissioner Cowling, to not have a workgroup and move de-regulation of Pancreas Transplantation Services to public hearing and the JLC. Motion Carried in a vote of 6- Yes, 3- No, and 0- Abstained.

Motion by Commissioner Sandler, seconded by Commissioner Mukherji, to accept the modified work plan. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

XVI. Election of Officers

Motion by Commissioner Sandler, seconded by Commissioner Hughes, to nominate and elect Commissioner Falahee as Chairperson. Motion carried in a vote of 8- Yes, 0- No, 0- Abstained.

Motion by Commissioner Mukherji, seconded by Commissioner Klott, to nominate and elect Commissioner Keshishian as Vice-chairperson. Motion carried in a vote of 8- Yes, 0- No, and 0- Abstained.

XVII. Adjournment

Motion by Commissioner Sandler, seconded by Commissioner Klott, to adjourn at 12:49 p.m. Motion carried in a vote of 9- Yes, 0- No, and 0- Abstained.

MDCH Recommendations for CON Standards Scheduled for 2012 Review ATTACHMENT A

Bone Marrow Transplantation (BMT) Services Standards (Please refer to MDCH staff summary of comments for additional details)		
Identified Issues	Recommended for Review?	Comments
Should services continue to be regulated under CON?	No.	MDCH recommends that the Commission consider deregulating BMT services. BMT is a well established and individualized service and there has been no evidence provided to support concerns regarding either a proliferation of services or a significant increase in treatment numbers.
Review access and expansion throughout the state	Yes.	Consider removing the cap and developing a facility-based need methodology if BMT services are going to remain under CON regulation.
Consider eliminating and/or separating autologous BMT services from the Standards	Yes.	Consider separate requirements if BMT services are going to remain under CON regulation.
Conduct review of project delivery requirements	Yes.	If BMT services are going to remain under CON regulation, update project delivery requirements and make any other technical changes consistent with other CON review standards. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.

MDCH Staff Analysis of Bone Marrow Transplant Services Standards

Statutory Assignment

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the BMT Services Standards are scheduled for review in calendar year 2012.

The Department held a Public Hearing to receive testimony regarding the Standards on October 12, 2011, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from seven (7) organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health System*
 - Recommends the removal of BMT services from CON regulation or, at a minimum, mandate an institution specific methodology for BMT or autologous-only BMT.
 - Argues that since 2009, MDCH data shows that demand for BMT has increased in the state of Michigan.
 - Requests the Commission to remove BMT from CON coverage per Section 22215(1) (a) of PA 619.
 - Suggests utilizing the Department or an unbiased consulting group to recommend an institution specific approach for establishing BMT for autologous-only services.

2. *Carol Christner, Karmanos Cancer Center*
 - Supports the standards approved by the Commission less than 18 months ago.
 - States there have been no significant changes in the field of BMT that would warrant revisions to the standards in 2012. Specifically; no significant change to the number of transplants conducted, geographic barriers have been addressed, and there continues to be excess bed capacity.

3. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
 - Supports continued regulation of BMT services and feels that it is too soon to re-open these standards to consider changes that may result in more providers.
 - Recommends Department-only technical changes, unless there is compelling evidence that would alter autologous only program discussion.
 - Recommends no SAC formation.

4. *Steve Szelag, University of Michigan Health System*
 - Recommends no revisions as capacity in Michigan appears to be adequate and forecasts indicate no drastic change in the number of patients requiring this therapy.
 - Suggests that it is too early to objectively evaluate the effects of the changes approved by the Commission March 2010.

5. *Robert Meeker, Spectrum Health*
 - Supports continued regulation of BMT services and feels that the revisions from March 2010 are serving the state very well.
 - Recommends no modifications at this time.

6. *Sean Gehle, Ascension Health- Michigan*
 - Recommends the separation of Allogenic and Autologous BMT services.

- Strongly recommends the deregulation of Autologous BMT services within CON.
- States that costs associated with alternative therapies are more expensive than the BMT treatment and follow up treatment.
- States quality related to BMT programs and practitioners is determined and monitored by the Foundation for the Accreditation of Hematopoietic Cellular Therapy (FAHCT).
- States access to BMT should be made available at community cancer centers where earlier treatment of cancer patients has shown to improve survival rates.
- Requests that if the Commission sees a need for continued regulation of Autologous BMT services, that they establish distinct standards applicable for Autologous only BMT programs.

7. *Karen Kippen, Henry Ford Health System*

- Supports continued regulation of BMT services.
- Recommends no revisions at this time.

Summary of the Covered Service and Consideration of “Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need Review”

Currently, Michigan is one of 21 states that regulate organ transplants through CON; less than 10 regulate BMT. There are currently 3 facilities approved to perform these types of transplantation services. In 2008, there were 534 Bone Marrow Transplants performed, 569 in 2009, and 593 in 2010, according to the MDCH annual survey report.

As part of the review, the Department considered the “Guiding Principles...” as follows:

While costs vary widely among facilities, the most recent CON application received for initiation of an adult BMT program (Spectrum Health Butterworth) indicated costs of \$499,835. Costs vary from facility to facility, and placing an exact dollar value on operating costs is difficult. As one example, to maintain an up-to-date BMT facility, the University of Michigan (U of M) recently spent \$1.5 million to update its stem cell processing lab; \$0.5 million to expand tissue typing lab and diagnostic equipment; and \$0.5 million for other laboratory equipment. The total costs for expanding and operating BMT services were approximately \$8 million for 2008-2009.¹ Looking at operational costs only, U of M expended approximately \$5.5 million.

Hematopoietic stem cell transplants are not necessarily the first treatment option for many diagnoses.² The most common indications for transplant in the United States in 2009 were multiple myeloma (nearly 5,000 transplants); non-Hodgkin’s lymphoma (just over 3,500 transplants); and acute myelogenous leukemia (just under 2,500 transplants). Some non-cancer diagnoses indicate immediate transplant, but these numbered fewer than 1,000 transplants nationwide in 2009.³

¹ University of Michigan testimony at February 5, 2009 CON Special Commission Meeting

² [http://marrow.org/Physicians/When_to_Transplant/Recommended_Timing_for_Transplant_\(PDF\).aspx](http://marrow.org/Physicians/When_to_Transplant/Recommended_Timing_for_Transplant_(PDF).aspx)

³ Pasquini MC, Wang Z (2011). Current use and outcome of hematopoietic stem cell transplantation: CIBMTR summary slides, available at: <http://www.cibmtr.org>

ATTACHMENT A

The Foundation for Accreditation of Cellular Therapy (FACT) provides voluntary accreditation to clinical programs and collection and processing facilities. All Michigan BMT programs are FACT accredited. In addition, facilities that manufacture human cell, tissue, and cellular and tissue-based products, including hematopoietic stem cells obtained from peripheral and cord blood, are subject to Title 21 CFR part 1271. However, minimally manipulated bone marrow does not fall under this regulation, instead falling under the authority of the Public Health Service Act, Section 361. Minimal manipulation is defined as “processing that does not alter the relevant biological characteristics of cells or tissues.”⁴

BCBS has created Blue Distinction Centers for Transplants that were developed in collaboration with expert physicians and medical organizations, including the Center for International Blood and Marrow Transplant Research (CIBMTR®), the Scientific Registry of Transplant Recipients (SRTR) and the Foundation for the Accreditation of Cellular Therapy (FACT). The selection designation criteria includes: an established transplant program, actively performing these procedures for the most recent 24-month period and performing a required minimum volume of transplant procedures. An established acute care inpatient facility, including intensive care, emergency and a full range of services as well as full accreditation by Centers for Medicare and Medicaid Services (CMS). Quality assurance measures include: evaluation of patient and graft aggregate outcomes including sufficiently low graft failures, mortality rates, a comprehensive quality management program and documented patient care and follow-up procedures at admission and discharge, including referral back to primary care physicians.⁵

CON review standards allow BMT to establish how need will be demonstrated. The 2009 BMT SAC concluded that “Access is somewhat a problem for those living in the farther regions of the state, but...it is impractical to provide access for everyone within a limited travel distance, however that might be defined.”⁶

Positive associations have been found between volume and transplant outcome. For example, Horowitz et al. (1992) found that patients receiving transplants in centers that performed fewer than five transplants per year had a 1.5-fold increase in transplant-related mortality risk, and a 1.4-fold increase in treatment failure risk. Similar correlations were found by Apperley et al. (2000) when evaluating center size plus years of experience, and positive associations were replicated in studies of transplant centers in Japan and Europe. However, these studies are insufficient to answer the question of quality’s association with volume, as most did not factor in variables such as rate of relapse, staffing, diseases treated, and autologous transplants. It is, therefore, unclear whether a true association exists between volume and quality, or if higher volume centers are simply characterized by variables that indicate more favorable outcomes. Loberiza, Serna, Horowitz, and Rizzo (2003) conclude:

“Based upon current evidence regarding procedure volume, it is not clear that any specific minimum number is justifiable. Restricting procedures to large centers may compromise patient access to HSCT⁷ in geographic areas where no large centers exist” (p. 420).⁸

⁴ <http://www.fda.gov/cber/faq/tisconsfaq.htm>

⁵ <http://www.bcbs.com/why-bcbs/blue-distinction/blue-distinction-transplants/bluedistinctiontransplants.pdf>

⁶ BMT SAC Report to CON Commission, December 2009

⁷ Hematopoietic stem cell transplant

⁸ Loberiza F. R., Serna D. S., Horowitz, M. M., & Rizzo, J. D. (2003). Transplant center characteristics and clinical outcomes after hematopoietic stem cell transplant: What do we know. *Bone Marrow Transplantation*, 31, 417-421.

While some aspects of bone marrow transplant saw an increase in CMS reimbursement effective January 1, 2012, other necessary treatment procedures have seen decreases. It is the opinion of the AABB⁹ that reimbursement for cellular therapy does not align with the true costs of providing such services.

MDCH Staff Recommendations

- The Department received public testimony supporting the elimination or separation of autologous and allogeneic transplant language from the standards. Autologous treatment represents a smaller capital expenditure and medical research reveals this transplant to be a lower risk option for patients, to deregulate would not lead to perverse incentives or a decline in quality patient care. CMS initially designated DRG 015 as an encompassing code to include all autologous treatments. CMS later determined, this classification did not take into account the severity of complications or comorbidities (CC) that may exist with certain patients. CMS has deleted DRG 015 and separated autologous bone marrow transplants into two classifications: MS-DRG 016 (autologous bone marrow transplant with CC/Major CC) and MS-DRG 017 (autologous bone marrow transplant without CC/Major CC).¹⁰ This will enable CMS to determine accurate reimbursement and monitor the quality of care, taking into account all the assigned diagnoses—not just principal diagnoses.
- These are highly specialized services usually located within university based and/or university affiliated programs or facilities where there is cutting edge technology and ongoing research. In a survey conducted with other CON states, Rhode Island and Virginia stated that they currently have one BMT provider within their state. Neither could identify any applications for initiation of new services, and both stated that the BMT programs were located in university settings.
- The numbers of transplants performed are so few and costs for these procedures are so high that these services are not viable for commercial use. Further, it is CMS's policy to reimburse after a patient receives the transplant. Consequently, if the patient does not receive the transplant due to death or other complications, the diagnostic testing & laboratory processing services associated with bone marrow and peripheral blood progenitor cell transplants are covered only if they are directly and immediately attributable to the stem cell donation procedure.¹¹
- The Department recommends that the Commission consider deregulating BMT services. BMT is a well established and individualized service and there has been no evidence provided to support concerns regarding either a proliferation of services or a significant increase in treatment numbers.

⁹ Formerly American Association of Blood Banks; now known only as AABB: www.aabb.org

¹⁰ <http://www.justcoding.com/274855/cms-makes-several-key-changes-to-msdrugs-for-fy-2012>

¹¹ <http://www.aabb.org/programs/reimbursementinitiatives/Pages/default.aspx>

B A R B A R A A N N
KARMANOS
 CANCER INSTITUTE
 Wayne State University

March 29, 2012 Certificate of Need Commission 2012 Workplan Meeting

Comments Regarding: CON Review Standards for Bone Marrow Transplantation
 Comments Submitted by: Joseph Uberti, M.D., Ph.D.
 Lambert/Webber Endowed Chair
 Division Head, BMT, Leukemia & Lymphoma
 Professor of Medicine - Wayne State University
 Co-Director, BMT Program Barbara Ann Karmanos Cancer Institute

The Barbara Ann Karmanos Cancer Institute *OPPOSES* the following recommendations made by the Department of Community Health:

1. Deregulation of BMT Services;
2. Review of the standards for consideration of expansion throughout the state;
3. Review of the standards for consideration of eliminating and/ or separating autologous BMT services.

We do support a review of project delivery requirements and believe department staff, with expert input, can complete this task. A standards advisory committee is not required to make any necessary technical changes.

- The department recommends deregulation of BMT services because, in their opinion, "it is a well-established and individualized service and there has been no evidence provided to support concerns regarding either a proliferation of the services or a significant increase in the number of treatments".

Just two years ago, the CON Commission adopted newly revised standards for Bone Marrow Transplantation (BMT) that allowed for the addition of a new planning area, with one adult program in western Michigan, based on the planning zones for pediatric BMT services. The new standards also continued regulation of BMT services and required adult services to perform a minimum of 30 transplants, of which at least 10 must be allogeneic.

There have been no significant changes in the field of BMT that would warrant revisions to the standards in 2012. There has been no significant change to the number of transplants conducted, geographic barriers have been addressed, and there continues to be excess capacity. And contrary to other public testimony, CON standards almost always take into consideration existing capacity as they determine need for additional programs.

Despite advancements made in BMT, the procedure still carries a mortality risk as high as 10% even in the autologous transplant setting. The complications of transplantation include infections and chemotherapy induced toxicity. In addition there is a limited stem cell availability, and significant operational expense, including requirement of highly trained and experienced staff who are in short supply in Michigan. Program expenses for nursing and patient care alone cost Karmanos in excess of \$7,000,000 annually.

While BMT is an established treatment for certain hematologic malignancies, the use of transplantation as a therapeutic modality is altered by new results and newer therapies, including the rapidly evolving option of new chemotherapy agents. As an example, the Karmanos Cancer Center has seen the number of transplants for breast cancer go from a high of 152 in a year to one to two per year. These changing practice patterns make long-term predictions difficult.

The department reports that there is no evidence to support concerns about proliferation of BMT services - this is simply inaccurate. There are currently 4 programs in Michigan, three of which are in Southeast Michigan. Two health systems have continually expressed their desire to open BMT programs in Southeast Michigan – making it safe to assume that just one region of the state would experience a 50% increase – a rather prolific number! This is in an area where all the existing programs have testified there is excess bed capacity.

It must be noted that one of the Health Systems supporting deregulation of BMT during public testimony in October, Ascension Health, recently opposed the deregulation of Lithotripsy due to safety and quality concerns.

- **The department recommends that, should regulation be continued, a review of the standards should be conducted to consider expansion of BMT programs throughout the state.**

In past years, others have maintained that a needs based methodology for BMT is preferred to a planning area threshold. The rationale for this methodology has been repeatedly disproven and continues to hold no merit when BMT standards are reviewed. This methodology is an attempt to predict the number of transplants based on the number of cancer patients seen in any area. To be effective, a needs based methodology must rely on an accurate assessment and estimation of the number of patients requiring a transplant. Presentation and discussion during the 2006 workgroup and the 2009 SAC indicated how difficult this estimation would be. The number of cancer cases seen at any individual center has no correlation to how many patients would ultimately require a transplant. Bone Marrow Transplant is often used in patients who have either advanced disease, relapsed disease or have failed several therapies. This data is not captured by any needs based methodology of cancer cases seen in any area. As I mentioned earlier with the example of breast cancer treatment, the use of transplantation as a therapeutic modality can fluctuate greatly based on new studies and new therapies.

If you had used a needs based methodology to determine transplant centers this would argue there would need to be an exponential rise of transplant centers. A transplant program was opened at Oakwood hospital based on the needs based methodology for breast cancer but closed for financial reasons as soon as the new data was available.

More BMT programs in the state will lower volume for all. The department subjectively states that scientific studies “are insufficient to answer the question of qualities association with volume.” However I have previously cited five studies that look at the relationship between quality and quantity of transplants conducted at BMT centers, all of which indicate there is a correlation between quality and volume. The only study that did not show a correlation between small and large centers defined a small transplant center as serving 70 patients per year with a median of eight years’ experience. Small centers can be started but the learning curve may be steep and no study has shown centers performing less than 70 transplants per year do as well as larger centers.

- **The department recommends that the standards be reviewed for consideration of eliminating and/ or separating autologous BMT services.** The previous SAC addressed this issue and on a 10 – 2 vote, (the two no’s coming from the Health Systems who would like to open more programs in Southeast

Michigan), the standards were actually modified to REQUIRE that all services perform a minimum volume of allogeneic transplants. The same expertise required for allogeneic transplantation should be required for autologous transplantation and the standards should not be lowered to accommodate new programs. The experts felt strongly that auto-only programs were not something that would serve this state well.

CONCLUSION

The Barbara Ann Karmanos Cancer Institute supports continued Certificate of Need regulation of BMT programs.

We do not support review of the Standards in 2012. Doing so will simply lead to recirculation of the same arguments that were disproven during the 2006 workgroup, the 2009 SAC and the continued written testimony submitted by interested parties in October 2011.

COST

Michigan's existing BMT programs provide a stable environment for patients, payers and providers. Establishing a BMT program is an extremely expensive undertaking. In March 2009, the Advisory Board projected that an average size unit would require start-up and maintenance costs of \$1,300,000. This amount does not take into consideration nursing and patient care expenses which cost Karmanos in excess of \$7,000,000 annually.

Transplantation is an extremely expensive procedure, sometimes requiring a 30 day hospitalization for many of our autologous patients. While some of these transplants may start as an outpatient procedure, they are often accompanied by prolonged hospitalizations due to toxicity from high dose chemotherapy, infections or bleeding, and may ultimately result in death.

QUALITY

Michigan's existing adult programs provide outstanding quality. To maintain the quality patients deserve and BMT guidelines require, experienced staff is needed. Shortages of transplant physicians, physician assistants, nurse practitioners, nurses and the support personnel who are needed to take care of transplant patients continue to be an obstacle in the field of BMT. Adding more programs will simply result in the cannibalization of existing programs, effectively decreasing their quality.

It has previously been argued that new BMT programs in the state are needed to allow patients to remain under the care of their current oncologist. All patients referred to Karmanos for BMT continue to have close contact with their referring physician. The BMT multi-disciplinary team at Karmanos is committed to developing a strong working relationship with referring physicians to help ease the patients' transition to our facility for transplantation. Pre and post treatment tests are performed by the referring physician as frequently as possible, eliminating duplicity or added burden for the patient. Patients return to their original physician as soon as possible after transplantation for additional care.

It has also been argued that Karmanos has turned away patients in need of transplantation. This is true. There are patients referred to us who potentially would benefit from transplantation, however, underlying medical conditions such as heart or lung problems may not make them a viable candidate. This is in keeping with the highest standards of medical care that any credible hospital would adhere to.

ACCESS

There continue to be no barriers to access for BMT. The existing programs have sufficient capacity to address the needs of the patient population and the addition of an adult program in Grand Rapids has answered concerns related to geographic barriers.

Previous arguments for more programs indicated that there is an underutilization of transplantation due to access issues, however there has never been any evidence that any alleged underutilization was due to a lack of capacity or sufficient transplant centers. What does effect underutilization, according to the NEJM, are poor insurance, poor socioeconomic issues and poor referral patterns.

These issues are not rectified by opening up more programs but by better physician and patient education, better insurance and a better economy. These issues would also be improved by increasing the number of available donors. However to increase the number of transplants by 1% we would need to add an additional 7,000,000 donors to the registry.

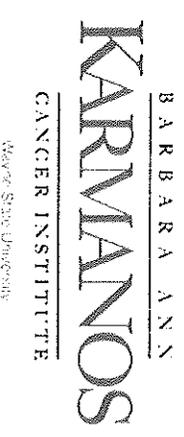
Do we need state regulation/limits?

BARBARA ANN
KARMANOS
CANCER INSTITUTE
George State University

- “Government regulation of HC therapy at the state level is fragmented, often voluntary and, in the opinion of the FDA inadequate to prevent transmission of disease. Many states have little specific regulation.”
- In order to overcome this
“Some states have adopted mechanisms of qualifying HCT programs and facilities such as the Certificate of Need Process.”

Hematopoietic Cell Procurement, Processing and Transplantation: Regulation and Accreditation Warkentin et al in Hematopoietic Stem-Cell Transplantation--2003

Flaws in Needs Based Methodology



- Changes in practice patterns affect needs for transplant
- Numbers fluctuate dramatically
- Examples Transplants/year Karmannos for breast cancer
- Change in transplants for CML

Breast Cancer (Karmannos) 152 to 1

CML 90% Reduction in the number of transplants around the world

Review:

Transplant Center Characteristics and Clinical Outcomes After Hematopoietic Stem Cell

Transplantation: What Do We Know, Loberiza, et al, Bone Marrow Transplantation 2003

BARBARA ANN
KARVMANOS
CANCER INSTITUTE
At the State University

- **Studies on Center Experience and Volume on Outcome Suggest the Following:**

1. Although a threshold for what is considered “high procedure volume” has not been consistently defined, the relation between high volume and superior clinical outcomes is replicable.
2. Outcomes associated with center effect (mainly procedure volume) include TRM, treatment failure and survival.

Association of Transplant Center and Physician Factors on Outcomes

BARBARA ANN
KARMANOS
CANCER INSTITUTE
Wayne State University

- Studies in experienced larger well established transplant centers have shown that after a certain threshold of volume there is no difference in survival
- In these studies “small centers” are defined by median of 70 transplants/year and a median of 11 years of center experience. When centers do a minimum of 70 transplants/year there is no difference in survival
- “Appears that the greater involvement of properly trained physicians is associated with better early outcomes, particularly in the allogeneic HSC T and autologous HSC T for high-risk patients, and should be encouraged.

Loberiza et al Blood 2005

Public Testimony
Certificate of Need (CON) Review Standards for
Bone Marrow Transplantation Services

March 28, 2012

Good morning, my name is Dr. Gregory Yanik, a Professor of Internal Medicine and Pediatrics, in the Blood and Marrow Transplant Program at the University of Michigan. UMHS strongly supports the continued regulation of BMT and believes deregulation would be a detriment to the citizens of Michigan. I will summarize my statements as follows:

Access to transplant:

The four approved bone marrow transplant centers in Michigan are collectively meeting the state's transplant needs. At the University of Michigan, bed utilization for our bone marrow transplant unit is under capacity. Over the past six months, we have run at approximately 75% bed capacity, with beds readily available throughout this period. Patients are not being turned away due to a lack of availability. Nor are patients experiencing long lag times to begin transplant.

A common argument regarding access to BMT services is that the numbers of bone marrow transplants in the state are increasing each year, and thus more centers are required to serve these increasing needs. The major reason for this increase has been the application of BMT to older patients, specifically those 60-75 years in age. We may have "tapped out" that market within the state, with the median age of our transplant population at UM now nearly 60 years in age. We do not see significant growth in this arena, as the field will not be doing transplants for individuals > 75 years in age.

Transplant Manpower: Current issues and future needs

An extreme manpower shortage currently exists for both transplant physicians and transplant personnel. This shortage will become further aggravated if the transplant market is diluted with multiple small volume transplant centers. A 2008 report from the American Society of Bone Marrow Transplant (ASBMT, J.Gajewski) identified 1115 transplant trained physicians in the US (959 adult, 156 pediatric), with a recognized shortage of 247 transplant physicians nationwide. The median age for transplant

physicians in the US is currently 50 years, with the majority of these transplant physicians anticipated to retire by 2025.

Unfortunately, there are few transplant training programs currently in existence. Given the national health care focus on training primary care physicians in the coming decade, the pool of available transplant trainees is expected to decrease significantly by 2020. Finally, there is an even more critical shortage of transplant trained RN's and physician extenders, with no policies established to meet this shortage.

Quality of care and Center Volume

Multiple studies over the past 2 decades have identified transplant center volume as a prognostic indicator of outcome, with higher volume centers having improved survival (Horowitz 1992, Hows 1993, Frassoni 2000, Matsuo 2000, Loberiza 2003). Similar results have been noted with liver (Ozathill 2011) and cardiac transplantation (Russo 2010). Providing optimal transplant care is a 24/7/365 task. Transplant centers that rely on dedicated transplant trained (and focused) physicians, nursing, and ancillary staff, 24 hours per day, provide this optimal care. At the University of Michigan, such staff also includes transplant trained nutritionists, pharmacists, and physical therapists. High volume centers provide such coverage. Smaller volume centers often rely on cross coverage by non-transplant staff to service their transplant population. Given the manpower shortage discussed previously, this issue will only be further magnified if bone marrow transplantation is deregulated in the state.

Costs of transplant:

The costs of a BMT program are enormous and extend beyond the creation of a dedicated transplant unit. To optimize patient care, transplant centers require additional infrastructure, including a dedicated stem cell processing lab, HLA typing facility, molecular diagnostics lab, apheresis unit, and trained Blood Bank personnel. All of these services are in place at the current transplant centers within the state. Duplication of these services at additional facilities within the state will have a profound impact on costs. In addition, given the manpower shortage there will be significant costs required to train staff or acquire the necessary complement of trained staff. The acquisition of such staff will typically require over compensating existing staff at outside facilities, increasing costs further.

Should autologous transplants be deregulated in Michigan.

Autologous transplant should not be viewed as a simple transplant. Historically, autologous transplants are associated with a 3-5% mortality rate within 100 days of transplant. Any procedure associated with a 3-5 % mortality rate should not be viewed as a “simple” procedure. Autologous transplants depend upon dose intensification of chemotherapy, with doses that significantly exceed non-transplant chemotherapy regimen, and often approach organ tolerance limits. The expertise of trained personnel is again paramount in the management of these patients.

Do current transplant centers affect the patient – primary oncologist relationship.

At the University of Michigan, we place great importance in protecting this relationship. Our policy is to return autologous transplant recipients to their primary oncologist’s care within 30 days of transplant. Optimal care for allogeneic transplant patients likewise depends upon a partnership between the referring oncologist and the transplant team. We have placed strong emphasis on this partnership by allowing pre and post-transplant evaluations to be done locally, negating duplicative testing. In addition, we frequently share our clinical practice guidelines with referring physicians, giving them a written guide to assist us with this shared care.

Current CON regulations and reporting are not burdensome

CON regulations and reporting provide a useful benchmark for transplant centers within the state, without adding additional work load. Patient care is optimized when transplant centers are required to adhere to recognized standards. In addition, the demographic data required for reporting has been gathered as part of other reporting projects, from projects involving primary insurers, and transplant governing bodies, including FAHCT, CIBMTR, and the NMDP.

In closing

UMHS would like to reiterate that it strongly supports the continued regulation of this CoN Covered Clinical Service. Providing access, to a program that offers leading technology, with senior level physicians and ancillary staff uniquely trained in this clinical process is fundamental for the residents of Michigan. Such technology and personnel are currently in place within existing facilities. The UMHS strongly believes any incremental BMT programs in Michigan will have an adverse impact on cost, quality and research potential while at the same time providing marginal benefit.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR HOSPITAL BEDS

(By authority conferred on the CON Commission by sections 22215 and 22217 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 333.22217, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. (1) These standards are requirements for approval ~~and delivery of services for all projects approved and certificates of need issued~~ under Part 222 of the Code that involve (a) beginning operation of a new hospital ~~increasing licensed beds in a hospital licensed under Part 215~~ or (b) replacing beds in a hospital or physically relocating hospital beds from one licensed site to another geographic location or (c) increasing licensed beds in a hospital licensed under Part 215 ~~replacing beds in a hospital~~ or (d) acquiring a hospital ~~or (e) beginning operation of a new hospital.~~ PURSUANT TO PART 222 OF THE CODE.

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

(~~3~~2) An increase in licensed hospital beds is a change in bed capacity for purposes of Part 222 of the Code.

(~~4~~3) The physical relocation of hospital beds from a licensed site to another geographic location is a change in bed capacity for purposes of Part 222 of the Code.

(~~5~~4) An increase in hospital beds certified for long-term care is a change in bed capacity for purposes of Part 222 of the Code and shall be subject to and reviewed under the CON Review Standards for Long-Term-Care Services.

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

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

Section 2. Definitions

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

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

(b) "ADJUSTED PATIENT DAYS" MEANS THE NUMBER OF PATIENT DAYS WHEN CALCULATED AS FOLLOWS:

(I) COMBINE ALL PEDIATRIC PATIENT DAYS OF CARE AND OBSTETRICS PATIENT DAYS OF CARE PROVIDED DURING THE PERIOD OF TIME UNDER CONSIDERATION AND MULTIPLY THAT NUMBER BY 1.1.

(II) ADD THE NUMBER OF NON-PEDIATRIC AND NON-OBSTETRIC PATIENT DAYS OF CARE, EXCLUDING PSYCHIATRIC PATIENT DAYS, PROVIDED DURING THE SAME PERIOD OF TIME TO

55 THE PRODUCT OBTAINED IN (I) ABOVE. THIS IS THE NUMBER OF ADJUSTED PATIENT DAYS
 56 FOR THE APPLICABLE PERIOD.

57 (C) "Alcohol and substance abuse hospital" means a licensed hospital within a long-term (acute) care
 58 (LTAC) hospital that exclusively provides inpatient medical detoxification and medical stabilization and
 59 related outpatient services for persons who have a primary diagnosis of substance dependence covered
 60 by DRGs 433 - 437.

61 (D) "AVERAGE ADJUSTED OCCUPANCY RATE" SHALL BE CALCULATED AS FOLLOWS:

62 (I) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,
 63 CONSECUTIVE 36-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION, FOR WHICH
 64 VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.

65 (II) CALCULATE THE TOTAL LICENSED BED DAYS FOR THE SAME 36-MONTH PERIOD AS IN
 66 (I) ABOVE BY MULTIPLYING THE TOTAL LICENSED BEDS BY THE NUMBER OF DAYS THEY WERE
 67 LICENSED.

68 (III) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (I) ABOVE BY THE
 69 TOTAL LICENSED BED DAYS CALCULATED IN (II) ABOVE, THEN MULTIPLY THE RESULT BY 100.

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

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

74 (eF) "Close a hospital" means an applicant will demonstrate to the satisfaction of the Department that
 75 a hospital licensed under Part 215, and whose licensed capacity for the most recent 24 months prior to
 76 submission of the application was at least 80 percent for acute care beds, will close and surrender its
 77 acute care hospital license upon completion of the proposed project.

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

80 (gH) "Common ownership or control" means a hospital that is owned by, is under common control of,
 81 or has a common parent as the applicant hospital.

82 (hI) "Compare group" means the applications that have been grouped for the same type of project in
 83 the same subarea HOSPITAL GROUP and are being reviewed comparatively in accordance with the
 84 CON rules.

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

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

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

94 (l) "Disproportionate share hospital payments" means the most recent payments to hospitals in the
 95 special pool for non-state government-owned or operated hospitals to assure funding for costs incurred
 96 by public facilities providing inpatient hospital services which serve a disproportionate number of low-
 97 income patients with special needs as calculated by the Medical Services Administration within the
 98 Department.

99 (m) "EXCLUDED HOSPITALS" MEANS HOSPITALS IN THE FOLLOWING CATEGORIES:

100 (I) CRITICAL ACCESS HOSPITALS DESIGNATED BY CMS PURSUANT TO 42 CFR 485.606

101 (II) HOSPITALS LOCATED IN RURAL OR MICROPOLITAN STATISTICAL AREA COUNTIES

102 (III) LTAC HOSPITALS

103 (IV) SOLE COMMUNITY HOSPITALS DESIGNATED BY CMS PURSUANT TO 42 CFR 412.92

104 (V) HOSPITALS WITH 25 OR FEWER LICENSED BEDS

105 (N) "Existing hospital beds" means, for a specific hospital subarea GROUP, the total of all of the
 106 following: (i) hospital beds licensed by the Department OF LICENSING AND REGULATORY AFFAIRS
 107 OR ITS SUCCESSOR; (ii) hospital beds with valid CON approval but not yet licensed; (iii) proposed
 108 hospital beds under appeal from a final decision of the Department; and (iv) proposed hospital beds that

109 are part of a completed application under Part 222 (other than the application under review) for which a
 110 proposed decision has been issued and which is pending final Department decision.

111 | (nO) "Gross hospital revenues" means the hospital's revenues as stated on the most recent Medicare
 112 and Michigan Medicaid forms filed with the Medical Services Administration within the Department.

113 | (oP) "Health service area" OR "HSA" means the groups of counties listed in [Section 18 APPENDIX A](#).

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

117 | (qR) "Hospital" means a hospital as defined in Section 20106(5) of the Code being Section
 118 333.20106(5) of the Michigan Compiled Laws and licensed under Part 215 of the Code. The term does
 119 not include a hospital or hospital unit licensed or operated by the Department of Mental Health.

120 | (rS) "HOSPITAL GROUP" MEANS A CLUSTER OR GROUPING OF HOSPITALS BASED ON
 121 GEOGRAPHIC PROXIMITY AND HOSPITAL UTILIZATION PATTERNS. THE LIST OF HOSPITAL
 122 GROUPS AND THE HOSPITALS ASSIGNED TO EACH HOSPITAL GROUP WILL BE POSTED ON
 123 THE STATE OF MICHIGAN CON WEB SITE AND WILL BE UPDATED PURSUANT TO SECTION 3.

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

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

130 | (tU) "Host hospital" means a licensed and operating hospital, which delicenss hospital beds, and
 131 which leases patient care space and other space within the physical plant of the host hospital, to allow a [N](#)
 132 [long-term \(acute\) care LTAC](#) hospital, or alcohol and substance abuse hospital, to begin operation.

133 | (uV) "Licensed site" means the location of the facility authorized by license and listed on that
 134 licensee's certificate of licensure.

135 | (vW) "Limited access area" means those [geographic UNDERSERVED](#) areas ~~containing a population~~
 136 ~~of 50,000 or more based on the planning year and not within 30 minutes drive time of an existing licensed~~
 137 ~~acute care hospital with 24 hour/7 days a week emergency services utilizing the slowest route available~~
 138 ~~as defined by the Michigan Department of Transportation (MDOT) WITH A PATIENT DAY DEMAND~~
 139 ~~THAT MEETS OR EXCEEDS THE STATE-WIDE AVERAGE OF PATIENT DAYS USED PER 50,000~~
 140 ~~RESIDENTS IN THE BASE YEAR~~ and as identified in Appendix [ED](#). Limited access areas shall be
 141 redetermined when a new hospital has been approved or an existing hospital closes.

142 | (wX) "Long-term (acute) care hospital" [OR "LTAC HOSPITAL"](#) means a hospital has been approved to
 143 participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital
 144 in accordance with 42 CFR Part 412.

145 | ~~(x) "Market forecast factors" (%N) means a mathematical computation where the numerator is the~~
 146 ~~number of total inpatient discharges indicated by the market survey forecasts and the denominator is the~~
 147 ~~base year MIDB discharges.~~

148 | (y) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and [TO](#)
 149 ~~1396r-8G AND 1396I~~ to ~~1396v1396U~~.

150 | (z) "Medicaid volume" means the number of Medicaid recipients served at the hospital as stated on
 151 the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration
 152 within the Department.

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

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

161 | ~~(cc) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as~~
 162 ~~that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by~~

163 ~~the statistical policy office of the office of information and regulatory affairs of the United States office of~~
164 ~~management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.~~
165 ~~(ddBB)~~ "New beds in a hospital" means hospital beds that meet at least one of the following: (i) are not
166 currently licensed as hospital beds, (ii) are currently licensed hospital beds at a licensed site in one
167 ~~subareaHOSPITAL GROUP~~ which are proposed for relocation in a different ~~subareaHOSPITAL GROUP~~
168 as determined by the Department pursuant to Section 3 of these standards, (iii) are currently licensed
169 hospital beds at a licensed site in one ~~subareaHOSPITAL GROUP~~ which are proposed for relocation to
170 another geographic site which is in the same ~~subareaHOSPITAL GROUP~~ as determined by the
171 Department, but which are not in the replacement zone, or (iv) are currently licensed hospital beds that
172 are proposed to be licensed as part of a new hospital in accordance with Section 6(2) of these standards.
173 ~~(eeCC)~~ "New hospital" means one of the following: (i) the establishment of a new facility that shall be
174 issued a new hospital license, (ii) for currently licensed beds, the establishment of a new licensed site
175 that is not in the same hospital ~~subareaGROUP~~ as the currently licensed beds, (iii) currently licensed
176 hospital beds at a licensed site in one ~~subareaHOSPITAL GROUP~~ which are proposed for relocation to
177 another geographic site which is in the same ~~subareaHOSPITAL GROUP~~ as determined by the
178 Department, but which are not in the replacement zone, or (iv) currently licensed hospital beds that are
179 proposed to be licensed as part of a new hospital in accordance with section 6(2) of these standards.
180 ~~(#DD)~~ "Obstetrics patient days of care" means inpatient days of care for patients in the applicant's
181 Michigan Inpatient Data Base data ages 15 through 44 with drgs 370 through 375 (obstetrical
182 discharges).
183 ~~(ggEE)~~ "Overbedded ~~subareaHOSPITAL GROUP~~" means a hospital ~~subareaGROUP~~ in which the total
184 number of existing hospital beds in that ~~subareaHOSPITAL GROUP~~ exceeds the ~~subareaHOSPITAL~~
185 ~~GROUP~~ needed hospital bed supply ~~as set forth in Appendix C.~~
186 ~~(hhFF)~~ "Pediatric patient days of care" means inpatient days of care for patients in the applicant's
187 Michigan Inpatient Data Base data ages 0 through 14 excluding normal newborns.
188 ~~(iiGG)~~ "Planning year" means five years beyond the base year, established by the CON Commission,
189 for which hospital bed need is developed, unless a different year is determined to be more appropriate by
190 the Commission.
191 ~~(jjHH)~~ "Qualifying project" means each application in a comparative group which has been reviewed
192 individually and has been determined by the Department to have satisfied all of the requirements of
193 Section 22225 of the code, being section 333.22225 of the Michigan Compiled Laws and all other
194 applicable requirements for approval in the Code or these Standards.
195 ~~_(kk) "Relevance index" or "market share factor" (%Z) means a mathematical computation where the~~
196 ~~numerator is the number of inpatient hospital patient days provided by a specified hospital subarea~~
197 ~~GROUP from a specific zip codeGEOGRAPHIC AREA and the denominator is the total number of~~
198 ~~inpatient hospital patient days provided by all hospitals to that specific zip codeGEOGRAPHIC AREA~~
199 ~~using MIDB data.~~
200 ~~(lll)~~ "Relocate existing licensed hospital beds" for purposes of sections 6(3) and 8 of these standards,
201 means a change in the location of existing hospital beds from the existing licensed hospital site to a
202 different existing licensed hospital site within the same hospital ~~subareaGROUP~~ or HSA. This definition
203 does not apply to projects involving replacement beds in a hospital governed by Section 7 of these
204 standards.
205 ~~(mmJJ)~~ "Remaining patient days of care" means total inpatient days of care in the applicant's Michigan
206 Inpatient Data Base data minus obstetrics patient days of care and pediatric patient days of care.
207 ~~(nnKK)~~ "Replacement beds in a hospital" means ~~hospital beds that meet all of the following conditions;~~
208 ~~(i) an equal or greater number of hospital beds are currently licensed to the applicant at the licensed site~~
209 ~~at which the proposed replacement beds are currently licensed; (ii) A CHANGE IN THE LOCATION OF~~
210 ~~THE LICENSED HOSPITAL, OR THE REPLACEMENT OF A PORTION OF THE LICENSED BEDS AT~~
211 ~~THE SAME LICENSED SITE. the The hospital beds are proposed for replacementWILL BE in new~~
212 ~~physical plant space being developed in new construction or in newly acquired space (purchase, lease,~~
213 ~~donation, etc.); and (iii) the hospital beds to be replaced will be located inWITHIN the replacement zone.~~
214 ~~(ooLL)~~ "Replacement zone" means a proposed licensed site that is (i) in the same ~~subareaHOSPITAL~~
215 ~~GROUP~~ as the existing licensed site as determined by the Department in accord with Section 3 of these
216 standards and (ii) on the same site, on a contiguous site, or on a site within 2 miles of the existing
217 licensed site if the existing licensed site is located in a county with a population of 200,000 or more, or on

218 a site within 5 miles of the existing licensed site if the existing licensed site is located in a county with a
 219 population of less than 200,000.

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

225 (qq) "Uncompensated care volume" means the hospital's uncompensated care volume as stated on
 226 the most recent Medicare and Michigan Medicaid forms filed with the Medical Services Administration
 227 within the Department.

228 (#NN) "UNDERSERVED AREA" MEANS THOSE GEOGRAPHIC AREAS NOT WITHIN 30 MINUTES
 229 DRIVE TIME OF AN EXISTING LICENSED ACUTE CARE HOSPITAL WITH 24 HOUR/7 DAYS A WEEK
 230 EMERGENCY ROOM SERVICES UTILIZING THE MOST DIRECT ROUTE USING THE LOWEST
 231 SPEED LIMITS POSTED AS DEFINED BY THE MICHIGAN DEPARTMENT OF TRANSPORTATION
 232 (MDOT).

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

235 ~~—(ss) "Zip code population" means the latest population estimates for the base year and projections for~~
 236 ~~the planning year, by zip code.~~

237
 238 (2) The definitions in Part 222 shall apply to these standards.
 239

240 Section 3. Hospital ~~subareas~~GROUPS

241
 242 Sec. 3. ~~(1)(a) Each existing hospital is assigned to a hospital subarea~~GROUP as set forth in
 243 Appendix A B which is incorporated as part of these standards, until Appendix A B is revised pursuant to
 244 this subsection (1).

245 (i) These hospital ~~subarea~~GROUPs, and the assignments of hospitals to ~~subarea~~HOSPITAL
 246 GROUPs, shall be updated BY THE DEPARTMENT EVERY FIVE YEARS OR, at the direction of the
 247 Commission, ~~starting in May 2003, to be completed no later than November 2003. Thereafter, at the~~
 248 ~~direction of the Commission, the updates shall occur no later than two years after the official date of the~~
 249 ~~federal decennial census, provided that:~~THE METHODOLOGY DESCRIBED IN "ANEW
 250 METHODOLOGY FOR DEFINING HOSPITAL GROUPS" BY PAUL L. DELAMATER, ASHTON M.
 251 SHORTRIDGE, AND JOSEPH P. MESSINA, 2011 SHALL BE USED AS FOLLOWS:

252 (AA) ~~Population data at the federal zip code level, derived from the federal decennial census, are~~
 253 ~~available; and final MIDB data are available to the Department for that same census year.~~FOR EACH
 254 HOSPITAL, CALCULATE THE PATIENT DAY COMMITMENT INDEX (%C – A MATHEMATICAL
 255 COMPUTATION WHERE THE NUMERATOR IS THE NUMBER OF INPATIENT HOSPITAL DAYS
 256 FROM A SPECIFIC GEOGRAPHIC AREA PROVIDED BY A SPECIFIED HOSPITAL AND THE
 257 DENOMINATOR IS THE TOTAL NUMBER OF PATIENT DAYS PROVIDED BY THE SPECIFIED
 258 HOSPITAL USING MIDB DATA) FOR ALL MICHIGAN ZIP CODES USING THE SUMMED PATIENT
 259 DAYS FROM THE MOST RECENT THREE YEARS OF MIDB DATA. INCLUDE ONLY THOSE ZIP
 260 CODES FOUND IN EACH YEAR OF THE MOST RECENT THREE YEARS OF MIDB DATA. ARRANGE
 261 OBSERVATIONS IN AN ORIGIN-DESTINATION TABLE SUCH THAT EACH HOSPITAL IS AN ORIGIN
 262 (ROW) AND EACH ZIP CODE IS A DESTINATION (COLUMN) AND INCLUDE ONLY HOSPITALS
 263 WITH INPATIENT RECORDS IN THE MIDB.

264 (b) ~~For an application involving a proposed new licensed site for a hospital (whether new or~~
 265 ~~replacement), the proposed new licensed site shall be assigned to an existing hospital subarea utilizing a~~
 266 ~~market survey conducted by the applicant and submitted with the application. The market survey shall~~
 267 ~~provide, at a minimum, forecasts of the number of inpatient discharges for each zip code that the~~
 268 ~~proposed new licensed site shall provide service. The forecasted numbers must be for the same year as~~
 269 ~~the base year MIDB data. The market survey shall be completed by the applicant using accepted~~
 270 ~~standard statistical methods. The market survey must be submitted on a computer media and in a format~~
 271 ~~specified by the Department. The market survey, if determined by the Department to be reasonable~~
 272 ~~pursuant to Section 15, shall be used by the Department to assign the proposed new site to an existing~~

273 subarea based on the methodology described by "The Specification of Hospital Service Communities in a
 274 Large Metropolitan Area" by J. William Thomas, Ph.D., John R. Griffith, and Paul Durance, April 1979 as
 275 follows: FOR EACH HOSPITAL, CALCULATE THE ROAD DISTANCE TO ALL OTHER HOSPITALS.
 276 ARRANGE OBSERVATIONS IN AN ORIGIN-DESTINATION TABLE SUCH THAT EACH HOSPITAL IS
 277 AN ORIGIN (ROW) AND EACH HOSPITAL IS ALSO A DESTINATION (COLUMN).

278 (iC) For the proposed new site, a discharge relevance factor for each of the zip codes identified in the
 279 application will be computed. Zip codes with a market forecast factor of less than .05 will be deleted from
 280 consideration. RESCALE THE ROAD DISTANCE ORIGIN-DESTINATION TABLE BY DIVIDING EVERY
 281 ENTRY IN THE ROAD DISTANCE ORIGIN-DESTINATION TABLE BY THE MAXIMUM DISTANCE
 282 BETWEEN ANY TWO HOSPITALS.

283 (iiD) The base year MIDD data will be used to compute discharge relevance factors (%Rs) for each
 284 hospital subarea for each of the zip codes identified in step (i) above. Hospital subareas with a %R of
 285 less than .10 for all zip codes identified in step (i) will be deleted from the computation. APPEND THE
 286 ROAD DISTANCE ORIGIN-DESTINATION TABLE TO THE %C ORIGIN-DESTINATION TABLE (BY
 287 HOSPITAL) TO CREATE THE INPUT DATA MATRIX FOR THE CLUSTERING ALGORITHM.

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

290 _____ P_i = Population of zip code i.

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

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

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

$$295 \quad \frac{\sum_{i \in I_j} P_i (d_{ij}/D_i)}{\sum_{i \in I_j} P_i}$$

296 then $\bar{R}_j =$

297 _____ $\sum_{i \in I_j} P_i$ GROUP HOSPITALS INTO CLUSTERS USING THE K-MEANS

298 CLUSTERING ALGORITHM WITH INITIAL CLUSTER CENTERS PROVIDED BY A WARDS
 299 HIERARCHICAL CLUSTERING METHOD. ITERATE OVER ALL CLUSTER SOLUTIONS FROM 2 TO
 300 THE NUMBER OF HOSPITALS (n) MINUS 1.

301 (iv) After \bar{R}_j is calculated for the applicant(s) and the included existing subareas, the
 302 hospital/subarea with the smallest \bar{R}_j ($S\bar{R}_j$) is grouped with the hospital/subarea having the greatest
 303 individual discharge relevance factor in the $S\bar{R}_j$'s home zip code. $S\bar{R}_j$'s home zip code is defined as
 304 the zip code from $S\bar{R}_j$'s with the greatest discharge relevance factor. FOR EACH CLUSTER
 305 SOLUTION, RECORD THE GROUP MEMBERSHIP OF EACH HOSPITAL, THE CLUSTER CENTER
 306 LOCATION FOR EACH OF THE CLUSTERS, THE r^2 VALUE FOR THE OVERALL CLUSTER
 307 SOLUTION, THE NUMBER OF SINGLE HOSPITAL CLUSTERS, AND THE MAXIMUM NUMBER OF
 308 HOSPITALS IN ANY CLUSTER.

309 (II) "K-MEANS CLUSTERING ALGORITHM" MEANS A METHOD FOR PARTITIONING
 310 OBSERVATIONS INTO A USER-SPECIFIED NUMBER OF GROUPS. IT IS A STANDARD ALGORITHM WITH
 311 A LONG HISTORY OF USE IN ACADEMIC AND APPLIED RESEARCH. THE APPROACH IDENTIFIES
 312 GROUPS OF OBSERVATIONS SUCH THAT THE SUM OF SQUARES FROM POINTS TO THE ASSIGNED
 313 CLUSTER CENTERS IS MINIMIZED, I.E., OBSERVATIONS IN A CLUSTER ARE MORE SIMILAR TO ONE
 314 ANOTHER THAN THEY ARE TO OTHER CLUSTERS. SEVERAL K-MEANS IMPLEMENTATIONS HAVE BEEN
 315 PROPOSED; THE BED NEED METHODOLOGY USES THE WIDELY-ADOPTED HARTIGAN-WONG
 316 ALGORITHM. ANY CLUSTERING OR DATA MINING TEXT WILL DISCUSS K-MEANS; ONE EXAMPLE IS B.S.
 317 EVERITT, S. LANDAU, M. LEESE, & D. STAHL (2011) CLUSTER ANALYSIS, 5TH EDITION. WILEY, 346 P.

318 (III) "WARDS HIERARCHICAL CLUSTERING METHOD" MEANS A METHOD FOR CLUSTERING
 319 OBSERVATIONS INTO GROUPS. THIS METHOD USES A BINARY TREE STRUCTURE TO SEQUENTIALLY
 320 GROUP DATA OBSERVATIONS INTO CLUSTERS, SEEKING TO MINIMIZE OVERALL WITHIN-GROUP
 321 VARIANCE. IN THE BED NEED METHODOLOGY, THIS METHOD IS USED TO IDENTIFY THE STARTING
 322 CLUSTER LOCATIONS FOR K-MEANS. ANY CLUSTERING TEXT WILL DISCUSS HIERARCHICAL CLUSTER

323 ANALYSIS, INCLUDING WARD'S METHOD; ONE EXAMPLE IS: G. GAN, C. MA, & J. WU (2007) DATA
 324 CLUSTERING: THEORY, ALGORITHMS, AND APPLICATIONS (ASA-SIAM SERIES ON STATISTICS AND
 325 APPLIED PROBABILITY). SOCIETY FOR INDUSTRIAL AND APPLIED MATHEMATICS (SIAM), 466 P.
 326 (vF) If there is only a single applicant, then the assignment procedure is complete. If there are
 327 additional applicants, then steps (iii), and (iv) must be repeated until all applicants have been assigned to
 328 an existing subarea. CALCULATE THE INCREMENTAL F SCORE (F_{inc}) FOR EACH CLUSTER
 329 SOLUTION (i) BETWEEN 3 AND $n-1$ LETTING:

330 _____ $r_i^2 = r^2$ OF SOLUTION i
 331 _____ $r_{i-1}^2 = r^2$ OF SOLUTION i-1
 332 _____ $k_i =$ NUMBER OF CLUSTERS IN SOLUTION i
 333 _____ $k_{i-1} =$ NUMBER OF CLUSTERS IN SOLUTION i-1
 334 _____ $n =$ TOTAL NUMBER OF HOSPITALS

335 _____ WHERE: $F_{inc,i} = \frac{\left(\frac{r_i^2 - r_{i-1}^2}{k_i - k_{i-1}} \right)}{\left(\frac{1 - r_i^2}{n - (k_i - 1)} \right)}$

336 _____
 337 (G) SELECT CANDIDATE SOLUTIONS BY FINDING THOSE WITH PEAK VALUES IN F_{inc}
 338 SCORES SUCH THAT $F_{inc,i}$ IS GREATER THAN BOTH $F_{inc,i-1}$ AND $F_{inc,i+1}$.
 339 (H) REMOVE ALL CANDIDATE SOLUTIONS IN WHICH THE LARGEST SINGLE CLUSTER
 340 CONTAINS MORE THAN 20 HOSPITALS.

341 (I) IDENTIFY THE MINIMUM NUMBER OF SINGLE HOSPITAL CLUSTERS FROM THE
 342 REMAINING CANDIDATE SOLUTIONS. REMOVE ALL CANDIDATE SOLUTIONS CONTAINING A
 343 GREATER NUMBER OF SINGLE HOSPITAL CLUSTERS THAN THE IDENTIFIED MINIMUM.

344 (J) FROM THE REMAINING CANDIDATE SOLUTIONS, CHOOSE THE SOLUTION WITH THE
 345 LARGEST NUMBER OF CLUSTERS (k). THIS SOLUTION (k CLUSTERS) IS THE RESULTING
 346 NUMBER AND CONFIGURATION OF THE HOSPITAL GROUPS.

347 (K) RENAME HOSPITAL GROUPS AS FOLLOWS:

348 (I) FOR EACH HOSPITAL GROUP, IDENTIFY THE HSA IN WHICH THE MAXIMUM NUMBER OF
 349 HOSPITALS ARE LOCATED. IN CASE OF A TIE, USE THE HSA NUMBER THAT IS LOWER.

350 (II) FOR EACH HOSPITAL GROUP, SUM THE NUMBER OF CURRENT LICENSED HOSPITAL
 351 BEDS FOR ALL HOSPITALS.

352 (III) ORDER THE GROUPS FROM 1 TO k BY FIRST SORTING BY HSA NUMBER, THEN
 353 SORTING WITHIN EACH HSA BY THE SUM OF BEDS IN EACH HOSPITAL GROUP. THE HOSPITAL
 354 GROUP NAME IS THEN CREATED BY APPENDING NUMBER IN WHICH IT IS ORDERED TO "HG"
 355 (E.G., HG1, HG2, ... HG k).

356 (IV) HOSPITALS THAT DO NOT HAVE PATIENT RECORDS IN THE MIDB - IDENTIFIED IN
 357 SUBSECTION (1)(A) - ARE DESIGNATED AS "NG" FOR NON-GROUPABLE HOSPITALS.

358 _____
 359 (2) FOR AN APPLICATION INVOLVING A PROPOSED NEW LICENSED SITE FOR A HOSPITAL
 360 (WHETHER NEW OR REPLACEMENT), THE PROPOSED NEW LICENSED SITE SHALL BE
 361 ASSIGNED TO AN EXISTING HOSPITAL GROUP UTILIZING THE METHODOLOGY DESCRIBED IN
 362 "A METHODOLOGY FOR DEFINING HOSPITAL GROUPS" BY PAUL L. DELAMATER, ASHTON M.
 363 SHORTRIDGE, AND JOSEPH P. MESSINA, 2011 AS FOLLOWS:

364 (A) CALCULATE THE ROAD DISTANCE FROM PROPOSED NEW SITE (s) TO ALL EXISTING
 365 HOSPITALS, RESULTING IN A LIST OF n OBSERVATIONS (s_n).

366 (B) RESCALE s_n BY DIVIDING EACH OBSERVATION BY THE MAXIMUM ROAD DISTANCE
 367 BETWEEN ANY TWO HOSPITALS IDENTIFIED IN SUBSECTION (1)(C).

368 (C) FOR EACH HOSPITAL GROUP, SUBSET THE CLUSTER CENTER LOCATION IDENTIFIED IN
 369 SUBSECTION (1)(E)(I) TO ONLY THE ENTRIES CORRESPONDING TO THE ROAD DISTANCE
 370 BETWEEN HOSPITALS. FOR EACH HOSPITAL GROUP, THE RESULT IS A LIST OF n
 371 OBSERVATIONS THAT DEFINE EACH HOSPITAL GROUP'S CENTRAL LOCATION IN RELATIVE
 372 ROAD DISTANCE.

373 (D) CALCULATE THE DISTANCE ($D_{k,s}$) BETWEEN THE PROPOSED NEW SITE AND EACH
 374 EXISTING HOSPITAL GROUP

375 WHERE: $d_{k,s} = \sqrt{(HG_{k,1} - s_1)^2 + (HG_{k,2} - s_2)^2 + (HG_{k,3} - s_3)^2 + \dots + (HG_{k,n} - s_n)^2}$

376 (E) ASSIGN THE PROPOSED NEW SITE TO THE CLOSEST HOSPITAL GROUP (HG k) BY
 377 SELECTING THE MINIMUM VALUE OF $d_{k,s}$.

378 (F) IF THERE IS ONLY A SINGLE APPLICANT, THEN THE ASSIGNMENT PROCEDURE IS
 379 COMPLETE. IF THERE ARE ADDITIONAL APPLICANTS, THEN STEPS (A-E) MUST BE REPEATED
 380 UNTIL ALL APPLICANTS HAVE BEEN ASSIGNED TO AN EXISTING HOSPITAL GROUP.

381
 382 (3) The Commission-DEPARTMENT shall amend Appendix A-THE HOSPITAL GROUPS to reflect:
 383 (a) approved new licensed site(s) assigned to a specific hospital subareaGROUP; (b) hospital closures;
 384 and (c) licensure action(s) as appropriate.

385
 386 (34) As directed by the Commission, new sub-areaHOSPITAL GROUP assignments established
 387 according to subsection (1)(a)(i) shall supersede Appendix A-THE PREVIOUS SUBAREA/HOSPITAL
 388 GROUP ASSIGNMENTS and shall be included as an amended appendix to these standards
 389 POSTED ON THE STATE OF MICHIGAN CON WEB SITE effective on the date determined by the Commission.

391 **Section 4. Determination of the needed hospital bed supply**

392
 393 Sec. 4. (1) The determination of the needed hospital bed supply for a limited access area and a
 394 hospital subareaGROUP for a planning year shall be made using the MIDB and population estimates and
 395 projections by zip code in the following methodology DETAILED IN "ANEW METHODOLOGY FOR
 396 DETERMINING NEEDED HOSPITAL BED SUPPLY" BY PAUL L. DELAMATER, ASHTON M.
 397 SHORTRIDGE, AND JOSEPH P. MESSINA, 2011 AS FOLLOWS:

398 (a) All hospital discharges for normal newborns (DRG 391 PRIOR TO 2008, DRG 795
 399 THEREAFTER) and psychiatric patients (ICD-9-CM codes 290 through 319 as a principal diagnosis) will
 400 be excluded.

401 (b) For each discharge from the selected zip codes for a limited access area or each hospital
 402 subarea discharge, as applicable, calculate the number of patient days (take the patient days for each
 403 discharge and accumulate it within the respective age group) for the following age groups: ages 0
 404 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15 through 44
 405 (DRGs 370 through 375 — obstetrical discharges), ages 45 through 64, ages 65 through 74, and ages 75
 406 and older. Data from non-Michigan residents are to be included for each specific age group. For limited
 407 access areas, proceed to section 4(1)(e)FOR EACH COUNTY, COMPILE THE MONTHLY PATIENT
 408 DAYS USED BY COUNTY RESIDENTS FOR THE PREVIOUS FIVE YEARS (BASE YEAR PLUS
 409 PREVIOUS FOUR YEARS). COMPILE THE MONTHLY PATIENT DAYS USED BY NON-MICHIGAN
 410 RESIDENTS IN MICHIGAN HOSPITALS FOR THE PREVIOUS FIVE YEARS AS AN "OUT-OF-STATE"
 411 UNIT. THE OUT-OF-STATE PATIENT DAYS UNIT IS CONSIDERED AN ADDITIONAL COUNTY
 412 THEREAFTER. PATIENT DAYS ARE TO BE ASSIGNED TO THE MONTH IN WHICH THE PATIENT
 413 WAS DISCHARGED. FOR PATIENT RECORDS WITH AN UNKNOWN COUNTY OF RESIDENCE,
 414 ASSIGN PATIENT DAYS TO THE COUNTY OF THE HOSPITAL WHERE THE PATIENT RECEIVED
 415 SERVICE.

416 (c) For each hospital subarea, calculate the relevance index (%Z) for each zip code and for each of
 417 the following age groups: ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through
 418 44, female ages 15 through 44 (DRGs 370 THROUGH 375 — obstetrical discharges), ages 45 through
 419 64, ages 65 through 74, and ages 75 and olderFOR EACH COUNTY, CALCULATE THE MONTHLY
 420 PATIENT DAYS FOR ALL MONTHS IN THE PLANNING YEAR. FOR EACH COUNTY, CONSTRUCT
 421 AN ORDINARY LEAST SQUARES LINEAR REGRESSION MODEL USING MONTHLY PATIENT DAYS
 422 AS THE DEPENDENT VARIABLE AND MONTHS (1-60) AS THE INDEPENDENT VARIABLE. IF THE
 423 LINEAR REGRESSION MODEL IS SIGNIFICANT AT A 90% CONFIDENCE LEVEL (F-SCORE, TWO
 424 TAILED p VALUE < 0.1), PREDICT PATIENT DAYS FOR MONTHS 109-120 USING THE MODEL
 425 COEFFICIENTS. IF THE LINEAR REGRESSION MODEL IS NOT SIGNIFICANT AT A 90%
 426 CONFIDENCE LEVEL (F-SCORE, TWO TAILED p VALUE > 0.1), CALCULATE THE PREDICTED

427 MONTHLY PATIENT DAY DEMAND IN THE PLANNING YEAR BY FINDING THE MONTHLY
 428 AVERAGE OF THE THREE PREVIOUS YEARS (MONTHS 25-60).

429 (d) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective base
 430 year zip code and age group specific year population. The result will be the zip code allocations by age
 431 group for each subareaFOR EACH COUNTY, CALCULATE THE PREDICTED YEARLY PATIENT DAY
 432 DEMAND IN THE PLANNING YEAR. FOR COUNTIES WITH A SIGNIFICANT REGRESSION MODEL,
 433 SUM THE MONTHLY PREDICTED PATIENT DAYS FOR THE PLANNING YEAR. FOR COUNTIES
 434 WITH A NON-SIGNIFICANT REGRESSION MODEL, MULTIPLY THE THREE YEAR MONTHLY
 435 AVERAGE BY 12.

436 (e) For each limited access area or hospital subarea, as applicable, calculate the subarea base year
 437 population by age group by adding together all zip code population allocations calculated in (d) for each
 438 specific age group in that subarea. For a limited access area, add together the age groups identified for
 439 the limited access area. The result will be six population age groups for each limited access area or
 440 subarea, as applicableFOR EACH COUNTY, CALCULATE THE BASE YEAR PATIENT DAY
 441 COMMITMENT INDEX (%C) TO EACH HOSPITAL GROUP. SPECIFICALLY, DIVIDE THE BASE YEAR
 442 PATIENT DAYS FROM EACH COUNTY TO EACH HOSPITAL GROUP BY THE TOTAL NUMBER OF
 443 BASE YEAR PATIENT DAYS FROM EACH COUNTY.

444 (f) For each limited access area or hospital subarea, as applicable, calculate the patient day use
 445 rates for ages 0 (excluding normal newborns) through 14 (pediatric), ages 15 through 44, female ages 15
 446 through 44 (DRGs 370 through 375 — obstetrical discharges), ages 45 through 64, ages 65 through 74,
 447 and ages 75 and older by dividing the results of (b) by the results of (e)FOR EACH COUNTY,
 448 ALLOCATE THE PLANNING YEAR PATIENT DAYS TO THE HOSPITAL GROUPS BY MULTIPLYING
 449 THE PLANNING YEAR PATIENT DAYS BY THE %C TO EACH HOSPITAL GROUP FROM
 450 SUBSECTION (E).

451 (g) For each hospital subarea, multiply each zip code %Z calculated in (c) by its respective planning
 452 year zip code and age group specific year population. The results will be the projected zip code
 453 allocations by age group for each subarea. For a limited access area, multiply the population projection
 454 for the plan year by the proportion of the zip code that is contained within the limited access area for each
 455 zip code age group. The results will be the projected zip code allocations by age group for each zip code
 456 within the limited access areaFOR EACH HOSPITAL GROUP, SUM THE PLANNING YEAR PATIENT
 457 DAYS ALLOCATED FROM EACH COUNTY.

458 (h) For each hospital subarea, calculate the subarea projected year population by age group by
 459 adding together all projected zip code population allocations calculated in (g) for each specific age group.
 460 For a limited access area, add together the zip code allocations calculated in (g) by age group identified
 461 for the limited access area. The result will be six population age groups for each limited access area or
 462 subarea, as applicableFOR EACH HOSPITAL GROUP, CALCULATE THE AVERAGE DAILY CENSUS
 463 (ADC) FOR THE PLANNING YEAR BY DIVIDING THE PLANNING YEAR PATIENT DAYS BY 365.
 464 ROUND EACH ADC VALUE UP TO THE NEAREST WHOLE NUMBER.

465 (i) For each limited access area or hospital subarea, as applicable, calculate the limited access area
 466 or hospital subarea, as applicable, projected patient days for each age group by multiplying the six
 467 projected populations by age group calculated in step (h) by the age specific use rates identified in step
 468 (f)FOR EACH HOSPITAL GROUP, SELECT THE APPROPRIATE OCCUPANCY RATE FROM THE
 469 OCCUPANCY TABLE IN APPENDIX C.

470 (j) For each limited access area or hospital subarea, as applicable, calculate the adult
 471 medical/surgical limited access area or hospital subarea, as applicable, projected patient days by adding
 472 together the following age group specific projected patient days calculated in (i): ages 15 through 44,
 473 ages 45 through 64, ages 65 through 74, and ages 75 and older. The 0 (excluding normal newborns)
 474 through 14 (pediatric) and female ages 15 through 44 (DRGs 370 through 375 — obstetrical discharges)
 475 age groups remain unchanged as calculated in (i)FOR EACH HOSPITAL GROUP, CALCULATE THE
 476 PLANNING YEAR BED NEED BY DIVIDING THE PLANNING YEAR ADC BY THE APPROPRIATE
 477 OCCUPANCY RATE. ROUND EACH BED NEED VALUE UP TO THE NEAREST WHOLE NUMBER.

478 (k) For each limited access area or hospital subarea, as applicable, calculate the limited access area
 479 or hospital subarea, as applicable, projected average daily census (ADC) for three age groups: Ages 0
 480 (excluding normal newborns) through 14 (pediatric), female ages 15 through 44 (DRGs 370 through 375
 481 — obstetrical discharges), and adult medical surgical by dividing the results calculated in (j) by 365 (or 366

482 ~~if the planning year is a leap year). Round each ADC to a whole number. This will give three ADC~~
 483 ~~computations per limited access area or subarea, as applicable.~~
 484 ~~—(l) For each limited access area or hospital subarea, as applicable, and age group, select the~~
 485 ~~appropriate occupancy rate from the occupancy rate table in Appendix D.~~
 486 ~~—(m) For each limited access area or hospital subarea, as applicable, and age group, calculate the~~
 487 ~~limited access area or subarea, as applicable, projected bed need number of hospital beds for the limited~~
 488 ~~access area or subarea, as applicable, by age group by dividing the ADC calculated in (k) by the~~
 489 ~~appropriate occupancy rate determined in (l). To obtain the total limited access area or hospital, as~~
 490 ~~applicable, bed need, add the three age group bed projections together. Round any part of a bed up to a~~
 491 ~~whole bed.~~

492
 493 (2) THE DETERMINATION OF THE NEEDED HOSPITAL BED SUPPLY FOR A LIMITED ACCESS
 494 AREA SHALL BE MADE USING THE MIDB AND THE METHODOLOGY DETAILED IN "A
 495 METHODOLOGY FOR DETERMINING NEEDED HOSPITAL BED SUPPLY" BY PAUL L. DELAMATER,
 496 ASHTON M. SHORTRIDGE, AND JOESPH P. MESSINA, 2011 AS FOLLOWS:

497 (A) ALL HOSPITAL DISCHARGES FOR NORMAL NEWBORNS (DRG 391 PRIOR TO 2008, DRG
 498 795 THEREAFTER) AND PSYCHIATRIC PATIENTS (ICD-9-CM CODES 290 THROUGH 319 AS A
 499 PRINCIPAL DIAGNOSIS) WILL BE EXCLUDED.

500 (B) CALCULATE THE AVERAGE PATIENT DAY USE RATE OF MICHIGAN RESIDENTS. SUM
 501 TOTAL PATIENT DAYS OF MICHIGAN RESIDENTS IN THE BASE YEAR AND DIVIDE BY ESTIMATED
 502 BASE YEAR POPULATION FOR THE STATE (POPULATION DATA AVAILABLE FROM US CENSUS
 503 BUREAU).

504 (C) CALCULATE THE MINIMUM NUMBER OF PATIENT DAYS FOR DESIGNATION OF A LIMITED
 505 ACCESS AREA BY MULTIPLYING THE AVERAGE PATIENT DAY USE RATE BY 50,000. ROUND UP
 506 TO THE NEAREST WHOLE NUMBER.

507 (D) FOLLOW STEPS OUTLINED IN SECTION 4(1)(B) – (D) TO PREDICT PLANNING YEAR
 508 PATIENT DAYS FOR EACH UNDERSERVED AREA. ROUND UP TO THE NEAREST WHOLE
 509 NUMBER. THE PATIENT DAYS FOR EACH UNDERSERVED AREA ARE DEFINED AS THE SUM OF
 510 THE ZIP CODES CORRESPONDING TO EACH UNDERSERVED AREA.

511 (E) FOR EACH UNDERSERVED AREA, COMPARE THE PLANNING YEAR PATIENT DAYS TO
 512 THE MINIMUM NUMBER OF PATIENT DAYS FOR DESIGNATION OF A LIMITED ACCESS AREA
 513 CALCULATED IN (C). ANY UNDERSERVED AREA WITH A PLANNING YEAR PATIENT DAY
 514 DEMAND GREATER THAN OR EQUAL TO THE MINIMUM IS DESIGNATED AS A LIMITED ACCESS
 515 AREA.

516 (F) FOR EACH LIMITED ACCESS AREA, CALCULATE THE PLANNING YEAR BED NEED USING
 517 THE STEPS OUTLINED IN SECTION 4(1)(H) – (J). FOR THESE STEPS, USE THE PLANNING YEAR
 518 PATIENT DAYS FOR EACH LIMITED ACCESS AREA.

519 **Section 5. Bed Need**

520
 521
 522 | Sec. 5. (1) The bed-need numbers ~~incorporated as part of these standards as Appendix C~~ shall apply
 523 | to projects subject to review under these standards, except where a specific CON review standard states
 524 | otherwise.

525
 526 | (2) The ~~Commission shall direct the Department, effective November 2004 and~~ SHALL re-calculate
 527 | the acute care bed need methodology in Section 4 every two years, thereafter OR AS DIRECTED BY
 528 | THE COMMISSION, to re-calculate the acute care bed need methodology in Section 4, within a specified
 529 | time frame.

530
 531 | (3) The Commission shall designate the base year and the future planning year which shall be
 532 | utilized in applying the methodology pursuant to subsection (2).

533
 534 | (4) ~~When the Department is directed by the Commission to apply the methodology pursuant to~~
 535 | subsection (2), the effective date of the bed-need numbers shall be established by the Commission.
 536

(5) ~~As directed by the Commission, n~~New bed-need numbers established by subsections (2) and (3) shall supersede ~~the PREVIOUS~~ bed-need numbers ~~shown in Appendix C~~ and shall be ~~included as an amended appendix to these standards~~ POSTED ON THE STATE OF MICHIGAN CON WEB SITE AS PART OF THE HOSPITAL BED INVENTORY.

(6) MODIFICATIONS MADE BY THE COMMISSION PURSUANT TO THIS SECTION SHALL NOT REQUIRE STANDARD ADVISORY COMMITTEE ACTION, A PUBLIC HEARING, OR SUBMITTAL OF THE STANDARD TO THE LEGISLATURE AND THE GOVERNOR IN ORDER TO BECOME EFFECTIVE.

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

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

(a) The new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or ~~50-25~~ beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to assure access to health-care services.

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

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

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

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

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

(i) That the host hospital shall delicense the same number of hospital beds proposed by the applicant for licensure in the new hospital or any subsequent application to add additional beds.

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

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

(A) Relicensure of the beds to the host hospital. The host hospital must obtain a CON to acquire the ~~long-term (acute) care~~LTC hospital. In the event that the host hospital applies for a CON to acquire the ~~long-term (acute) care~~LTC hospital [including the beds leased by the host hospital to the ~~long-term (acute) care~~LTC hospital] within six months following the termination of the lease with the ~~long-term (acute) care~~LTC hospital, it shall not be required to be in compliance with the hospital bed supply ~~set forth in Appendix C~~ if the host hospital proposes to add the beds of the ~~long-term (acute) care~~LTC hospital to the host hospital's medical/surgical licensed capacity and the application meets all other

592 applicable project delivery requirements. The beds must be used for general medical/surgical purposes.
 593 Such an application shall not be subject to comparative review and shall be processed under the
 594 procedures for non-substantive review (as this will not be considered an increase in the number of beds
 595 originally licensed to the applicant at the host hospital);

596 (B) Delicensure of the hospital beds; or

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

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

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

605 (e) The new hospital shall be assigned to the same [subareaHOSPITAL GROUP](#) as the host hospital.

606 (f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute
 607 a change in bed capacity under Section 1(32) of these standards.

608 (g) The lease will not result in an increase in the number of licensed hospital beds in the
 609 [subareaHOSPITAL GROUP](#).

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

612
 613 (3) An applicant proposing to add new hospital beds, as the receiving licensed hospital under
 614 Section 8, shall demonstrate that it meets all of the requirements of this subsection and shall not be
 615 required to be in compliance with the needed hospital bed supply [set forth in Appendix C](#) if the application
 616 meets all other applicable CON review standards and agrees and assures to comply with all applicable
 617 project delivery requirements.

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

620 (i) In the [subareaHOSPITAL GROUP PURSUANT TO SECTION 8\(2\)\(A\)](#), or

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

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

623 ~~(b) AN APPLICANT PROPOSING TO ADD NEW LICENSED BEDS AS THE RECEIVING~~
 624 ~~HOSPITAL WHERE THE SOURCE HOSPITAL WAS SUBJECT TO SECTION 8(3)(B) SHALL MEET~~
 625 ~~THE FOLLOWING REQUIREMENTS:THE RECEIVING HOSPITAL MUSTSHALL HAVE AN AVERAGE~~
 626 ~~ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE.~~

627 ~~(IC) FOR THE PURPOSES OF SUBSECTION (I) ABOVE, THE REVISED NUMBER OF LICENSED~~
 628 ~~BEDS AT THE RECEIVING HOSPITAL SHALL BE CALCULATED AS FOLLOWS:THE ADDITION OF~~
 629 ~~THE PROPOSED ADDITION OF NEW HOSPITAL BEDS SHALL NOT EXCEED THE NUMBER~~
 630 ~~DETERMINED BY THE FOLLOWING CALCULATION:~~

631 ~~(AI) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,~~
 632 ~~CONSECUTIVE 36-MONTH PERIODFOR WHICH VERIFIABLE DATA ARE AVAILABLE TO THE~~
 633 ~~DEPARTMENTAS OF THE DATE OF THE APPLICATION, CALCULATE THE ADJUSTED PATIENT~~
 634 ~~DAYS FOR THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS~~
 635 ~~AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.~~

636 ~~(BII) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN SUBSECTION (A)~~
 637 ~~ABOVE BY .40 TO DETERMINE LICENSED BED DAYS AT 40 PERCENT OCCUPANCYDIVIDE THE~~
 638 ~~RESULT OF SUBSECTION (I) BY 1095 (OR 1096, IF THE 36-MONTH PERIOD INCLUDES A LEAP~~
 639 ~~YEAR) AND ROUND UP TO NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE~~
 640 ~~MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE RECEIVING HOSPITAL.~~

641 ~~(GIII) DIVIDE THE RESULT OF SUBSECTION (B) ABOVE BY 1095 (OR 1096 IF INCLUDING A LEAP~~
 642 ~~YEAR) AND ROUND THE QUOTIENT UP TO THE NEXT WHOLE NUMBER. THIS IS THE MAXIMUM~~
 643 ~~NUMBER OF BEDS THAT CAN BE LICENSED AT THE RECEIVING HOSPITAL AFTER THE~~
 644 ~~ACCEPTANCE OF THE NEW BEDS, OR 25 WHICHEVER IS LARGERSUBTRACT THE RECEIVING~~
 645 ~~HOSPITAL'S TOTAL NUMBER OF LICENSED BEDS AND APPROVED BEDS FROM THE RESULT OF~~

646 SUBSECTION (II). THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE ADDED TO THE
 647 RECEIVING HOSPITAL.

648 (IID) THE NUMBER OF BEDS TO BE ADDED SHALL BE NO MORE THAN THE NUMBER, WHICH,
 649 WHEN ADDED TO THE NUMBER OF LICENSED BEDS PRIOR TO THE ADDITION, WOULD RESULT
 650 IN THE ADJUSTED OCCUPANCY RATE FOR THE RECEIVING HOSPITAL'S AVERAGE ADJUSTED
 651 OCCUPANCY RATE MUST NOT TO BE AT LEAST LESS THAN 40 PERCENT IF AFTER THE
 652 ADDITION OF THE PROPOSED ADDITION OF NEW HOSPITAL BEDS IS APPROVED.

653 (GE) SUBSECTION (3)(B), (C), AND (D) SHALL NOT APPLY TO EXCLUDED HOSPITALS.

654 (DF) The proposed project to add new hospital beds, under this subsection, shall constitute a change
 655 in bed capacity under Section 1(32) of these standards.

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

658
 659 (4) An applicant may apply for the addition of new beds if all of the following subsections are met.
 660 Further, an applicant proposing new beds at an existing licensed hospital site shall not be required to be
 661 in compliance with the needed hospital bed supply ~~set forth in Appendix C~~ if the application meets all
 662 other applicable CON review standards and agrees and assures to comply with all applicable project
 663 delivery requirements.

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

665 (b) The hospital at the existing licensed hospital site has operated at an adjusted occupancy rate of
 666 80 percent or above for the previous, consecutive 24 months based on its licensed and approved hospital
 667 bed capacity. The adjusted occupancy rate shall be calculated as follows:

668 (i) ~~Combine all pediatric patient days of care and obstetrics patient days of care provided during the~~
 669 ~~most recent, consecutive 24-month period for which verifiable data are available to the Department and~~
 670 ~~multiply that number by 1.1.~~

671 ~~—(ii) Add remaining patient days of care provided during the most recent, consecutive 24-month~~
 672 ~~period for which verifiable data are available to the Department to the number calculated in (i) above.~~
 673 ~~This is the adjusted patient days. CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING~~
 674 ~~THE MOST RECENT, CONSECUTIVE 24-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE~~
 675 ~~AVAILABLE TO THE DEPARTMENT.~~

676 (iii) Divide the number calculated in (ii) above by the total possible patient days [licensed and
 677 approved hospital beds multiplied by 730 (or 731 if including a leap year)]. This is the adjusted
 678 occupancy rate.

679 (c) The number of beds that may be approved pursuant to this subsection shall be the number of
 680 beds necessary to reduce the adjusted occupancy rate for the hospital to 75 percent. The number of
 681 beds shall be calculated as follows:

682 (i) Divide the number of adjusted patient days calculated in subsection (b)(ii) by .75 to determine
 683 licensed bed days at 75 percent occupancy.

684 (ii) Divide the result of step (i) by 730 (or 731 if including a leap year) and round the result up to the
 685 next whole number.

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

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

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

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

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

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

706 (b) The Department shall assign the proposed new hospital to an existing ~~subarea~~HOSPITAL
 707 GROUP based on the current market use patterns of existing ~~subarea~~HOSPITAL GROUPs.

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

711 (d) The new beds in a hospital in a limited access area shall result in a hospital of at least 100 beds
 712 in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. If the
 713 bed need for a limited access area, as shown in Appendix ~~ED~~, is less, then that will be the minimum
 714 number of beds for a new hospital under this provision. If an applicant for new beds in a hospital under
 715 this provision simultaneously applies for status as a critical access hospital, the minimum hospital size
 716 shall be that number allowed under state/federal critical access hospital designation.

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

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

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

726 (i) In a metropolitan statistical area county, an applicant proposing to add a new hospital pursuant to
 727 this subsection shall locate the new hospital within the limited access area and serve a population of
 728 50,000 or more inside the limited access area and within 30 minutes drive time from the proposed new
 729 hospital.

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

734

735 **Section 7. Requirements for approval --~~TO replacement beds in a hospital in a replacement zone~~**

736

737 Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing
 738 ~~TO replacement~~ beds in a hospital ~~WITH~~in the replacement zone shall demonstrate that the new beds in
 739 a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or ~~50-25~~
 740 beds in a rural or micropolitan statistical area county. This subsection may be waived by the Department
 741 if the Department determines, in its sole discretion, that a smaller hospital is necessary or appropriate to
 742 assure access to health-care services.

743

744 (2) ~~THE APPLICANT SHALL SPECIFY WHETHER THE PROPOSED PROJECT IS TO REPLACE~~
 745 ~~THE LICENSED HOSPITAL TO A NEW SITE OR TO REPLACE A PORTION OF THE LICENSED BEDS~~
 746 ~~AT THE EXISTING LICENSED SITE. †~~

747

748 ~~(3) In order to be approved, the applicant~~ ~~SHALL DEMONSTRATE THAT THE new licensed site is~~
 749 ~~in the replacement zone.~~

750

751 ~~(34) IN ORDER TO BE APPROVED, THE APPLICANT SHALL COMPLY WITH THE FOLLOWING~~
 752 ~~REQUIREMENTS, AS APPLICABLE:~~

753 ~~(A) THE APPLICANT'S shall propose to (i) replace an equal or lesser number of beds currently~~
 754 ~~licensed to the applicant at the licensed site at which the proposed replacement beds are located, and (iii)~~

755 ~~that the proposed new licensed site is in the replacement zone. IF THE HOSPITAL SHALL HAVE AT~~
756 ~~THE EXISTING LICENSED HOSPITAL SITE HAS OPERATED AT AN AVERAGE ADJUSTED~~
757 ~~OCCUPANCY RATE OF 40 PERCENT OR ABOVE. FOR THE PREVIOUS, CONSECUTIVE 36~~
758 ~~MONTHS, BASED ON ITS LICENSED AND APPROVED HOSPITAL BED CAPACITY, THE AVERAGE~~
759 ~~ADJUSTED OCCUPANCY RATE SHALL BE CALCULATED AS FOLLOWS:~~
760 ~~___ (I) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,~~
761 ~~CONSECUTIVE 36-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION, FOR WHICH~~
762 ~~VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.~~
763 ~~___ (II) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (I) ABOVE BY 1095~~
764 ~~(OR 1096 IF INCLUDING A LEAP YEAR).~~
765 ~~(B) IF THE APPLICANT HOSPITAL DOES NOT HAVE AN AT THE EXISTING LICENSED~~
766 ~~HOSPITAL SITE HAS OPERATED AT AN AVERAGE ADJUSTED OCCUPANCY RATE LESS THAN OF~~
767 ~~40 PERCENT OR ABOVE, THEN THE APPLICANT HOSPITAL SHALL REDUCE THE APPROPRIATE~~
768 ~~NUMBER OF LICENSED BEDS TO ACHIEVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF FOR~~
769 ~~THE PREVIOUS, CONSECUTIVE 36 MONTHS, THE REVISED NUMBER OF BEDS AT THE~~
770 ~~LICENSED SITE SHALL BE NO MORE THAN THE NUMBER OF BEDS WHICH WOULD RESULT IN~~
771 ~~AN ADJUSTED OCCUPANCY RATE FOR THE HOSPITAL OF 60 PERCENT OR ABOVE. THE~~
772 ~~REVISED APPLICANT HOSPITAL SHALL NOT EXCEED THE NUMBER OF LICENSED BEDS AT THE~~
773 ~~HOSPITAL SHALL BE CALCULATED AS FOLLOWS:~~
774 ~~___ (I) AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF ADJUSTED~~
775 ~~PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD FOR~~
776 ~~WHICH WHERE VERIFIABLE DATA ARE IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.~~
777 ~~___ (II) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN RESULT OF~~
778 ~~SUBSECTION (I) ABOVE BY .60 TO DETERMINE LICENSED BED DAYS AT 60 PERCENT~~
779 ~~OCCUPANCY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP~~
780 ~~TO THE NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE MAXIMUM~~
781 ~~NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED HOSPITAL SITE AFTER~~
782 ~~THE REPLACEMENT.~~
783 ~~___ (III) DIVIDE THE RESULT OF SUBSECTION (II) ABOVE BY 1095 (OR 1096 IF INCLUDING A LEAP~~
784 ~~YEAR) AND ROUND THE RESULT UP TO THE NEXT WHOLE NUMBER. THIS IS THE MAXIMUM~~
785 ~~NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED HOSPITAL SITE AFTER~~
786 ~~THE REPLACEMENT, OR 25 WHICHEVER IS LARGER.~~
787 ~~___ (C) SUBSECTION (34)(A) AND (B) SHALL NOT APPLY TO EXCLUDED HOSPITALS.~~

788
789 (345) An applicant proposing replacement beds in the replacement zone shall not be required to be in
790 compliance with the needed hospital bed supply set forth in Appendix C if the application meets all other
791 applicable CON review standards and agrees and assures to comply with all applicable project delivery
792 requirements.

794 **Section 8. Requirements for approval of an applicant proposing to relocate existing licensed** 795 **hospital beds**

796
797 Sec 8. (1) The proposed project to relocate beds, under this section, shall constitute a change in
798 bed capacity under Section 1(43) of these standards.

799
800 (2) Any existing licensed acute care hospital (SOURCE HOSPITAL) may relocate all or a portion of
801 its beds to another existing licensed acute care hospital as follows:

- 802 (a) The licensed acute care hospitals are located within the same subarea HOSPITAL GROUP, or
803 (b) the licensed acute care hospitals are located within the same HSA if the receiving hospital meets
804 the requirements of Section 6(4)(b) of these standards.

805
806 (3) ~~IN ORDER TO BE APPROVED, THE APPLICANT SHALL COMPLY WITH THE FOLLOWING~~
807 ~~REQUIREMENTS, AS APPLICABLE:~~

808 (A) ~~ANY EXISTING LICENSED ACUTE CARE HOSPITAL (THE SOURCE HOSPITAL) MAY~~
809 ~~RELOCATE ALL OR A PORTION OF ITS BEDS TO ANOTHER EXISTING LICENSED ACUTE CARE~~

810 ~~HOSPITAL(S) IF THE EXISTING LICENSED SOURCE HOSPITAL HAS OPERATED AT SHALL HAVE~~
 811 ~~AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE. FOR THE PREVIOUS,~~
 812 ~~CONSECUTIVE 36 MONTHS, BASED ON ITS LICENSED AND APPROVED HOSPITAL BED~~
 813 ~~CAPACITY, THE AVERAGE ADJUSTED OCCUPANCY RATE SHALL BE CALCULATED AS~~
 814 ~~FOLLOWS:~~

815 ~~— (I) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,~~
 816 ~~CONSECUTIVE 36-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION, FOR WHICH~~
 817 ~~VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.~~

818 ~~— (II) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (I) ABOVE BY 1095~~
 819 ~~(OR 1096 IF INCLUDING A LEAP YEAR).~~

820 ~~(B) IF THE EXISTING LICENSED SOURCE HOSPITAL SITE HAS DOES NOT HAVE OPERATED~~
 821 ~~AT AN AVERAGE ADJUSTED OCCUPANCY RATE OF LESS THAN 40 PERCENT OR ABOVE FOR~~
 822 ~~THE PREVIOUS, CONSECUTIVE 36 MONTHS, IN ORDER TO BE APPROVED, THEN THE SOURCE~~
 823 ~~HOSPITAL SHALL REDUCE THE APPROPRIATE NUMBER OF LICENSED BEDS TO ACHIEVE AN~~
 824 ~~AVERAGE ADJUSTED OCCUPANCY RATE OF 60 PERCENT OR ABOVE. THE SOURCE HOSPITAL~~
 825 ~~SHALL NOT EXCEED THE NUMBER OF BEDS CALCULATED AS THE FOLLOWING~~
 826 ~~REQUIREMENTS MUST BE MET:~~

827 ~~— (I) UPON COMPLETION OF THE RELOCATION(S), THE REVISED NUMBER OF BEDS AT THE~~
 828 ~~EXISTING LICENSED HOSPITAL (“SOURCE HOSPITAL”) SHALL BE NO MORE THAN THE NUMBER~~
 829 ~~OF BEDS WHICH WOULD RESULT IN AN ADJUSTED OCCUPANCY RATE FOR THE SOURCE~~
 830 ~~HOSPITAL OF 60 PERCENT.~~

831 ~~— (II) MULTIPLE RELOCATIONS CAN BE REQUESTED AT THE SAME TIME AND CAN BE~~
 832 ~~COMBINED TO MEET THE CRITERIA OF (I) ABOVE. A SEPARATE CON MUST BE SUBMITTED FOR~~
 833 ~~EACH RELOCATION AND MULTIPLE APPLICATIONS FILED ON THE SAME APPLICATION DATE~~
 834 ~~SHALL BE CONSIDERED TOGETHER TO MEET THIS CRITERION.~~

835 ~~— (C) FOR THE PURPOSES OF SUBSECTION (3)(B)(I), THE REVISED NUMBER OF LICENSED~~
 836 ~~BEDS AT THE SOURCE HOSPITAL SHALL BE CALCULATED AS FOLLOWS:~~

837 ~~— (I) AS OF THE DATE OF THE APPLICATION, CALCULATE THE NUMBER OF ADJUSTED~~
 838 ~~PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD FOR~~
 839 ~~WHICH WHERE VERIFIABLE DATA ARE IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.~~

840 ~~— (II) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (I) ABOVE BY .60 TO~~
 841 ~~DETERMINE LICENSED BED DAYS AT 60 PERCENT OCCUPANCY RESULT OF SUBSECTION (I) BY~~
 842 ~~1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE~~
 843 ~~NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF~~
 844 ~~BEDS THAT CAN BE LICENSED AT THE SOURCE HOSPITAL SITE AFTER THE RELOCATION.~~

845 ~~— (III) DIVIDE THE RESULT OF SUBSECTION (II) ABOVE BY 1095 (OR 1096 IF INCLUDING A LEAP~~
 846 ~~YEAR) AND ROUND THE RESULT UP TO THE NEXT WHOLE NUMBER. THIS IS THE MAXIMUM~~
 847 ~~NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED HOSPITAL SITE AFTER~~
 848 ~~THE RELOCATION, OR 25 WHICHEVER IS LARGER.~~

849 ~~(C) SUBSECTIONS (3)(A) AND (B) SHALL NOT APPLY TO EXCLUDED HOSPITALS MULTIPLE~~
 850 ~~RELOCATIONS CAN BE REQUESTED AT THE SAME TIME AND CAN BE COMBINED TO MEET THE~~
 851 ~~CRITERIA OF (B)(I) ABOVE. A SEPARATE CON MUST BE SUBMITTED FOR EACH RELOCATION~~
 852 ~~AND MULTIPLE APPLICATIONS FILED ON THE SAME APPLICATION DATE SHALL BE~~
 853 ~~CONSIDERED TOGETHER TO MEET THIS CRITERION.~~

854
 855 ~~(D4) SUBSECTION (3)(B) SHALL NOT APPLY TO EXCLUDED HOSPITALS A SOURCE HOSPITAL~~
 856 ~~SHALL APPLY FOR MULTIPLE RELOCATIONS ON THE SAME APPLICATION DATE, AND THE~~
 857 ~~APPLICATIONS CAN BE COMBINED TO MEET THE CRITERIA OF (B) ABOVE. A SEPARATE~~
 858 ~~APPLICATION SHALL BE SUBMITTED FOR EACH PROPOSED RELOCATION.~~

859
 860 ~~(45) The hospital from which the beds are being relocated, and the hospital receiving the beds, shall~~
 861 ~~not require any ownership relationship.~~

862
 863 ~~(456) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory~~
 864 ~~for the applicable subarea HOSPITAL GROUP.~~

865
866 | (56) The relocation of beds under this section shall not be subject to a mileage limitation.
867

868 | **Section 9. Project delivery requirements – terms of approval for all applicants**
869

870 | Sec. 9. (4) An applicant shall agree that, if approved, the project shall be delivered in compliance with
871 the following terms of CON approval:
872

873 | (a1) Compliance with these standards.
874

875 | (2) Compliance with the following quality assurance standards:

876 | (A) The applicant shall assure compliance with Section 20201 of the Code, being Section 333.20201
877 of the Michigan Compiled Laws.
878

879 | (3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

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

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

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

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

886 | (iii) Provide services to any individual based on clinical indications of need for the services.
887

888 | (4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

889 | (A) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75
890 percent over the last 12-month period in the three years after the new beds are put into operation, and for
891 each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a
892 minimum of 75 percent average annual occupancy for the revised licensed bed complement.

893 | (B) The applicant must submit documentation acceptable and reasonable to the Department, within
894 30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-
895 month period after the new beds are put into operation and for each subsequent calendar year, within 30
896 days after the end of the year.

897 | (DC) The applicant shall participate in a data collection SYSTEM established and administered by the
898 Department or its designee. The data may include, but is not limited to, annual budget and cost
899 information, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, and demographic, morbidity,
900 and mortality information, as well as the volume of care provided to patients from all payor sources. The
901 applicant shall provide the required data on a separate basis for each licensed site; in a format
902 established by the Department, and in a mutually agreed upon media. The Department may elect to
903 verify the data through on-site review of appropriate records.

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

906 | (EE) The applicant shall provide the Department with a notice stating the date the hospital beds are
907 placed in operation and such TIMELY notice shall be submitted to the Department OF THE PROPOSED
908 PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

909 | ~~(b) Compliance with applicable operating standards.~~

910 | ~~(i) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75~~
911 ~~percent over the last 12-month period in the three years after the new beds are put into operation, and for~~
912 ~~each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a~~
913 ~~minimum of 75 percent average annual occupancy for the revised licensed bed complement.~~

914 | ~~(ii) The applicant must submit documentation acceptable and reasonable to the Department, within~~
915 ~~30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-~~
916 ~~month period after the new beds are put into operation and for each subsequent calendar year, within 30~~
917 ~~days after the end of the year.~~

918 | ~~(c) Compliance with the following quality assurance standards:~~

- 919 ~~—(i) The applicant shall provide the Department with a notice stating the date the hospital beds are~~
 920 ~~placed in operation and such notice shall be submitted to the Department consistent with applicable~~
 921 ~~statute and promulgated rules.~~
 922 ~~—(ii) The applicant shall assure compliance with Section 20201 of the Code, being Section 333.20204~~
 923 ~~of the Michigan Compiled Laws.~~
 924 ~~—(iii) The applicant shall participate in a data collection network established and administered by the~~
 925 ~~Department or its designee. The data may include, but is not limited to, annual budget and cost~~
 926 ~~information and demographic, diagnostic, morbidity, and mortality information, as well as the volume of~~
 927 ~~care provided to patients from all payor sources. The applicant shall provide the required data on a~~
 928 ~~separate basis for each licensed site; in a format established by the Department, and in a mutually~~
 929 ~~agreed upon media. The Department may elect to verify the data through on-site review of appropriate~~
 930 ~~records.~~
 931 ~~—(A) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The~~
 932 ~~data shall be submitted to the Department or its designee.~~
 933 ~~—(iv) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years~~
 934 ~~of operation and continue to participate annually thereafter.~~
 935 ~~—(d) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:~~
 936 ~~—(i) Not deny services to any individual based on ability to pay or source of payment.~~
 937 ~~—(ii) Maintain information by source of payment to indicate the volume of care from each payor and~~
 938 ~~non-payor source provided annually.~~
 939 ~~—(iii) Provide services to any individual based on clinical indications of need for the services.~~
 940
 941 (25) The agreements and assurances required by this section shall be in the form of a certification
 942 agreed to by the applicant or its authorized agent.

943 **Section 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan** 944 **counties**

945
 946
 947 Sec. 10. Rural, micropolitan statistical area, and metropolitan statistical area Michigan counties, for
 948 purposes of these standards, are incorporated as part of these standards as Appendix B. The
 949 Department may amend Appendix B as appropriate to reflect changes by the statistical policy office of the
 950 office of information and regulatory affairs of the United States office of management and budget.
 951

952 **Section 11. Department inventory of beds**

953
 954 Sec. 11. The Department shall maintain and provide on request a listing of the Department inventory
 955 of beds for each ~~subarea~~HOSPITAL GROUP.
 956

957 **Section 12. Effect on prior planning policies; comparative reviews**

958
 959 Sec. 12. (1) These CON review standards supersede and replace the CON standards for hospital
 960 beds approved by the CON Commission on December ~~429, 2006-2008~~ and effective March ~~82,~~
 961 20072009.
 962

963 (2) Projects reviewed under these standards shall be subject to comparative review except those
 964 projects meeting the requirements of Section 7 involving the replacement of beds in a hospital within the
 965 replacement zone and projects involving acquisition (including purchase, lease, donation or comparable
 966 arrangements) of a hospital.
 967

968 **Section 13. Additional requirements for applications included in comparative reviews**

969
 970 Sec. 13. (1) Except for those applications for limited access areas, any application for hospital beds,
 971 that is subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the
 972 Michigan Compiled Laws, or under these standards shall be grouped and reviewed comparatively with
 973 other applications in accordance with the CON rules.

974

975 (2) Each application in a comparative review group shall be individually reviewed to determine
 976 whether the application is a qualifying project. If the Department determines that two or more competing
 977 applications are qualifying projects, it shall conduct a comparative review. The Department shall approve
 978 those qualifying projects which, when taken together, do not exceed the need, as defined in Section
 979 22225(1) of the Code, and which have the highest number of points when the results of subsection (3)
 980 are totaled. If two or more qualifying projects are determined to have an identical number of points, then
 981 the Department shall approve those qualifying projects that, when taken together, do not exceed the need
 982 in the order in which the applications were received by the Department based on the date and time stamp
 983 placed on the applications by the department in accordance with rule 325.9123.

984

985 (3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's
 986 uncompensated care volume and as measured by percentage of gross hospital revenues as set forth in
 987 the following table. The applicant's uncompensated care volume will be the cumulative of all currently
 988 licensed Michigan hospitals under common ownership or control with the applicant that are located in the
 989 same health service area as the proposed hospital beds. If a hospital under common ownership or
 990 control with the applicant has not filed a Cost Report, then the related applicant shall receive a score of
 991 zero. The source document for the calculation shall be the most recent Cost Report filed with the
 992 Department for purposes of calculating disproportionate share hospital payments.

993

994	<u>Percentile Ranking</u>	<u>Points Awarded</u>
995	90.0 – 100	25 pts
996	80.0 – 89.9	20 pts
997	70.0 – 79.9	15 pts
998	60.0 – 69.9	10 pts
999	50.0 – 59.9	5 pts

1000

1001 Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to
 1002 be closed shall be excluded from this calculation.

1003 (b) A qualifying project will be awarded points based on the health service area percentile rank of the
 1004 applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the
 1005 following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all
 1006 currently licensed Michigan hospitals under common ownership or control with the applicant that are
 1007 located in the same health service area as the proposed hospital beds. If a hospital under common
 1008 ownership or control with the applicant has not filed a Cost Report, then the related applicant shall
 1009 receive a score of zero. The source document for the calculation shall be the most recent Cost Report
 1010 filed with the department for purposes of calculating disproportionate share hospital payments.

1011

1012	<u>percentile rank</u>	<u>points awarded</u>
1013	87.5 – 100	20 pts
1014	75.0 – 87.4	15 pts
1015	62.5 – 74.9	10 pts
1016	50.0 – 61.9	5 pts
1017	less than 50.0	0 pts

1018

1019 Where an applicant proposes to close a hospital(s) as part of its application, data from the hospital(s) to
 1020 be closed shall be excluded from this calculation.

1021 (c) A qualifying project shall be awarded points as set forth in the following table in accordance with
 1022 its impact on inpatient capacity. If an applicant proposes to close a hospital(s), points shall only be
 1023 awarded if (i) closure of that hospital(s) does not create a bed need in any subareaHOSPITAL GROUP
 1024 as a result of its closing; (ii) the applicant stipulates that the hospital beds to be closed shall not be
 1025 transferred to another location or facility; and (iii) the utilization (as defined by the average daily census

1026 over the previous 24-month period prior to the date that the application is submitted) of the hospital to be
 1027 closed is at least equal to 50 percent of the size of the proposed hospital (as defined by the number of
 1028 proposed new licensed beds).

<u>Impact on Capacity</u>	<u>Points Awarded</u>
1030 Closure of hospital(s)	25 pts
1031 Closure of hospital(s)	
1032 which creates a bed need	-15 pts

1034
 1035 (d) A qualifying project will be awarded points based on the percentage of the applicant's historical
 1036 market share of inpatient discharges of the population in an area which will be defined as that area
 1037 circumscribed by the proposed hospital locations defined by all of the applicants in the comparative
 1038 review process under consideration. This area will include any zip code completely within the area as
 1039 well as any zip code which touches, or is touched by, the lines that define the area included within the
 1040 figure that is defined by the geometric area resulting from connecting the proposed locations. In the case
 1041 of two locations or one location or if the exercise in geometric definition does not include at least ten zip
 1042 codes, the market area will be defined by the zip codes within the county (or counties) that includes the
 1043 proposed site (or sites). Market share used for the calculation shall be the cumulative market share of
 1044 the population residing in the set of above-defined zip codes of all currently licensed Michigan hospitals
 1045 under common ownership or control with the applicant, which are in the same health service area.

<u>Percent</u>	<u>Points Awarded</u>
1047 % of market share	% of market share served x 30
1048	(total pts. awarded)

1049
 1050
 1051 The source for calculations under this criterion is the MIDB.

1052 **Section 14. Review standards for comparative review of a limited access area**

1053
 1054
 1055 Sec. 14. (1) Any application subject to comparative review, under Section 22229 of the Code, being
 1056 Section 333.22229 of the Michigan Compiled Laws, or under these standards, shall be grouped and
 1057 reviewed comparatively with other applications in accordance with the CON rules.

1058
 1059 (2) Each application in a comparative group shall be individually reviewed to determine whether the
 1060 application has satisfied all the requirements of Section 22225 of the Code, being Section 333.22225 of
 1061 the Michigan Compiled Laws and all other applicable requirements for approval in the Code and these
 1062 standards. If the Department determines that two or more competing applications satisfy all of the
 1063 requirements for approval, these projects shall be considered qualifying projects. The Department shall
 1064 approve those qualifying projects which, when taken together, do not exceed the need, as defined in
 1065 Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws, and which
 1066 have the highest number of points when the results of subsection (3) are totaled. If two or more
 1067 qualifying projects are determined to have an identical number of points, then the Department shall
 1068 approve those qualifying projects, when taken together, that do not exceed the need, as defined in
 1069 Section 22225(1) in the order in which the applications were received by the Department based on the
 1070 date and time stamp placed on the application by the Department when the application is filed.

1071
 1072 (3)(a) A qualifying project will be awarded points based on the percentile ranking of the applicant's
 1073 uncompensated care volume as measured by percentage of gross hospital revenues as set forth in the
 1074 following table. For purposes of scoring, the applicant's uncompensated care will be the cumulative of all
 1075 currently licensed Michigan hospitals under common ownership or control with the applicant. The source
 1076 document for the calculation shall be the most recent Cost Report submitted to MDCH for purposes of
 1077 calculating disproportionate share hospital payments. If a hospital under common ownership or control
 1078 with the applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

<u>Percentile Ranking</u>	<u>Points Awarded</u>
---------------------------	-----------------------

1081	90.0 – 100	25 pts
1082	80.0 – 89.9	20 pts
1083	70.0 – 79.9	15 pts
1084	60.0 – 69.9	10 pts
1085	50.0 – 59.9	5 pts

1086
1087 Where an applicant proposes to close a hospital as part of its application, data from the closed hospital
1088 shall be excluded from this calculation.

1089 (b) A qualifying project will be awarded points based on the statewide percentile rank of the
1090 applicant's Medicaid volume as measured by percentage of gross hospital revenues as set forth in the
1091 following table. For purposes of scoring, the applicant's Medicaid volume will be the cumulative of all
1092 currently licensed Michigan hospitals under common ownership or control with the applicant. The source
1093 documents for the calculation shall be the Cost Report submitted to MDCH for purposes of calculating
1094 disproportionate share hospital payments. If a hospital under common ownership or control with the
1095 applicant has not filed a Cost Report, then the related applicant shall receive a score of zero.

1096	<u>Percentile Rank</u>	<u>Points Awarded</u>
1097	87.5 – 100	20 pts
1098	75.0 – 87.4	15 pts
1099	62.5 – 74.9	10 pts
1100	50.0 – 61.9	5 pts
1101	Less than 50.0	0 pts

1102
1103
1104 Where an applicant proposes to close a hospital as part of its application, data from the closed hospital
1105 shall be excluded from this calculation.

1106 (c) A qualifying project shall be awarded points as set forth in the following table in accordance with
1107 its impact on inpatient capacity in the health service area of the proposed hospital site.

1108	<u>Impact on Capacity</u>	<u>Points Awarded</u>
1109	Closure of hospital(s)	15 pts
1110	Move beds	0 pts
1111	Adds beds (net)	-15 pts
1112	or	
1113	Closure of hospital(s)	
1114	or delicensure of beds	
1115	which creates a bed need	
1116	or	
1117	Closure of a hospital	
1118	which creates a new Limited Access Area	

1119
1120 (d) A qualifying project will be awarded points based on the percentage of the applicant's market
1121 share of inpatient discharges of the population in the limited access area as set forth in the following
1122 table. Market share used for the calculation shall be the cumulative market share of Michigan hospitals
1123 under common ownership or control with the applicant.

1124	<u>Percent</u>	<u>Points Awarded</u>
1125	% of market share	% of market share served x 15
1126		(total pts awarded)

1127
1128
1129 The source for calculations under this criterion is the MIDB.

1130 (e) A qualifying project will be awarded points based on the percentage of the limited access area's
1131 population within a 30 minute travel time of the proposed hospital site if in a metropolitan statistical area

1132 county, or within 60 minutes travel time if in a rural or micropolitan statistical area county as set forth in
 1133 the following table.

1134	<u>Percent</u>	<u>Points Awarded</u>
1135	% of population within	% of population
1136	30 (or 60) minute travel	covered x 15 (total pts
1137	time of proposed site	awarded)

1139
 1140 (f) All applicants will be ranked in order according to their total project costs as stated in the CON
 1141 application divided by its proposed number of beds in accordance with the following table.

1142	<u>Cost Per Bed</u>	<u>Points Awarded</u>
1143	Lowest cost	10 pts
1144	2nd Lowest cost	5 pts
1145	All other applicants	0 pts

1146 **Section 15. Documentation of market survey**

1147
 1148 ~~—Sec. 15. An applicant required to conduct a market survey under Section 3 shall specify how the~~
 1149 ~~market survey was developed. This specification shall include a description of the data source(s) used,~~
 1150 ~~assessments of the accuracy of these data, and the statistical method(s) used. Based on this~~
 1151 ~~documentation, the Department shall determine if the market survey is reasonable.~~

1152 **Section 4615. Requirements for approval -- acquisition of a hospital**

1153
 1154
 1155 Sec. 4615. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance
 1156 with the needed hospital bed supply ~~set forth in Appendix C~~ for the ~~subarea~~HOSPITAL GROUP in which
 1157 the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the
 1158 following are met:

- 1159 (a) the acquisition will not result in a change in bed capacity,
- 1160 (b) the licensed site does not change as a result of the acquisition,
- 1161 (c) the project is limited solely to the acquisition of a hospital with a valid license, and
- 1162 (d) if the application is to acquire a hospital, which was proposed in a prior application to be
 1163 established as a ~~N long-term (acute) care~~LTAC hospital (~~LTAC~~) and which received CON approval, the
 1164 applicant also must meet the requirements of Section 6(2). Those hospitals that received such prior
 1165 approval are so identified ~~in Appendix A~~ON THE DEPARTMENT INVENTORY OF BEDS.

1166
 1167 ~~(2) IN ORDER TO BE APPROVED, THE APPLICANT SHALL COMPLY WITH THE FOLLOWING~~
 1168 ~~REQUIREMENTS, AS APPLICABLE:~~

1169 ~~(A) THE EXISTING LICENSED HOSPITAL SHALL HAVE HAS OPERATED AT AN AVERAGE~~
 1170 ~~ADJUSTED OCCUPANCY RATE OF AT LEAST 40 PERCENT OR ABOVE FOR THE PREVIOUS~~
 1171 ~~CONSECUTIVE 36 MONTHS BASED ON ITS LICENSED AND APPROVED HOSPITAL BED~~
 1172 ~~CAPACITY. AVERAGE ADJUSTED OCCUPANCY SHALL BE CALCULATED AS FOLLOWS:~~

1173 ~~(I) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,~~
 1174 ~~CONSECUTIVE 36-MONTH PERIOD, AS OF THE DATE OF THE APPLICATION, FOR WHICH~~
 1175 ~~VERIFIABLE DATA ARE AVAILABLE TO THE DEPARTMENT.~~

1176 ~~(II) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (I) ABOVE BY 1095~~
 1177 ~~(OR 1096 IF INCLUDING A LEAP YEAR).~~

1178 ~~(B) IF THE EXISTING LICENSED HOSPITAL DOES NOT HAVE HAS OPERATED AT AN~~
 1179 ~~AVERAGE ADJUSTED OCCUPANCY RATE OF LESS THAN 40 PERCENT OR ABOVE FOR THE~~
 1180 ~~PREVIOUS CONSECUTIVE 36 MONTHS, AS CALCULATED IN (A) ABOVE, IN ORDER TO BE~~
 1181 ~~APPROVED, THE APPLICANT SHALL AGREE TO ALL OF THE FOLLOWING:~~

1182 ~~(I) THE HOSPITAL TO BE ACQUIRED WILL ACHIEVE AN ANNUAL ADJUSTED ANNUAL~~
 1183 ~~OCCUPANCY OF AT LEAST 40% DURING ANY CONSECUTIVE 12-MONTH PERIOD BY THE END~~

1186 OF THE THIRD YEAR OF OPERATION AFTER COMPLETION OF THE ACQUISITION.
 1187 AVERAGE ANNUAL ADJUSTED OCCUPANCY SHALL BE CALCULATED AS FOLLOWS:
 1188 (A) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,
 1189 CONSECUTIVE 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA ARE IS AVAILABLE TO THE
 1190 DEPARTMENT.
 1191 (B) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (A) ABOVE BY 365
 1192 (OR 366 IF A LEAP YEAR).
 1193 (C) IF THE HOSPITAL TO BE ACQUIRED DOES NOT ACHIEVE AN ANNUAL ADJUSTED
 1194 ANNUAL OCCUPANCY OF AT LEAST 40 PERCENT, AS CALCULATED IN (B) ABOVE, DURING ANY
 1195 CONSECUTIVE 12-MONTH PERIOD BY THE END OF THE THIRD YEAR OF OPERATION AFTER
 1196 COMPLETION OF THE ACQUISITION, THE APPLICANT SHALL RELINQUISH SUFFICIENT BEDS AT
 1197 THE EXISTING HOSPITAL TO RAISE ITS ADJUSTED OCCUPANCY TO 60 PERCENT. THE
 1198 REVISED NUMBER OF LICENSED BEDS AT THE HOSPITAL SHALL BE CALCULATED AS
 1199 FOLLOWS:
 1200 (I) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT,
 1201 CONSECUTIVE 12-MONTH PERIOD FOR WHICH WHERE VERIFIABLE DATA ARE IS AVAILABLE TO
 1202 THE DEPARTMENT, AND DIVIDE BY .60.
 1203 (II) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN RESULT OF
 1204 SUBSECTION (I) ABOVE BY 365 (OR 366 IF THE 12-MONTH PERIOD INCLUDES A LEAP YEAR)
 1205 AND ROUND UP TO THE NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE
 1206 MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED HOSPITAL
 1207 SITE AFTER ACQUISITION. 60 TO DETERMINE LICENSED BED DAYS AT 60 PERCENT
 1208 OCCUPANCY.
 1209 (III) DIVIDE THE RESULT OF STEP SUBSECTION (II) ABOVE BY 365 (OR 366 IF A LEAP YEAR)
 1210 AND ROUND THE RESULT UP TO THE NEXT WHOLE NUMBER. THIS IS THE MAXIMUM NUMBER
 1211 OF LICENSED BEDS. THE NUMBER OF LICENSED BEDS PERMITTED FOR THE LICENSED
 1212 HOSPITAL SHALL BE THE MAXIMUM NUMBER OF LICENSED BEDS, OR 25, WHICHEVER IS
 1213 LARGER.
 1214 (D) SUBSECTION (2) SHALL NOT APPLY TO EXCLUDED HOSPITALS.

1215
 1216 **Section 4716. Requirements for approval – all applicants**

1217
 1218 Sec. 4716. (1) An applicant shall provide verification of Medicaid participation. An applicant that is a
 1219 new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be
 1220 provided to the Department within six (6) months from the offering of services if a CON is approved.
 1221

1222 (2) THE APPLICANT CERTIFIES ALL OUTSTANDING DEBT OBLIGATIONS OWED TO THE
 1223 STATE OF MICHIGAN FOR QUALITY ASSURANCE ASSESSMENT PROGRAM (QAAP) OR CIVIL
 1224 MONETARY PENALTIES (CMP) HAVE BEEN PAID IN FULL.
 1225

1226 (3) THE APPLICANT CERTIFIES THAT THE HEALTH FACILITY FOR THE PROPOSED PROJECT
 1227 HAS NOT BEEN CITED FOR A STATE OR FEDERAL CODE DEFICIENCY WITHIN THE 12 MONTHS
 1228 PRIOR TO THE SUBMISSION OF THE APPLICATION. IF A STATE CODE DEFICIENCY HAS BEEN
 1229 ISSUED, THE APPLICANT SHALL CERTIFY THAT A PLAN OF CORRECTION FOR CITED STATE
 1230 DEFICIENCIES AT THE HEALTH FACILITY HAS BEEN SUBMITTED AND APPROVED BY THE
 1231 BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT OF LICENSING AND REGULATORY
 1232 AFFAIRS. IF A FEDERAL CODE DEFICIENCY HAS BEEN ISSUED, THE APPLICANT SHALL
 1233 CERTIFY THAT A PLAN OF CORRECTION FOR CITED FEDERAL DEFICIENCIES AT THE HEALTH
 1234 FACILITY HAS BEEN SUBMITTED AND APPROVED BY THE CENTERS FOR MEDICARE AND
 1235 MEDICAID SERVICES. IF CODE DEFICIENCIES INCLUDE ANY UNRESOLVED DEFICIENCIES
 1236 STILL OUTSTANDING WITH THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS OR
 1237 THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THAT ARE THE BASIS FOR THE
 1238 DENIAL, SUSPENSION, OR REVOCATION OF AN APPLICANT'S HEALTH FACILITY LICENSE,
 1239 POSES AN IMMEDIATE JEOPARDY TO THE HEALTH AND SAFETY OF PATIENTS, OR MEETS A
 1240 FEDERAL CONDITIONAL DEFICIENCY LEVEL, THE PROPOSED PROJECT CANNOT BE

1241 | APPROVED WITHOUT APPROVAL FROM THE BUREAU OF HEALTH SYSTEMS OR, IF
1242 | APPLICABLE, THE CENTERS FOR MEDICARE AND MEDICAID SERVICES.

APPENDIX A

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Section 18. Health service areas

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

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

**CON REVIEW STANDARDS
 FOR HOSPITAL BEDS**

HOSPITAL SUBAREA ASSIGNMENTS
 Revised 11/19/08

Health

Service — Sub

Area — Area — Hospital Name — City

1 - Southeast

1A	North Oakland Med Center (Fac #63-0110)	Pontiac
1A	Pontiac Osteopathic Hospital (Fac #63-0120)	Pontiac
1A	St. Joseph Mercy — Oakland (Fac #63-0140)	Pontiac
1A	Select Specialty Hospital — Pontiac (LTAC — Fac #63-0172)*	Pontiac
1A	Crittenton Hospital (Fac #63-0070)	Rochester
1A	Huron Valley — Sinai Hospital (Fac #63-0014)	Commerce Township
1A	Wm Beaumont Hospital (Fac #63-0030)	Royal Oak
1A	Wm Beaumont Hospital — Troy (Fac #63-0160)	Troy
1A	Providence Hospital & Medical Center (Fac #63-0130)	Southfield
1A	Oakland Regional Hospital (Fac #63-0013)	Southfield
1A	Straith Hospital for Special Surg (Fac #63-0150)	Southfield
1A	MI Orthopaedic Specialty Hospital (Fac #63-0060)	Madison Heights
1A	St. John Macomb — Oakland Hospital — Oakland (Fac #63-0080)	Madison Heights
1A	Southeast Michigan Surgical Hospital (Fac #50-0100)	Warren
1A	Henry Ford West Bloomfield Hospital (Fac #63-0176)	West Bloomfield
1A	Providence Med Ctr-Providence Park (Fac #63-0177)	Novi
1B	Henry Ford Bi-County Hospital (Fac #50-0020)	Warren
1B	St. John Macomb — Oakland Hospital — Macomb (fac #50-0070)	Warren
1C	Oakwood Hospital and Medical Center (Fac #82-0120)	Dearborn
1C	Garden City Hospital (Fac #82-0070)	Garden City
1C	Henry Ford — Wyandotte Hospital (Fac #82-0230)	Wyandotte
1C	Select Specialty Hosp — Downriver (LTAC — Fac #82-0272)*	Wyandotte
1C	Oakwood Annapolis Hospital (Fac #82-0010)	Wayne
1C	Oakwood Heritage Hospital (Fac #82-0250)	Taylor
1C	Riverside Osteopathic Hospital (Fac #82-0160)	Trenton
1C	Oakwood Southshore Medical Center (Fac #82-0170)	Trenton
1C	Vibra of Southeastern Michigan (Fac #82-0130)	Lincoln Park
1D	Sinai-Grace Hospital (Fac #83-0450)	Detroit
1D	Rehabilitation Institute of Michigan (Fac #83-0410)	Detroit
1D	Harper University Hospital (Fac #83-0220)	Detroit
1D	Henry Ford Hospital (Fac #83-0190)	Detroit
1D	St. John Hospital & Medical Center (Fac #83-0420)	Detroit
1D	Children's Hospital of Michigan (Fac #83-0080)	Detroit
1D	Detroit Receiving Hospital & Univ Hlth (Fac #83-0500)	Detroit
1D	Karmanos Cancer Center (Fac #83-0520)	Detroit
1D	Triumph Hospital Detroit (LTAC - Fac #83-0521)*	Detroit
1D	Detroit Hope Hospital (Fac #83-0390)	Detroit

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

APPENDIX A (continued)

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Health**Service Sub****Area Area Hospital Name City****1--Southeast (continued)**

	1D	Hutzel Women's Hospital (Fac #83-0240)	Detroit
	1D	Select Specialty Hosp - NW Detroit (LTAC - Fac #83-0523)*	Detroit
	1D	Beaumont Hospital, Grosse Pointe (Fac #82-0030)	Grosse Pointe
	1D	Henry Ford Cottage Hospital (Fac #82-0040)	Grosse Pointe Farm
	1D	Select Specialty Hospital - Grosse Pointe (LTAC - Fac #82-0276)*	Grosse Pointe
	1E	Botsford Hospital (Fac #63-0050)	Farmington Hills
	1E	St. Mary Mercy Hospital (Fac #82-0190)	Livonia
	1F	Mount Clemens Regional Medical Center (Fac #50-0060)	Mt. Clemens
	1F	Select Specialty Hosp - Macomb Co. (Fac #50-0111)*	Mt. Clemens
	1F	St. John North Shores Hospital (Fac #50-0030)	Harrison Twp.
	1F	Henry Ford Macomb Hospital (Fac #50-0110)	Clinton Township
	1F	Henry Ford Macomb Hospital - Mt. Clemens (Fac #50-0080)	Mt. Clemens
	1G	Mercy Hospital (Fac #74-0010)	Port Huron
	1G	Port Huron Hospital (Fac #74-0020)	Port Huron
	1H	St. Joseph Mercy Hospital (Fac #81-0030)	Ann Arbor
	1H	University of Michigan Health System (Fac #81-0060)	Ann Arbor
	1H	Select Specialty Hosp - Ann Arbor (LTAC - Fac #81-0081)*	Ypsilanti
	1H	Chelsea Community Hospital (Fac #81-0080)	Chelsea
	1H	Saint Joseph Mercy Livingston Hosp (Fac #47-0020)	Howell
	1H	Saint Joseph Mercy Saline Hospital (Fac #81-0040)	Saline
	1H	Forest Health Medical Center (Fac #81-0010)	Ypsilanti
	1H	Brighton Hospital (Fac #47-0010)	Brighton
	1I	St. John River District Hospital (Fac #74-0030)	East China
	1J	Mercy Memorial Hospital System (Fac #58-0030)	Monroe

2--Mid-Southern

	2A	Clinton Memorial Hospital (Fac #19-0010)	St. Johns
	2A	Eaton Rapids Medical Center (Fac #23-0010)	Eaton Rapids
	2A	Hayes Green Beach Memorial Hosp (Fac #23-0020)	Charlotte
	2A	Ingham Regional Medical Center (Greenlawn) (Fac #33-0020)	Lansing
	2A	Ingham Regional Orthopedic Hospital (Fac #33-0010)	Lansing
	2A	Edward W. Sparrow Hospital (Fac #33-0060)	Lansing
	2A	Sparrow Health System - St. Lawrence Campus (Fac #33-0050)	Lansing
	2A	Sparrow Specialty Hospital (LTAC - FAC #33-0061)*	Lansing
	2B	Carelink of Jackson (LTAC Fac #38-0030)*	Jackson
	2B	Allegiance Health (Fac #38-0010)	Jackson

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

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Health**Service — Sub**

Area — Area — Hospital Name — City

2— Mid-Southern (continued)

2C Hillsdale Community Health Center (Fac #30-0010) Hillsdale
2D Emma L. Bixby Medical Center (Fac #46-0020) Adrian
2D Herrick Memorial Hospital (Fac #46-0052) Tecumseh

3— Southwest

3A Borgess Medical Center (Fac #39-0010) Kalamazoo
3A Bronson Methodist Hospital (Fac #39-0020) Kalamazoo
3A Borgess-Pipp Health Center (Fac #03-0031) Plainwell
3A Bronson Lakeview Hospital (Fac #80-0030) Paw Paw
3A Bronson Vicksburg Hospital (Fac #39-0030) Vicksburg
3A Pennock Hospital (Fac #08-0010) Hastings
3A Three Rivers Health (Fac #75-0020) Three Rivers
3A Sturgis Hospital (Fac #75-0010) Sturgis
3A Select Specialty Hospital — Kalamazoo (LTAC - Fac #39-0032)* Kalamazoo
3B Battle Creek Health System (Fac #13-0031) Battle Creek
3B SW Regional Rehabilitation Center (Fac #13-0100) Battle Creek
3B Oaklawn Hospital (Fac #13-0080) Marshall
3C Community Hospital (Fac #11-0040) Watervliet
3C Lakeland Hospital, St. Joseph (Fac #11-0050) St. Joseph
3C Lakeland Specialty Hospital (LTAC - Fac #11-0080)* Berrien Center
3C South Haven Community Hospital (Fac #80-0020) South Haven
3D Lakeland Hospital, Niles (Fac #11-0070) Niles
3D Borgess-Lee Memorial Hospital (A) (Fac #14-0010) Dowagiac
3E Community Health Center of Branch County (Fac #12-0010) Coldwater

4— WEST

4A Memorial Medical Center of West MI (Fac #53-0010) Ludington
4B Spectrum Health United Memorial — Kelsey (A) (Fac #59-0050) Lakeview
4B Mecosta County Medical Center (Fac #54-0030) Big Rapids
4C Spectrum Health-Reed City Campus (Fac #67-0020) Reed City
4D Lakeshore Community Hospital (Fac #64-0020) Shelby
4E Gerber Memorial Hospital (Fac #62-0010) Fremont

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

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

1455				1456
1457	Health			1458
1458	Service	Sub		
1459	Area	Area	Hospital Name	City
1460	=====			
1461	4--West (continued)			
1462				
1463	4F		Carson City Hospital (Fac #59-0010)	Carson City
1464	4F		Gratiot Medical Center (Fac #29-0010)	Alma
1465				
1466	4G		Hackley Hospital (Fac #61-0010)	Muskegon
1467	4G		Mercy General Health Partners (Sherman) (Fac #61-0020)	Muskegon
1468	4G		Mercy General Health Partners (Oak) (Fac #61-0030)	Muskegon
1469	4G		Lifecare Hospitals of Western MI (LTAC - Fac #61-0052)*	Muskegon
1470	4G		Select Specialty Hospital - Western MI (LTAC - Fac #61-0051)*	Muskegon
1471	4G		North Ottawa Community Hospital (Fac #70-0010)	Grand Haven
1472				
1473	4H		Spectrum Health - Blodgett Campus (Fac #41-0010)	E. Grand Rapids
1474	4H		Spectrum Health Hospitals (Fac #41-0040)	Grand Rapids
1475	4H		Spectrum Health - Kent Community Campus (Fac #41-0090)	Grand Rapids
1476	4H		Mary Free Bed Hospital & Rehab Ctr (Fac #41-0070)	Grand Rapids
1477	4H		Metro Health Hospital (Fac #41-0060)	Wyoming
1478	4H		Saint Mary's Health Care (Fac #41-0080)	Grand Rapids
1479				
1480	4I		Sheridan Community Hospital (A) (Fac #59-0030)	Sheridan
1481	4I		Spectrum Health United Memorial - United Campus (Fac #59-0060)	Greenville
1482				
1483	4J		Holland Community Hospital (Fac #70-0020)	Holland
1484	4J		Zeeland Community Hospital (Fac #70-0030)	Zeeland
1485				
1486	4K		Ionia County Memorial Hospital (A) (Fac #34-0020)	Ionia
1487				
1488	4L		Allegan General Hospital (A) (Fac #03-0010)	Allegan
1489				
1490	5--GLS			
1491				
1492	5A		Memorial Healthcare (Fac #78-0010)	Owosso
1493				
1494	5B		Genesys Regional Medical Center - Health Park (Fac #25-0072)	Grand Blanc
1495	5B		Hurley Medical Center (Fac #25-0040)	Flint
1496	5B		Mclaren Regional Medical Center (Fac #25-0050)	Flint
1497	5B		Select Specialty Hospital-Flint (LTAC - Fac #25-0071)*	Flint
1498				
1499	5C		Lapeer Regional Medical Center (Fac #44-0010)	Lapeer
1500				
1501	6--East			
1502				
1503	6A		West Branch Regional Medical Center (Fac #65-0010)	West Branch
1504	6A		Tawas St. Joseph Hospital (Fac #35-0010)	Tawas City
1505				
1506	6B		Central Michigan Community Hospital (Fac #37-0010)	Mt. Pleasant
1507				
1508	*This is a hospital that must meet the requirement(s) of Section 16(1)(d) - LTAC.			
1509				
1510	(A) This is a hospital that has state/federal critical access hospital designation.			

1511	Health				
1512	Service	Sub			
1513	Area	Area	Hospital Name		City
1514	=====				
1515	6--East (continued)				
1516					
1517					
1518					
1519		6C	MidMichigan Medical Center - Clare (Fac #18-0010)		Clare
1520					
1521		6D	Mid-Michigan Medical Center - Gladwin (A) (Fac #26-0010)		Gladwin
1522		6D	Mid-Michigan Medical Center - Midland (Fac #56-0020)		Midland
1523					
1524		6E	Bay Regional Medical Center (Fac #09-0050)		Bay City
1525		6E	Bay Regional Medical Center - West (Fac #09-0020)		Bay City
1526		6E	Bay Special Care (LTAC - Fac #09-0010)*		Bay City
1527		6E	St. Mary's Standish Community Hospital (A) (Fac #06-0020)		Standish
1528					
1529		6F	Select Specialty Hospital - Saginaw (LTAC - Fac #73-0062)*		Saginaw
1530		6F	Covenant Medical Center - Cooper (Fac #73-0040)		Saginaw
1531		6F	Covenant Medical Center - N Michigan (Fac #73-0030)		Saginaw
1532		6F	Covenant Medical Center - N Harrison (Fac #73-0020)		Saginaw
1533		6F	Healthsource Saginaw (Fac #73-0060)		Saginaw
1534		6F	St. Mary's of Michigan Medical Center (Fac #73-0050)		Saginaw
1535		6F	Care Community Hospital (Fac #79-0010)		Care
1536		6F	Hills and Dales General Hospital (Fac #79-0030)		Cass City
1537					
1538		6G	Harbor Beach Community Hospital (A) (Fac #32-0040)		Harbor Beach
1539		6G	Huron Medical Center (Fac #32-0020)		Bad Axe
1540		6G	Scheurer Hospital (A) (Fac #32-0030)		Pigeon
1541					
1542		6H	Deckerville Community Hospital (A) (Fac #76-0010)		Deckerville
1543		6H	Mckenzie Memorial Hospital (A) (Fac #76-0030)		Sandusky
1544					
1545		6I	Marlette Regional Hospital (Fac #76-0040)		Marlette
1546					
1547					
1548					
1549		7A	Cheboygan Memorial Hospital (Fac #16-0020)		Cheboygan
1550					
1551		7B	Charlevoix Area Hospital (Fac #15-0020)		Charlevoix
1552		7B	Mackinac Straits Hospital (A) (Fac #49-0030)		St. Ignace
1553		7B	Northern Michigan Hospital (Fac #24-0030)		Petoskey
1554					
1555		7C	Rogers City Rehabilitation Hospital (Fac #71-0030)		Rogers City
1556					
1557		7D	Otsego Memorial Hospital (Fac #69-0020)		Gaylord
1558					
1559		7E	Alpena General Hospital (Fac #04-0010)		Alpena
1560					
1561		7F	Kalkaska Memorial Health Center (A) (Fac #40-0020)		Kalkaska
1562					
1563					
1564					
1565					

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

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

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Health

Service Sub

Area Area Hospital Name City

7- Northern Lower (continued)

7F	Munson Medical Center (Fac #28-0010)	Traverse City
7F	Paul Oliver Memorial Hospital (A) (Fac #10-0020)	Frankfort
7G	Mercy Hospital - Cadillac (Fac #84-0010)	Cadillac
7H	Mercy Hospital - Grayling (Fac #20-0020)	Grayling
7I	West Shore Medical Center (Fac #51-0020)	Manistee

8- Upper Peninsula

8A	Grand View Hospital (Fac #27-0020)	Ironwood
8B	Aspirus Ontonagon Hospital, Inc. (A) (Fac #66-0020)	Ontonagon
8C	Iron County Community Hospital (Fac #36-0020)	Iron River
8D	Baraga County Memorial Hospital (A) (Fac #07-0020)	L'anse
8E	Keweenaw Memorial Medical Center (Fac #31-0010)	Laurium
8E	Portage Health Hospital (Fac #31-0020)	Hancock
8F	Dickinson County Memorial Hospital (Fac #22-0020)	Iron Mountain
8G	Bell Memorial Hospital (Fac #52-0010)	Ishpeming
8G	Marquette General Hospital (Fac #52-0050)	Marquette
8H	St. Francis Hospital (Fac #21-0010)	Escanaba
8I	Munising Memorial Hospital (A) (Fac #02-0010)	Munising
8J	Schoolcraft Memorial Hospital (A) (Fac #77-0010)	Manistique
8K	Helen Newberry Joy Hospital (A) (Fac #48-0020)	Newberry
8L	Chippewa County War Memorial Hospital (Fac #17-0020)	Sault Ste Marie

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

APPENDIX B

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**CON REVIEW STANDARDS
 FOR HOSPITAL BEDS**

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

**CON REVIEW STANDARDS
FOR HOSPITAL BEDS**

The hospital bed need for purposes of these standards, effective March 2, 2009, and until otherwise changed by the Commission are as follows:

Health Service Area	SA No.	Bed Need
1 - SOUTHEAST		
	1A	2946
	1B	480
	1C	1481
	1D	2979
	1E	495
	1F	700
	1G	267
	1H	1648
	1I	53
	1J	177
2 - MID-SOUTHERN		
	2A	889
	2B	306
	2C	59
	2D	117
3 - SOUTHWEST		
	3A	890
	3B	281
	3C	282
	3D	89
	3E	71
4 - WEST		
	4A	65
	4B	52
	4C	19
	4D	13
	4E	38
	4F	133
	4G	373
	4H	1400
	4I	48
	4J	157
	4K	18
	4L	30
5 - GLS		
	5A	78
	5B	1163
	5C	109

1726	Health	SA	Bed
1727	Service	No.	Need
1728	Area		
1729	6 - EAST		
1730		6A	96
1731		6B	62
1732		6C	42
1733		6D	184
1734		6E	324
1735		6F	820
1736		6G	48
1737		6H	16
1738		6I	22
1739			
1740	7 - NORTHERN LOWER		
1741		7A	38
1742		7B	200
1743		7C	19
1744		7D	35
1745		7E	102
1746		7F	392
1747		7G	64
1748		7H	59
1749		7I	36
1750			
1751	8 - UPPER PENINSULA		
1752		8A	30
1753		8B	12
1754		8C	22
1755		8D	12
1756		8E	54
1757		8F	93
1758		8G	226
1759		8H	53
1760		8I	7
1761		8J	9
1762		8K	14
1763		8L	54
1764			
1765			
1766			
1767			

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OCCUPANCY RATE TABLE

Adult Medical/Surgical			Pediatric Beds						
HOSPITAL GROUP PROJECTED BED ADC		Occup	ADJUSTED Beds/Bed RANGE		ADC >	ADC =	Occu p	Beds	
ADC >= LOW	ADC < HIGH		Start BES L OW	Stop BED S HIGH				Start p	Sto p <=5
<u>30</u>	<u>3031</u>	0.60%	<u>50</u>	<u><=5052</u>		30	0.50		0
<u>3432</u>	<u>3235</u>	0.6061%	<u>5253</u>	<u>5258</u>	30	33	0.50	61	66
<u>3236</u>	<u>3439</u>	0.6162%	<u>5359</u>	<u>5653</u>	34	40	0.51	67	79
<u>3540</u>	<u>3745</u>	0.6263%	<u>5764</u>	<u>6072</u>	41	46	0.52	80	88
<u>3846</u>	<u>4150</u>	0.6364%	<u>6172</u>	<u>6579</u>	47	53	0.53	89	100
<u>4251</u>	<u>4658</u>	0.6465%	<u>6679</u>	<u>7290</u>	54	60	0.54	101	111
<u>4759</u>	<u>5067</u>	0.6566%	<u>7390</u>	<u>77102</u>	61	67	0.55	112	121
<u>5468</u>	<u>5677</u>	0.6667%	<u>78102</u>	<u>85115</u>	68	74	0.56	122	131
<u>5778</u>	<u>6388</u>	0.6768%	<u>86115</u>	<u>94130</u>	75	80	0.57	132	139
<u>6489</u>	<u>70101</u>	0.6869%	<u>95129</u>	<u>103147</u>	81	87	0.58	140	149
<u>74102</u>	<u>79117</u>	0.6970%	<u>104146</u>	<u>114168</u>	88	94	0.59	150	158
<u>80118</u>	<u>89134</u>	0.7071%	<u>115167</u>	<u>126189</u>	95	101	0.60	159	167
<u>90135</u>	<u>100154</u>	0.7172%	<u>127188</u>	<u>140214</u>	102	108	0.61	168	175
<u>104155</u>	<u>114176</u>	0.7273%	<u>141213</u>	<u>157242</u>	109	114	0.62	176	182
<u>115177</u>	<u>130204</u>	0.7374%	<u>158240</u>	<u>177276</u>	115	121	0.63	183	190
<u>134205</u>	<u>149258</u>	0.7475%	<u>178274</u>	<u>200344</u>	122	128	0.64	191	198
<u>150259</u>	<u>172327</u>	0.7576%	<u>201341</u>	<u>227431</u>	129	135	0.65	199	206
<u>173328</u>	<u>200424</u>	0.7677%	<u>228426</u>	<u>261551</u>	136	142	0.66	207	213
<u>204425</u>	<u>234561</u>	0.7778%	<u>262545</u>	<u>301720</u>	143	149	0.67	214	220
<u>235562</u>	<u>276760</u>	0.7879%	<u>302712</u>	<u>350963</u>	150	155	0.68	221	226
<u>277761</u>	<u>327895</u>	0.7980%	<u>351952</u>	<u>4101119</u>	156	162	0.69	227	232
328	391	0.80	411	484	163	169	0.70	233	239
392	473	0.81	485	578	170	176	0.71	240	245
474	577	0.82	579	696	177	183	0.72	246	252
578	713	0.83	697	850	184	189	0.73	253	256
714	894	0.84	851	894	190	196	0.74	257	262
895		0.85	>=1054		197		0.75	>=26 3	
Obstetric Beds			Obstetric Beds cont.						
ADC >	ADC <=	Occup	Start	Stop	ADC >	ADC =	Occu p	Start p	Sto p
	30	0.50		<=50	115	121	0.63	183	190
30	33	0.50	61	66	122	128	0.64	191	198
34	40	0.51	67	79	129	135	0.65	199	206
41	46	0.52	80	88	136	142	0.66	207	213
47	53	0.53	89	100	143	149	0.67	214	220
54	60	0.54	101	111	150	155	0.68	221	226
61	67	0.55	112	121	156	162	0.69	227	232
68	74	0.56	122	131	163	169	0.70	233	239
75	80	0.57	132	139	170	176	0.71	240	245
81	87	0.58	140	149	177	183	0.72	246	252
88	94	0.59	150	158	184	189	0.73	253	256

1771

95	101	0.60	159	167	190	196	0.71	257	262
102	108	0.61	168	175	197			>=26	
109	114	0.62	176	182			0.75	3	

Attachment D

LIMITED ACCESS AREAS

1772 |
 1773 |
 1774 |
 1775 | Limited access areas and the hospital bed need, effective ~~March 2, 2009~~ **(INSERT EFFECTIVE DATE)**,
 1776 | for each of those areas are identified below. The hospital bed need for limited access areas shall be
 1777 | changed by the department in accordance with section 2(1)(~~vv~~) of these standards, and this appendix
 1778 | shall be updated accordingly.

HEALTH SERVICE AREA	LIMITED ACCESS AREA	BED NEED	POPULATION FOR PLANNING YEAR
7	Alpena/Plus 0808	358	66,946
8	Upper Peninsula 0808	415	135,215

1787 |
 1788 |
 1789 |
 1790 |
 1791 | (NEEDS TO BE UPDATED WHEN BED NEED IS RUN.)

Sources:

- 1792 |
 1793 |
 1794 |
 1795 | 1) Michigan State University
 1796 | Department of Geography
 1797 | Hospital Site Selection Final Report
 1798 | November 3, 2004, as amended
 1799 |
 1800 | 2) Section 4 of these standards
 1801 |
 1802 | 3) Michigan State University
 1803 | Department of Geography
 1804 | 2011 Planning Year Hospital Bed Need Calculations
 1805 | August 28, 2008

1806 |
 1807 | (SOURCES MAY NEED UPDATING)

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

~~(By authority conferred on the CON Commission by sections 22215 and 22217 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 333.2217, 24.207, and 24.208 of the Michigan Compiled Laws.)~~

Section 1. Applicability; definitions

~~—Sec. 1. (1) This addendum supplements the CON Review Standards for Hospital Beds and may be used for determining the need for projects established to meet the needs of HIV infected individuals.~~

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

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

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

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

Section 2. Requirements for approval; change in bed capacity

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

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

~~—(3) In order to be approved under this addendum, an applicant shall demonstrate all of the following:~~

~~—(a) The Director of the Department has determined that action is necessary and appropriate to meet the needs of HIV infected individuals for quality, accessible and efficient health care.~~

~~—(b) The hospital will provide services only to HIV infected individuals.~~

~~—(c) The applicant has obtained an obligation, enforceable by the Department, from existing licensed hospital(s) in any subarea of this state to voluntarily delicense a number of hospital beds equal to the number proposed in the application. The effective date of the delicensure action will be the date the beds approved pursuant to this addendum are licensed. The beds delicensed shall not be beds already subject to delicensure under a bed reduction plan.~~

~~—(d) The application does not result in more than 20 beds approved under this addendum in the State.~~

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

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

1866 | ~~—Sec. 3. (1) An applicant shall agree that, if approved, the services provided by the beds for HIV~~
1867 | ~~infected individuals shall be delivered in compliance with the following terms of CON approval:~~
1868 | ~~—(a) The license to operate the hospital will be limited to serving the needs of patients with the clinical~~
1869 | ~~spectrum of HIV infection and any other limitations established by the Department to meet the purposes~~
1870 | ~~of this addendum.~~
1871 | ~~—(b) The hospital shall be subject to the general license requirements of Part 215 of the Code except~~
1872 | ~~as waived by the Department to meet the purposes of this addendum.~~
1873 | ~~—(c) The applicant agrees that the Department shall revoke the license of the hospital if the hospital~~
1874 | ~~provides services to inpatients other than HIV infected individuals.~~

1875 |
1876 | **Section 4. Comparative reviews**

1877 |
1878 | ~~Sec. 4. (1) Projects proposed under Section 3 shall be subject to comparative review.~~

DakLawn

Amend Section 2(1)(m) to read as follows:

(m) "EXCLUDED HOSPITALS" MEANS HOSPITALS IN THE FOLLOWING CATEGORIES:

(I) CRITICAL ACCESS HOSPITALS DESIGNATED BY CMS PURSUANT TO 42 CFR 485.606

(II) HOSPITALS LOCATED IN RURAL OR MICROPOLITAN STATISTICAL AREA COUNTIES

(III) LTAC HOSPITALS

(IV) SOLE COMMUNITY HOSPITALS DESIGNATED BY CMS PURSUANT TO 42 CFR 412.92

(V) HOSPITALS WITH 25 OR FEWER LICENSED BEDS

(VI) HOSPITALS LOCATED IN A COUNTY WITH A POPULATION OF LESS THAN 200,000 AND NO OTHER HOSPITAL WITH AT LEAST 100 BEDS LOCATED WITHIN 10 MILES.

Jane's attachment

Amend Section 6(3)(b) [Lines 623-626] to read as follows:

(b) WHERE THE SOURCE HOSPITAL WAS SUBJECT TO SECTION 8(3)(B) THE RECEIVING HOSPITAL SHALL HAVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE.

Amend Section 6(3)(c) [Lines 627-630] to read as follows:

(C) WHERE THE SOURCE HOSPITAL WAS SUBJECT TO SECTION 8(3)(B) THE ADDITION OF THE PROPOSED NEW HOSPITAL BEDS AT THE RECEIVING HOSPITAL SHALL NOT EXCEED THE NUMBER DETERMINED BY THE FOLLOWING CALCULATION:

Amend Section 6(3)(d) [Lines 648-652] to read as follows:

(D) WHERE THE SOURCE HOSPITAL WAS SUBJECT TO SECTION 8(3)(B) THE RECEIVING HOSPITAL'S AVERAGE ADJUSTED OCCUPANCY RATE MUST NOT BE LESS THAN 40 PERCENT AFTER THE ADDITION OF THE PROPOSED NEW HOSPITAL BEDS.

Amend Section 8(3)(b) [Lines 820-826] to read as follows:

(B) IF THE SOURCE HOSPITAL DOES NOT HAVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE, THEN THE SOURCE HOSPITAL SHALL REDUCE THE APPROPRIATE NUMBER OF LICENSED BEDS TO ACHIEVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 60 PERCENT OR ABOVE UPON COMPLETION OF THE RELOCATION(S). THE SOURCE HOSPITAL SHALL NOT EXCEED THE NUMBER OF BEDS CALCULATED AS FOLLOWS:

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS

FOR HEART/LUNG AND LIVER (HLL) 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 HLL services under Part 222 of the Code. ~~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.~~ Pursuant to Part 222 of the Code, heart/lung and liver transplantation 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) 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.~~

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.~~

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

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

~~(eD)~~ "Health service area" or "HSA" means the geographic area set forth in Section 9APPENDIX A.

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

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

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

~~(iG)~~ "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.

~~(jH)~~ "Organ Procurement Organization" or "OPO" means an organ procurement organization as defined by CFR Title 42, Part 485.302.

~~(kI)~~ "Pediatric" means any patient less than 15 years of age or any patient with congenital anomalies related to the proposed transplantation service.

~~(L)~~ "Planning area" means the state of Michigan.

~~(m) "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.~~

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

73 |
 74 | (2) The definitions of Part 222 shall apply to these standards.
 75 |

76 | **Section 3. Requirements for all applicants TO INITIATE A HEART, HEART/LUNG OR LIVER**
 77 | **TRANSPLANTATION SERVICE**
 78 |

79 | **Sec. 3. ~~(1)~~ Initiate or implement means the performance of the first transplant procedure. The term of**
 80 | **an approved CON shall be 18 months or the extended period established by Rule 325.9403(2).**
 81 |

82 | **(1) An applicant proposing to INITIATE perform either a heart, heart/lung, lung or liver transplantation**
 83 | **service shall demonstrate that it offers all of the following services or programsSPECIALTIES:**

- 84 | (a) operating rooms;
 85 | (b) anesthesiology;
 86 | (c) microbiology and virology laboratory;
 87 | (d) continuous availability, either on-site or on-call, of:
 88 | (i) diagnostic imaging services including CT scanning; magnetic resonance imaging; and nuclear
 89 | medicine; and
 90 | (ii) a broad range of sub-specialty consultants, adult and pediatric, as appropriate, in both medical
 91 | and surgical specialties including but not limited to: pulmonary medicine with respiratory therapy support;
 92 | cardiology; gastroenterology; pediatrics, as appropriate; nephrology; and immunology.
 93 | (e) dialysis;
 94 | (f) infectious disease;
 95 | (g) inpatient-outpatient social work;
 96 | (h) inpatient-outpatient psychiatry/psychology;
 97 | (i) clinical research;
 98 | (j) a histocompatibility laboratory that meets the standards of the American Society for
 99 | Histocompatibility and Immunogenetics or an equivalent organization that is an approved member of the
 100 | OPTN, either on-site or through written agreement;
 101 | (k) other support services, as necessary, such as physical therapy and rehabilitation medicine;
 102 | (l) continuous availability of anatomic and clinical pathology and laboratory services including
 103 | clinical chemistry, immuno-suppressive drug monitoring and tissue typing;
 104 | (m) continuous availability of red cells, platelets, and other blood components;
 105 | (n) an established organ donation protocol, with brain death protocol, consistent with applicable
 106 | Michigan law; and
 107 | (o) a written transplant agreement with Michigan's federally designated OPO to promote organ
 108 | donation at the applicant hospital(s).

109
110 | (2) An applicant ~~PROPOSING TO INITIATE must~~ **SHALL** provide an implementation plan for the
111 proposed transplantation service. Implementation plan means a plan that documents how a proposed
112 transplantation service will be initiated within the **SPECIFIED** time period ~~specified in these standards or~~
113 ~~the CON Rules. AS APPLICABLE TO THE PROPOSED PROJECT. At a minimum, the The~~
114 implementation plan shall identify:

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

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

120 | (c) ~~if the applicant SHALL DOCUMENT what changes have or will be made to ensure that the~~
121 ~~proposed service can be initiated and provided on a regular basis, IF previously has been PREVIOUSLY~~
122 approved for a transplantation service for which either the CON expired or the service did not perform a
123 transplant procedure during any consecutive 12-month period, ~~what changes have or will be made to~~
124 ~~ensure that the proposed service can be initiated and provided on a regular basis.~~
125

126 | ~~(3) An application APPLICANT(S) which proposes~~ **PROPOSING TO INITIATE** a joint sharing
127 arrangement for a transplantation service ~~which THAT~~ involves more than one licensed site shall
128 demonstrate all of the following:

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

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

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

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

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

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

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

145 (v) the applicant shall agree that the two licensed sites will jointly apply to perform transplantation
146 procedures under the same OPTN certification.
147

148 | ~~(4) An applicant shall provide verification of Medicaid participation. An applicant that is a new~~
149 ~~provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided~~
150 ~~to the Department within six (6) months from the offering of services if a CON is approved.~~
151

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

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

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

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

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

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

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

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

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

178 **Section 4. Additional requirements for heart, heart/lung or lung transplantation services**

180
 181 Sec. 4. (1) Approval of an application proposing to provide heart, heart/lung or lung transplantation
 182 services shall not result in more than three (3) heart, heart/lung or lung transplantation services in the
 183 planning area. In evaluating compliance with this subsection, an application submitted or a certificate
 184 approved pursuant to Section 3(54) of these standards shall be considered as a single service.

185
 186 (2) Except for an application pursuant to Section 3(54) of these standards, an applicant for a heart,
 187 heart/lung or lung transplantation service shall project a minimum of 12 heart, heart/lung or lung
 188 transplantation procedures annually in the second 12-months of operation following the date on which the
 189 first heart, heart/lung or lung transplant procedure is performed and annually thereafter.

190
 191 (3) An applicant proposing to provide heart, heart/lung or lung transplantation services shall
 192 demonstrate that it either operates an existing renal transplant service or has a written agreement with a
 193 renal transplant service in the same hospital subarea that ensures that the professional expertise of the
 194 renal transplant service is readily available to the proposed transplantation service.

195
 196 (4) An applicant proposing to provide a heart, heart/lung or lung transplantation service shall
 197 demonstrate that it offers all of the following services or programs:

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

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

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

205 (d) continuously available coagulation laboratory services; and

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

208 **Section 5. Additional requirements for liver transplantation services**

209
 210 Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not
 211 result in more than three (3) liver transplantation services in the planning area. In evaluating compliance
 212 with this subsection, an application submitted or a certificate approved pursuant to Section 3(54) of these
 213 standards shall be considered as a single service.
 214

215
216 | (2) Except for an application pursuant to Section 3(54) of these standards, an applicant for a liver
217 transplantation service shall project a minimum of 12 liver transplantation procedures annually in the
218 second 12-months of operation following the date on which the first liver transplant procedure is
219 performed, and annually thereafter.

220
221 (3) An applicant proposing to provide liver transplantation services shall demonstrate that it either
222 operates an existing renal transplant service or has a written agreement with a renal transplant service in
223 the same hospital subarea that ensures that the professional expertise of the renal transplant service is
224 readily available to the proposed transplantation service.

225
226 (4) An applicant proposing to provide a liver transplantation service shall demonstrate that it offers all
227 of the following services or programs:

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

236 237 **SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION**

238
239 SEC. 6. An applicant shall provide verification of Medicaid participation. An applicant that is a new
240 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
241 to the Department within six (6) months from the offering of services if a CON is approved.

242 243 **Section 67. Review standards for comparative reviews**

244
245 Sec. 67. (1) Any application subject to comparative review under Section 22229 of the Code, being
246 Section 333.22229 of the Michigan Compiled Laws, or under these standards shall be grouped and
247 reviewed comparatively with other applications in accordance with the CON rules. FOR PURPOSES OF
248 THESE STANDARDS, comparative group means the applications that have been grouped for the same
249 type of project in the same planning area and are being reviewed comparatively in accordance with the
250 CON rules.

251
252 (21) Qualifying project means each application in a comparative group which has been reviewed
253 individually and has been determined by the Department to have satisfied all of the requirements of
254 Section 22225 of the Code, being Section 333.22225 of the Michigan Compiled Laws, and all other
255 applicable requirements for approval in the Code and these standards.

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

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

	Number of Transplant Programs in HSA	Points Awarded
269		
270		
271		
272		
273		
274	Two or more programs	0
275	One program	2
276	No programs	4
277		

278 (c) A qualifying project will have up to 4 points awarded based on the percentage of the
279 medical/surgical indigent volume at the licensed site at which the proposed heart/lung or liver
280 transplantation service will be provided in accordance with the following:

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

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

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

293 (d) A qualifying project will have 2 points awarded if an applicant documents that, during the 36-
294 month period prior to the date an application is submitted to the Department, at least 15 patients received
295 pre- and post-transplant care at the licensed site at which the heart/lung or liver transplant procedures will
296 be performed and were referred for and received a heart/lung or liver transplant at an existing heart/lung
297 or liver transplantation service, and submits documentation from the existing heart/lung or liver
298 transplantation service(s) of these referrals.

299
300 (3) Each application in a comparative review group shall be individually reviewed to determine
301 whether the application has satisfied all the requirements of Section 22225 of the Code, being Section
302 333.22225 of the Michigan Compiled Laws, and all other applicable requirements for approval in the
303 Code and these standards. If the Department determines that one or more of the competing applications
304 satisfies all of the requirements for approval, these projects shall be considered qualifying projects. The
305 Department shall approve those qualifying projects which, taken together, do not exceed the need, as
306 defined in Section 22225(1) being Section 333.22225(1) of the Michigan Compiled Laws, and which have
307 the highest number of points when the results of subsection (2) are totaled. If two or more qualifying
308 projects are determined to have an identical number of points, the Department shall approve those
309 qualifying projects which, taken together, do not exceed the need, as defined in Section 22225(1) of the
310 Code, being Section 333.22225(1) of the Michigan Compiled Laws, in the order in which the applications
311 were received by the Department, based on the date and time stamp placed on the application by the
312 CON administrative unit of the Department responsible for administering the CON program when an
313 application is submitted.

314
315 (4) Submission of conflicting information in this section may result in a lower point reward. If an
316 application contains conflicting information which could result in a different point value being awarded in
317 this section, the Department will award points based on the lower point value that could be awarded from
318 conflicting information. For example, if submitted information would result in 6 points being awarded, but
319 other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the
320 conflicting information does not affect the point value, the Department will award points accordingly. For
321 example, if submitted information would result in 12 points being awarded and other conflicting
322 information would also result in 12 points being awarded, then 12 points will be awarded.

323
324 **Section 78. Project delivery requirements -- terms of approval**
325

326 Sec. 78. ~~(1)~~—An applicant shall agree that, if approved, the HLL service(s) shall be delivered in
327 compliance with the following terms of CON approval:
328

329 (a1) Compliance with these standards. An applicant shall immediately report to the Department any
330 changes in key staff or other aspects of the transplantation service that may affect its ability to comply
331 with these standards.
332

333 ~~(b2) Compliance with applicable safety and operating standards.~~
334

335 ~~(c) Compliance with the following quality assurance standardsREQUIREMENTS, as applicable:~~

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

338 ~~(iiA) The applicant shall comply and remain MAINTAIN a functionally active program with~~
339 ~~thePURSUANT TO OPTN and its by-laws and policies.~~

340 ~~(A) The applicant shall comply with the Center for Medicare and Medicaid Services (CMS) standards~~
341 ~~and shall become Medicare approved within THE FIRST five years of implementation of services.~~

342 ~~(Bii) The applicant must be in good standing with the OPTN.~~

343 ~~(iiiB) The transplantation service shall have a transplant team leader and coordinator.~~

344 ~~(ivC) The applicant shall have patient management plans and protocols that include the following: (A)~~
345 ~~therapeutic and evaluative procedures for the acute and long-term management of a patient; (B) patient~~
346 ~~management and evaluation during the waiting, in-hospital and immediate post-discharge phases of the~~
347 ~~service; and (C) long-term management and evaluation, including education of the patient, liaison with~~
348 ~~the patient's attending physician, and the maintenance of active patient records for at least 5 years.~~

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

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

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

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

358 ~~(ixH) The applicant shall maintain an organized institutional transplant registry for recording ongoing~~
359 ~~information on its patients being evaluated for transplant. The applicant shall also maintain a registry of~~
360 ~~patients listed for a transplant and for transplant recipients as required by the federal OPTN.~~

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

364 ~~(J) Compliance with the Uniform Anatomical Gift Law, pursuant to MCL Section 333.10101 et seq. of~~
365 ~~the Michigan Compiled Laws.~~
366

367 ~~(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:~~

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

370 ~~(B) The applicant, to assure that the transplantation service(s) will be utilized by all segments of the~~
371 ~~Michigan population, shall:~~

372 ~~(I) not deny the services to any individual based on ability to pay or source of payment;~~

373 ~~(II) provide the services to all individuals in accordance with the patient selection criteria developed~~
374 ~~by appropriate medical professionals, and approved by the Department; and~~

375 ~~(III) maintain information by payor and non-paying sources to indicate the volume of care from each~~
 376 ~~source provided annually. Compliance with selective contracting requirements shall not be construed as~~
 377 ~~a violation of this term.~~

378
 379 **(4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:**

380 ~~—(A)—(x) The applicant shall perform the applicable required volumes within the time periods specified~~
 381 ~~in these standards, and annually thereafter.~~

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

392 ~~(xi) The applicant, to assure that the transplantation service(s) will be utilized by all segments of the~~
 393 ~~Michigan population, shall:~~

394 ~~—(A) not deny the services to any individual based on ability to pay or source of payment;~~

395 ~~—(B) provide the services to all individuals in accordance with the patient selection criteria developed~~
 396 ~~by appropriate medical professionals, and approved by the Department; and~~

397 ~~—(C) maintain information by payor and non-paying sources to indicate the volume of care from each~~
 398 ~~source provided annually.~~

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

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

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

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

408 ~~—(d) Compliance with the Uniform Anatomical Gift Law, pursuant to MCL Section 333.10101 et seq. of~~
 409 ~~the Michigan Compiled Laws.~~

410
 411 **(25)** The agreements and assurances required by this section, as applicable, shall be in the form of a
 412 certification agreed to by the applicant or its authorized agent.

413
 414 **Section 89. Documentation of projections**

415
 416 Sec. 8. An applicant required to project volumes of service under sections 4 or 5 shall specify how the
 417 volume projections were developed. This specification of projections shall include a description of the
 418 data source(s) used, assessments of the accuracy of these data and the statistical method used to make
 419 the projections. Based on this documentation, the Department shall determine if the projections are
 420 reasonable.

421
 422 **Section 910. Health Service Areas Effect on prior CON Review Standards; comparative reviews**

423
 424 ~~Sec. 11. These CON review standards supersede and replace the CON Review Standards for~~
 425 ~~Heart/Lung and Liver Transplantation Services approved by the CON Commission on March 25, 2010~~
 426 ~~and effective on MAY 28, 2010.~~

427
 428 ~~(1) Projects reviewed under these standards shall be subject to comparative review.~~
 429

APPENDIX A

Counties assigned to each health service area are as follows:

HEALTH SERVICE AREA COUNTIES

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

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

Section 10. Effect on prior CON Review Standards; comparative reviews

Sec. 10. (1) These CON review standards supersede and replace the CON Review Standards for Heart/Lung and Liver Transplantation Services approved by the CON Commission on March 9, 2004 and effective on June 4, 2004.

483 | —(21) Projects reviewed under these standards shall be subject to comparative review.

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

Highlights of Proposed Changes to Include Hybrid Modalities

Section 2 - Definitions

(1)(bb): Added definition for "MRI-Guided Electrophysiology intervention" or "MRI-Guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac catheterization lab.

(cc): Added to the definition of "MRI procedure" to include: Positron Emission Tomography (PET)/MRI Scanner Hybrids if used for MRI only procedures.

Section 11 - Hospital based MRI-Guided EPI Service

- The Department drafted requirements for this NEW section as requested by the CON Commission and is modeled after the Intra-operative magnetic resonance imaging (IMRI) language. It will allow for an MRI-guided EPI service to be located at a hospital that has an existing fixed MRI service that has been operational for 36 months and is meeting its minimum volume requirements. The proposed site has an existing and operational therapeutic cardiac catheterization service and is meeting its minimum volume requirements. Its open heart surgery service must be meeting its minimum volume requirements too.

The MRI-guided EPI unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 12 - FDA-Approved PET/MRI Scanner Hybrid

- The Department drafted requirements for this NEW section as requested by the CON Commission. This language is modeled after the PET/CT language which will allow the use of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures. There must be an approved PET CON, and it must be in compliance with applicable project delivery requirements as set forth in the CON review standards for PET.

The FDA-approved PET/MRI scanner hybrid unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the FDA-approved PET/MRI scanner hybrid unit to demonstrate need or to satisfy MRI CON review standards requirements.

Section 14 - Project Delivery Requirements

(1)(d)(iii): Added project delivery requirements for data reporting for the MRI-Guided EPI UNIT similar to IMRI. At a minimum, the data reported shall include how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic.

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 ~~1315~~, 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 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 submitted by the Department.

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).

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

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

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

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

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

67 (o) "Group practice" means a group practice as defined pursuant to the provisions of 42 U.S.C.
68 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
69 published in the Federal Register on August 14, 1995, or its replacement.

70 (p) "Health service area" or "HSA" means the geographic areas set forth in Section 4921.

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

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

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

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

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

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

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

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

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

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

97 (z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been
98 adjusted in accordance with the applicable provisions of Section 4315.

99 (aa) "MRI database" means the database, maintained by the Department pursuant to Section 42-14
100 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

101 (BB) "MRI-GUIDED ELECTROPHYSIOLOGY INTERVENTION" OR "MRI-GUIDED EPI" MEANS
102 EQUIPMENT SPECIFICALLY DESIGNED FOR THE INTEGRATED USE OF MRI TECHNOLOGY FOR
103 THE PURPOSES OF ELECTROPHYSIOLOGY INTERVENTIONAL PROCEDURES WITHIN A
104 CARDIAC CATHETERIZATION LAB.

105 (bbcc) "MRI procedure" means a procedure conducted by an MRI unit approved pursuant to sections
106 3, 4, 5, 6, 7, or 9 of these standards which is either a single, billable diagnostic magnetic resonance

107 procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic
 108 radiology residency program, under a research protocol approved by an IRB. The capital and operating
 109 costs related to the research use are charged to a specific research account and not charged to or
 110 collected from third-party payors or patients. **THE TERM INCLUDES FDA-APPROVED POSITRON**
 111 **EMISSION TOMOGRAPHY (PET)/MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES.**
 112 The term does not include a procedure conducted by an MRI unit approved pursuant to Section 8(1).
 113 (eeDD) "MRI services" means either the utilization of an authorized MRI unit(s) at one site in the case
 114 of a fixed MRI service or in the case of a mobile MRI service, the utilization of an authorized mobile MRI
 115 unit at each host site.
 116 (eeEE) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines
 117 and related equipment necessary to produce the images and/or spectroscopic quantitative data from
 118 scans. The term does not include MRI simulators used solely for treatment planning purposes in
 119 conjunction with an MRT unit.
 120 (eeFF) "MRI visit" means a single patient visit to an MRI service/unit that may involve one or more MRI
 121 procedures.
 122 (#GG) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6
 123 and 1396r-8 to 1396v.
 124 (ggHH) "Metropolitan statistical area county" means a county located in a metropolitan statistical area
 125 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
 126 by the statistical policy office of the office of information and regulatory affairs of the United States office
 127 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
 128 (hhII) "Micropolitan statistical area county" means a county located in a micropolitan statistical area
 129 as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas"
 130 by the statistical policy office of the office of information and regulatory affairs of the United States office
 131 of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix A.
 132 (#JJ) "Mobile MRI unit" means an MRI unit operating at two or more host sites and that has a central
 133 service coordinator. The mobile MRI unit shall operate under a contractual agreement for the provision of
 134 MRI services at each host site on a regularly scheduled basis.
 135 (#KK) "Ownership interest, direct or indirect" means a direct ownership relationship between a doctor
 136 and an applicant entity or an ownership relationship between a doctor and an entity that has an
 137 ownership relationship with an applicant entity.
 138 (kkLL) "Pediatric patient" means a patient who is 12 years of age or less, except for Section 9.
 139 (#MM) "Planning area" means
 140 (i) in the case of a proposed fixed MRI service or unit, the geographic area within a 20-mile radius
 141 from the proposed site if the proposed site is not in a rural or micropolitan statistical area county and a
 142 75-mile radius from the proposed site if the proposed site is in a rural or micropolitan statistical area
 143 county.
 144 (ii) in the case of a proposed mobile MRI service or unit, except as provided in subsection (iii), the
 145 geographic area within a 20-mile radius from each proposed host site if the proposed site is not in a rural
 146 or micropolitan statistical area county and within a 75-mile radius from each proposed host site if the
 147 proposed site is in a rural or micropolitan statistical area county.
 148 (iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section
 149 ~~1315~~(2)(d), the health service area in which all the proposed mobile host sites will be located.
 150 (mmNN) "Referring doctor" means the doctor of record who ordered the MRI procedure(s) and either to
 151 whom the primary report of the results of an MRI procedure(s) is sent or in the case of a teaching facility,
 152 the attending doctor who is responsible for the house officer or resident that requested the MRI
 153 procedure.
 154 (nnOO) "Relocate an existing MRI service and/or MRI unit(s)" means a change in the location of an
 155 existing MRI service and/or MRI unit(s) from the existing site to a different site within the relocation zone.
 156 (ooPP) "Relocation zone" means the geographic area that is within a 10-mile radius of the existing site
 157 of the MRI service or unit to be relocated.

- 158 | (~~pp~~QQ) "Renewal of a lease" means extending the effective period of a lease for an existing MRI unit
 159 | that does not involve either replacement of the MRI unit, as defined in Section 2(1)(~~pp~~RR)(i), or (ii) a
 160 | change in the parties to the lease.
- 161 | (~~qq~~RR) "Replace an existing MRI unit" means (i) any equipment change involving a change in, or
 162 | replacement of, the magnet resulting in an applicant operating the same number and type (fixed or
 163 | mobile) of MRI units before and after project completion or (ii) an equipment change other than a change
 164 | in the magnet that involves a capital expenditure of \$750,000 or more in any consecutive 24-month
 165 | period or (iii) the renewal of a lease. The term does not include an upgrade of an existing MRI service or
 166 | unit, and it does not include a host site that proposes to receive mobile MRI services from a different
 167 | central service coordinator if the requirements of Section 3(5) have been met.
- 168 | (~~#~~SS) "Research scan" means an MRI scan administered under a research protocol approved by the
 169 | applicant's IRB.
- 170 | (~~ss~~TT) "Re-sedated patient" means a patient, either pediatric or adult, who fails the initial sedation
 171 | during the scan time and must be extracted from the unit to rescue the patient with additional sedation.
- 172 | (~~#~~UU) "Rural county" means a county not located in a metropolitan statistical area or micropolitan
 173 | statistical areas as those terms are defined under the "standards for defining metropolitan and
 174 | micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of
 175 | the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as
 176 | shown in Appendix A.
- 177 | (~~uu~~VV) "Sedated patient" means a patient that meets all of the following:
 178 | (i) whose level of consciousness is either conscious-sedation or a higher level of sedation, as
 179 | defined by the American Association of Anesthesiologists, the American Academy of Pediatrics, the Joint
 180 | Commission on the Accreditation of Health Care Organizations, or an equivalent definition.
 181 | (ii) who is monitored by mechanical devices while in the magnet.
 182 | (iii) who requires observation while in the magnet by personnel, other than employees routinely
 183 | assigned to the MRI unit, who are trained in cardiopulmonary resuscitation (CPR).
- 184 | (~~vv~~WW) "Site" means
 185 | (i) in the case of a licensed hospital site, a location that is part of the licensed hospital site or a
 186 | location that is contiguous to the licensed hospital site or
 187 | (ii) in the case of a location that is not a licensed hospital site, a location at the same address or a
 188 | location that is contiguous to that address.
- 189 | (~~ww~~XX) "Special needs patient" means a non-sedated patient, either pediatric or adult, with any of the
 190 | following conditions: down syndrome, autism, attention deficit hyperactivity disorder (ADHD),
 191 | developmental delay, malformation syndromes, hunter's syndrome, multi-system disorders, psychiatric
 192 | disorders, and other conditions that make the patient unable to comply with the positional requirements of
 193 | the exam.
- 194 | (~~xx~~YY) "Teaching facility" means a licensed hospital site, or other location, that provides either fixed or
 195 | mobile MRI services and at which residents or fellows of a training program in diagnostic radiology, that is
 196 | approved by the Accreditation Council on Graduate Medical Education or American Osteopathic
 197 | Association, are assigned.
- 198 | (~~yy~~ZZ) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as
 199 | defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section
 200 | 1315.
- 201 | (~~zz~~AAA) "Upgrade an existing MRI unit" means any equipment change that
 202 | (i) does not involve a change in, or replacement of, the magnet; does not result in an increase in
 203 | the number of MRI units; or does not result in a change in the type of MRI unit (e.g., changing a mobile
 204 | MRI unit to a fixed MRI unit); and
 205 | (ii) involves a capital expenditure related to the MRI equipment of less than \$750,000 in any
 206 | consecutive 24-month period.
- 207 |
 208 | (2) Terms defined in the Code have the same meanings when used in these standards.
 209 |
 210 |

Section 3. Requirements to initiate an MRI service

211
212 Sec. 3. An applicant proposing to initiate an MRI service or a host site shall demonstrate the
213 following requirements, as applicable:
214

215 (1) An applicant proposing to initiate a fixed MRI service shall demonstrate 6,000 available MRI
216 adjusted procedures per proposed fixed MRI unit from within the same planning area as the proposed
217 service/unit.
218

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

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

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

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

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

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

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

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

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

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

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

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

238 (e) The applicant shall cease operation as a host site and not become a host site for at least 12
239 months from the date the fixed service and its unit becomes operational.
240

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

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

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

247 (c) Identify a minimum of two (2) host sites for the proposed service.
248

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

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

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

255 (c) The proposed host site has not received any mobile MRI service within the most recent 12-
256 month period as of the date an application is submitted to the Department.
257

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

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

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

264
265 (6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available
266 MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as
267 applicable, are from the most recently published MRI lists as of the date an application is deemed
268 submitted by the Department.

269 **Section 4. Requirements to replace an existing MRI unit**

270
271
272 Sec. 4. An applicant proposing to replace an existing MRI unit shall demonstrate the following
273 requirements, as applicable:

274
275 (1) An applicant shall demonstrate that the applicable MRI adjusted procedures are from the most
276 recently published MRI Service Utilization List as of the date an application is deemed submitted by the
277 Department:

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

280 (b) Each existing fixed MRI unit at the current site has performed at least an average of 6,000 MRI
281 adjusted procedures per MRI unit unless the applicant demonstrates compliance with one of the
282 following:

283 (i) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) has performed at least 4,000
284 MRI adjusted procedures and is the only fixed MRI unit at the current site.

285 (ii) The existing fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) has performed at least 3,000
286 MRI adjusted procedures and is the only fixed MRI unit at the current site.

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

289
290 (2) Equipment that is replaced shall be removed from service and disposed of or rendered
291 considerably inoperable on or before the date that the replacement equipment becomes operational.

292
293 (3) The replacement unit shall be located at the same site unless the requirements of the
294 relocation section have been met.

295
296 (4) An applicant proposing to replace an existing MRI unit that does not involve a renewal of a
297 lease shall demonstrate that the MRI unit to be replaced is fully depreciated according to generally
298 accepted accounting principles; the existing equipment clearly poses a threat to the safety of the public;
299 or the proposed replacement equipment offers a significant technological improvement which enhances
300 quality of care, increases efficiency, and reduces operating costs.

301 **Section 5. Requirements to expand an existing MRI service**

302
303
304 Sec. 5. An applicant proposing to expand an existing MRI service shall demonstrate the following:

305
306 (1) An applicant shall demonstrate that the applicable MRI adjustable procedures are from the
307 most recently published MRI Service Utilization List as of the date of an application is deemed submitted
308 by the Department:

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

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

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

316 (2) The additional fixed unit shall be located at the same site unless the requirements of the
317 relocation section have been met.
318
319

320 **Section 6. Requirements to relocate an existing fixed MRI service and/or MRI unit(s)**
 321

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

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

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

327 (c) Each existing MRI unit to be relocated performed at least the applicable minimum number of
 328 | MRI adjusted procedures set forth in Section ~~42-14~~ based on the most recently published MRI Service
 329 Utilization List as of the date an application is deemed submitted by the Department.

330
 331 (2) An applicant proposing to relocate a fixed MRI unit of an existing MRI service shall
 332 demonstrate the following:

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

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

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

337 (d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the
 338 | applicable minimum number of MRI adjusted procedures set forth in Section ~~42-14~~ based on the most
 339 recently published MRI Service Utilization List as of the date an application is deemed submitted by the
 340 Department.

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

343
 344 **Section 7. Requirements to acquire an existing MRI service or an existing MRI unit(s)**
 345

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

348 (a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after
 349 July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in
 350 compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs.

351 | The MRI service shall be operating at the applicable volume requirements set forth in Section ~~42-14~~ of
 352 these standards in the second 12 months after the effective date of the acquisition, and annually
 353 thereafter.

354 (b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s),
 355 except the first application approved pursuant to subsection (a), an applicant shall be required to
 356 document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume
 357 | requirements set forth in Section ~~42-14~~ of these standards applicable to an existing MRI service on the
 358 date the application is submitted to the Department.

359
 360 (2) An applicant proposing to acquire an existing fixed or mobile MRI unit of an existing MRI
 361 service shall demonstrate that the proposed project meets all of the following:

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

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

368
 369 **Section 8. Requirements to establish a dedicated research MRI unit**
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371 Sec. 8. An applicant proposing an MRI unit to be used exclusively for research shall demonstrate the
 372 following:

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(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. Requirements for all applicants proposing to initiate, replace, or acquire a hospital based IMRI

Sec. 10. An applicant proposing to initiate, replace, or acquire a hospital based IMRI service shall demonstrate each of the following, as applicable to the proposed project.

(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.

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

428
429 (4) The applicant has achieved one of the following:

430 (a) at least 1,500 oncology discharges in the most recent year of operation; or

431 (b) at least 1,000 neurological surgeries in the most recent year of operation; or

432 (c) at least 7,000 pediatric (<18 years old) discharges (excluding normal newborns) and at least
433 5,000 pediatric (<18 years old) surgeries in the most recent year of operation.

434
435 (5) The proposed IMRI unit must be located in an operating room or a room adjoining an operating
436 room allowing for transfer of the patient between the operating room and this adjoining room.

437
438 (6) Non-surgical diagnostic studies shall not be performed on an IMRI unit approved under this
439 section unless the patient meets one of the following criteria:

440 (a) the patient has been admitted to an inpatient unit; or

441 (b) the patient is having the study performed on an outpatient basis, but is in need of general
442 anesthesia or deep sedation as defined by the American Society of Anesthesiologists.

443
444 (7) The approved IMRI unit will not be subject to MRI volume requirements.

445
446 (8) The applicant shall not utilize the procedures performed on the IMRI unit to demonstrate need
447 or to satisfy MRI CON review standards requirements.

448
449 **SECTION 11. REQUIREMENTS FOR ALL APPLICANTS PROPOSING TO INITIATE, REPLACE, OR**
450 **ACQUIRE A HOSPITAL BASED MRI-GUIDED EPI SERVICE**

451
452 **SEC. 11. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL**
453 **BASED MRI-GUIDED EPI SERVICE SHALL DEMONSTRATE EACH OF THE FOLLOWING, AS**
454 **APPLICABLE TO THE PROPOSED PROJECT.**

455
456 **(1) THE PROPOSED SITE IS A LICENSED HOSPITAL UNDER PART 215 OF THE CODE.**

457
458 **(2) THE PROPOSED SITE HAS AN EXISTING FIXED MRI SERVICE THAT HAS BEEN**
459 **OPERATIONAL FOR THE PREVIOUS 36 CONSECUTIVE MONTHS AND IS MEETING ITS MINIMUM**
460 **VOLUME REQUIREMENTS.**

461
462 **(3) THE PROPOSED SITE HAS AN EXISTING AND OPERATIONAL THERAPEUTIC CARDIAC**
463 **CATHETERIZATION SERVICE AND IS MEETING ITS MINIMUM VOLUME REQUIREMENTS**
464 **PURSUANT TO THE CON REVIEW STANDARDS FOR CARDIAC CATHETERIZATION SERVICES**
465 **AND OPEN HEART SURGERY SERVICES.**

466
467 **(4) THE PROPOSED MRI-GUIDED EPI UNIT MUST BE LOCATED IN A CARDIAC**
468 **CATHETERIZATION LAB CONTAINING A FLOUROSCOPY UNIT WITH AN ADJOINING ROOM**
469 **CONTAINING AN MRI SCANNER. THE ROOMS SHALL CONTAIN A PATIENT TRANSFER SYSTEM**
470 **ALLOWING FOR TRANSFER OF THE PATIENT BETWEEN THE CARDIAC CATHETERIZATION LAB**
471 **AND THE MRI UNIT, UTILIZING ONE OF THE FOLLOWING:**

472 **(A) MOVING THE PATIENT TO THE MRI SCANNER, OR**

473 **(B) INSTALLING THE MRI SCANNER ON A SLIDING GANTRY TO ALLOW THE PATIENT TO**
474 **REMAIN STATIONARY.**

477 (5) NON-CARDIAC MRI DIAGNOSTIC STUDIES SHALL NOT BE PERFORMED IN AN MRI-
 478 GUIDED EPI UNIT APPROVED UNDER THIS SECTION UNLESS THE PATIENT MEETS ONE OF THE
 479 FOLLOWING CRITERIA:

- 480 (A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR
 481 (B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS AS
 482 FOLLOWS:
 483 (I) IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE
 484 AMERICAN SOCIETY OF ANESTHESIOLOGISTS, OR
 485 (II) HAS AN IMPLANTABLE CARDIAC DEVICE.

486
 487 (6) THE APPROVED MRI-GUIDED EPI UNIT SHALL NOT BE SUBJECT TO MRI VOLUME
 488 REQUIREMENTS.

489
 490 (7) THE APPLICANT SHALL NOT UTILIZE THE PROCEDURES PERFORMED ON THE MRI-
 491 GUIDED EPI UNIT TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS
 492 REQUIREMENTS.

493
 494 **SECTION 12. REQUIREMENTS FOR APPROVAL OF AN FDA-APPROVED PET/MRI SCANNER**
 495 **HYBRID FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION**

496
 497 **SEC. 12. AN APPLICANT PROPOSING TO INITIATE, EXPAND, REPLACE, OR ACQUIRE AN FDA-**
 498 **APPROVED PET/MRI SCANNER HYBRID SHALL DEMONSTRATE THAT IT MEETS ALL OF THE**
 499 **FOLLOWING:**

500
 501 (1) THERE IS AN APPROVED PET CON FOR THE FDA-APPROVED PET/MRI HYBRID, AND
 502 THE FDA-APPROVED PET/MRI SCANNER HYBRID IS IN COMPLIANCE WITH ALL APPLICABLE
 503 PROJECT DELIVERY REQUIREMENTS AS SET FORTH IN THE CON REVIEW STANDARDS FOR
 504 PET.

505
 506 (2) THE APPLICANT AGREES TO OPERATE THE FDA-APPROVED PET/MRI SCANNER
 507 HYBRID IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET
 508 FORTH IN SECTION 4314 OF THESE STANDARDS.

509
 510 (3) THE APPROVED FDA-APPROVED PET/MRI SCANNER HYBRID SHALL NOT BE SUBJECT
 511 TO MRI VOLUME REQUIREMENTS.

512
 513 (4) AN FDA-APPROVED PET/MRI SCANNER HYBRID APPROVED UNDER THE CON REVIEW
 514 STANDARDS FOR PET SCANNER SERVICES AND THE REVIEW STANDARDS FOR MRI SCANNER
 515 SERVICES MAY NOT UTILIZE MRI PROCEDURES PERFORMED ON AN FDA-APPROVED PET/MRI
 516 SCANNER HYBRID TO DEMONSTRATE NEED OR TO SATISFY MRI CON REVIEW STANDARDS
 517 REQUIREMENTS.

518
 519 **Section 4413. Requirements for all applicants**

520
 521 Sec. 4413. An applicant shall provide verification of Medicaid participation. An applicant that is a new
 522 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
 523 to the Department within six (6) months from the offering of services if a CON is approved.

524
 525 **Section 4214. Project delivery requirements – terms of approval**

526
 527 Sec. 4214. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall
 528 be delivered and maintained in compliance with the following:

- 529 (a) Compliance with these standards.

- 530 (b) Compliance with applicable safety and operating standards.
- 531 (c) Compliance with the following quality assurance standards:
- 532 (i) An applicant shall develop and maintain policies and procedures that establish protocols for
533 assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI
534 service.
- 535 (ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.
- 536 (iii) An applicant shall provide documentation identifying the specific individuals that form the MRI
537 team. At a minimum, the MRI team shall consist of the following professionals:
- 538 (A) Physicians who shall be responsible for screening of patients to assure appropriate utilization
539 of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a
540 board-certified radiologist.
- 541 (B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.
- 542 (C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual
543 basis.
- 544 (iv) An applicant shall document that the MRI team members have the following qualifications:
- 545 (A) Each physician credentialed to interpret MRI scans meets the requirements of each of the
546 following:
- 547 (1) The physician is licensed to practice medicine in the State of Michigan.
- 548 (2) The physician has had at least 60 hours of training in MRI physics, MRI safety, and MRI
549 instrumentation in a program that is part of an imaging program accredited by the Accreditation Council
550 for Graduate Medical Education or the American Osteopathic Association, and the physician meets the
551 requirements of subdivision (i), (ii), or (iii):
- 552 (i) Board certification by the American Board of Radiology, the American Osteopathic Board of
553 Radiology, or the Royal College of Physicians and Surgeons of Canada. If the diagnostic radiology
554 program completed by a physician in order to become board certified did not include at least two months
555 of MRI training, that physician shall document that he or she has had the equivalent of two months of
556 postgraduate training in clinical MRI imaging at an institution which has a radiology program accredited
557 by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.
- 558 (ii) Formal training by an imaging program(s), accredited by the Accreditation Council for Graduate
559 Medical Education or the American Osteopathic Association, that included two years of training in cross-
560 sectional imaging and six months training in organ-specific imaging areas.
- 561 (iii) A practice in which at least one-third of total professional time, based on a full-time clinical
562 practice during the most recent 5-year period, has been the primary interpretation of MR imaging.
- 563 (3) The physician has completed and will complete a minimum of 40 hours every two years of
564 Category in Continuing Medical Education credits in topics directly involving MR imaging.
- 565 (4) The physician interprets, as the primary interpreting physician, at least 250 unadjusted MRI
566 scans annually.
- 567 (B) An MRI technologist who is registered by the American Registry of Radiologic Technicians or
568 by the American Registry of Magnetic Resonance Imaging Technologists (ARMRIT) and has, or will have
569 within 36 months of the effective date of these standards or the date a technologist is employed by an
570 MRI service, whichever is later, special certification in MRI. If a technologist does not have special
571 certification in MRI within either of the 3-year periods of time, all continuing education requirements shall
572 be in the area of MRI services.
- 573 (C) An applicant shall document that an MRI physicist/engineer is appropriately qualified. For
574 purposes of evaluating this subdivision, the Department shall consider it prima facie evidence as to the
575 qualifications of the physicist/engineer if the physicist/engineer is certified as a medical physicist by the
576 American Board of Radiology, the American Board of Medical Physics, or the American Board of Science
577 in Nuclear Medicine. However, the applicant may submit and the Department may accept other evidence
578 that an MRI physicist/engineer is qualified appropriately.
- 579 (v) The applicant shall have, within the MRI unit/service, equipment and supplies to handle clinical
580 emergencies that might occur in the unit. MRI service staff will be trained in CPR and other appropriate
581 emergency interventions. A physician shall be on-site, in, or immediately available to the MRI unit at all
582 times when patients are undergoing scans.

- 583 (vi) An applicant shall participate in Medicaid at least 12 consecutive months within the first two
584 years of operation and continue to participate annually thereafter.
- 585 (d) Compliance with the following terms of approval, as applicable:
- 586 (i) MRI units shall be operating at a minimum average annual utilization during the second 12
587 months of operation, and annually thereafter, as applicable:
- 588 (A) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),
589 (1) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii)
590 and is the only fixed MRI unit at the current site,
591 (2) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii)
592 and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,
593 (B) 5,500 MRI adjusted procedures per unit for mobile MRI services.
594 (C) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.
595 (D) Each mobile host site in a rural or micropolitan statistical area county shall have provided at
596 least a total of 400 adjusted procedures during its second 12 months of operation, and annually
597 thereafter, from all mobile units providing services to the site. Each mobile host site not in a rural or
598 micropolitan statistical area county shall have provided at least a total of 600 adjusted procedures during
599 its second 12 months of operation and annually thereafter, from all mobile units providing services to the
600 site.
- 601 (E) In meeting these requirements, an applicant shall not include any MRI adjusted procedures
602 performed on an MRI unit used exclusively for research and approved pursuant to Section 8(1) or for an
603 IMRI unit approved pursuant to Section 10.
- 604 (ii) The applicant, to assure that the MRI unit will be utilized by all segments of the Michigan
605 population, shall
- 606 (A) provide MRI services to all individuals based on the clinical indications of need for the service
607 and not on ability to pay or source of payment.
- 608 (B) maintain information by source of payment to indicate the volume of care from each source
609 provided annually.
- 610 (iii) The applicant shall participate in a data collection network established and administered by the
611 Department or its designee. The data may include, but is not limited to, operating schedules,
612 demographic and diagnostic information, and the volume of care provided to patients from all payor
613 sources, as well as other data requested by the Department or its designee and approved by the
614 Commission. The applicant shall provide the required data in a format established by the Department
615 and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which
616 data are being reported to the Department. An applicant shall be considered in violation of this term of
617 approval if the required data are not submitted to the Department within 30 days following the last day of
618 the quarter for which data are being reported. The Department may elect to verify the data through
619 on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9,
620 ~~or Section 10, OR SECTION 11~~ shall be reported separately.
- 621 For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is
622 used and for what type of services, i.e., intra-operative or diagnostic. **FOR PURPOSES OF SECTION**
623 **11, THE DATA REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE MRI-GUIDED EPI**
624 **UNIT IS USED AND FOR WHAT TYPE OF SERVICES, I.E., ELECTROPHYSIOLOGY OR**
625 **DIAGNOSTIC.**
- 626 (iv) The operation of and referral of patients to the MRI unit shall be in conformance with 1978 PA
627 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
- 628 (e) The applicant shall provide the Department with a notice stating the first date on which the MRI
629 unit became operational, and such notice shall be submitted to the Department consistent with applicable
630 statute and promulgated rules.
- 631 (f) An applicant who is a central service coordinator shall notify the Department of any additions,
632 deletions, or changes in the host sites of each approved mobile MRI unit within 10 days after the
633 change(s) in host sites is made.
634

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

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

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

642

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

645

646 | **Section 1315. MRI procedure adjustments**

647

648 | Sec. 1315. (1) The Department shall apply the following formula, as applicable, to determine the
649 number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

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

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

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

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

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

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

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

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

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

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

668

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

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

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

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

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

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

686

687 (3) The number of MRI adjusted procedures performed by an existing MRI service is the sum of
 688 the results of subsections (1) and (2).
 689

690 | **Section 1416. Documentation of actual utilization**
 691

692 | Sec. 1416. Documentation of the number of MRI procedures performed by an MRI unit shall be
 693 substantiated by the Department utilizing data submitted by the applicant in a format and media specified
 694 by the Department and as verified for the 12-month period reported on the most recently published "MRI
 695 Service Utilization List" as of the date an application is deemed submitted by the Department. The
 696 number of MRI procedures actually performed shall be documented by procedure records and not by
 697 application of the methodology required in Section 1517. The Department may elect to verify the data
 698 through on-site review of appropriate records.
 699

700 | **Section 1517. Methodology for computing the number of available MRI adjusted procedures**
 701

702 | Sec. 1517. (1) The number of available MRI adjusted procedures required pursuant to Section 3
 703 shall be computed in accordance with the methodology set forth in this section. In applying the
 704 methodology, the following steps shall be taken in sequence, and data for the 12-month period reported
 705 on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is
 706 deemed submitted by the Department, shall be used:

707 (a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service
 708 as determined pursuant to Section 1315.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

749 (viii) The result shall be the "Available MRI Adjusted Procedures List."
 750

751 (2) After publication of the "Available MRI Adjusted Procedures List" resulting from (1) above, the
 752 data shall be updated to account for a) doctor commitments of available MRI adjusted procedures in
 753 subsequent MRI CON applications and b) MRI adjusted procedures used in subsequent MRI CON
 754 applications received in which applicants apply for fixed MRI services pursuant to Section 3(2).
 755

756 | **Section 4618. Procedures and requirements for commitments of available MRI adjusted**
 757 **procedures**

759 | Sec. 4618. (1) If one or more host sites on a mobile MRI service are located within the planning area
 760 of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile
 761 MRI service.
 762

763 (2)(a) At the time the application is submitted to the Department, the applicant shall submit a signed
 764 data commitment on a form provided by the Department in response to the applicant's letter of intent for
 765 each doctor committing available MRI adjusted procedures to that application for a new MRI unit that
 766 requires doctor commitments.

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

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

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

776 (c) If the required documentation for the doctor commitments submitted under this subsection is
 777 not submitted with the application on the designated application date, the application will be deemed
 778 submitted on the first applicable designated application date after all required documentation is received
 779 by the Department.
 780

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

784 (a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for
 785 | each specified MRI service, calculated pursuant to Section 4517, is being committed and specifies the
 786 CON application number for the MRI unit to which the data commitment is made. A doctor shall not be
 787 required to commit available MRI adjusted procedures from all MRI services to which his or her patients
 788 are referred for MRI services but only from those MRI services specified by the doctor in the data
 789 commitment form provided by the Department and submitted by the applicant in support of its application.

790 (b) A committing doctor certifies ownership interest, either direct or indirect, in the applicant entity.
791 Indirect ownership includes ownership in an entity that has ownership interest in the applicant entity. This
792 requirement shall not apply if the applicant entity is a group practice of which the committing doctor is a
793 member. Group practice means a group practice as defined pursuant to the provisions of 42 U.S.C.
794 1395nn (h)(4), commonly known as Stark II, and the Code of Federal Regulations, 42 CFR, Part 411,
795 published in the Federal Register on August 14, 1995, or its replacement.

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

799
800 (4)(a) The Department shall not consider a data commitment from a doctor for available MRI adjusted
801 procedures from a specific MRI service if the available MRI adjusted procedures from that specific MRI
802 service were used to support approval of an application for a new or additional MRI unit, pursuant to
803 Section 3, for which a final decision to approve has been issued by the Director of the Department until
804 either of the following occurs:

805 (i) The approved CON is withdrawn or expires.

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

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

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

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

817
818 (5) The Department shall not consider a data commitment from a committing doctor for available
819 MRI adjusted procedures from the same MRI service if that doctor has submitted a signed data
820 commitment, on a form provided by Department, for more than one (1) application for which a final
821 decision has not been issued by the Department. If the Department determines that a doctor has
822 submitted a signed data commitment for the same available MRI adjusted procedures from the same MRI
823 service to more than one CON application pending a final decision for a new fixed or mobile MRI unit or
824 additional mobile MRI unit pursuant to Section 3, the Department shall,

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

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

838
839 (6) The Department shall not consider any data commitment submitted by an applicant after the
840 date an application is deemed submitted unless an applicant is notified by the Department, pursuant to
841 subsection (5), that one or more committing doctors submitted data commitments for available MRI
842 adjusted procedures from the same MRI service. If an applicant is notified that one or more doctors' data

843 commitments will not be considered by the Department, the Department shall consider data commitments
 844 submitted after the date an application is deemed submitted only to the extent necessary to replace the
 845 data commitments not being considered pursuant to subsection (5).

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

848

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

851 (a) on or after the date an application is deemed submitted by the Department.

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

853

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

858

859 | **Section 4719. Lists published by the Department**

860

861 | Sec. 4719. (1) On or before May 1 and November 1 of each year, the Department shall publish the
 862 following lists:

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

865 (i) The number of actual MRI adjusted procedures;

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

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

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

871 (i) The number of available MRI adjusted procedures;

872 (ii) The name, address, and license number of each referring doctor, identified in Section

873 | 4517(1)(c)(v), whose patients received MRI services at that MRI service; and

874 (iii) The number of available MRI adjusted procedures performed on patients referred by each
 875 | referring doctor, identified in Section 4517(1)(c)(v), and if any are committed to an MRI service. This
 876 | number shall be calculated in accordance with the requirements of Section 4517(1). A referring doctor
 877 | may have fractional portions of available MRI adjusted procedures.

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

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

884

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

891

892 (3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported
 893 | data in compliance with the requirements of Section 4214, the Department shall indicate on both lists that

894 | the MRI service is in violation of the requirements set forth in Section **1214**, and no data will be shown for
 895 | that service on either list.

896

897 | **Section 1820. Effect on prior CON Review Standards; Comparative reviews**

898

899 | Sec. **1820**. (1) These CON review standards supersede and replace the CON Review Standards for
 900 | MRI Services approved by the CON Commission on **December 15, 2010** **September 22, 2011** and
 901 | effective **March 14** **November 21, 2011**.

902

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

904

905 | **Section 1921. Health Service Areas**

906

907 | Sec. **1921**. Counties assigned to each of the health service areas are as follows:

908

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

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947

Dickinson

Luce

Schoolcraft

APPENDIX A

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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

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
POSITRON EMISSION TOMOGRAPHY (PET) SERVICES STANDARDS
SUMMARY OF PROPOSED CHANGES

Highlights of Proposed Changes to Include Hybrid Modalities

Section 2 - Definitions

- 2(1)(q) – Added to the existing definition of “PET scanner” to include: FDA-Approved PET/Magnetic Resonance Imaging (MRI) scanner hybrids. If the FDA-Approved PET/MRI scanner hybrid will be used for MRI scans only in conjunction with the PET scan, then no separate CON is required for that MRI use.

Section 3- Requirements to initiate a PET scanner service

- 3(4)(d) – Added language to exempt a host site that is initiating FDA-approved PET/MRI scanner hybrid service(s) from having to cease operation as a host site so that it can continue to conduct PET only scans.

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR

POSITRON EMISSION TOMOGRAPHY (PET) SCANNER 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, replacement, expansion, or acquisition of PET scanner services, and the delivery of these services under Part 222 of the Code. Pursuant to Part 222 of the Code PET scanner services are 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) "Central service coordinator" means the legal entity that has operational responsibility for a mobile PET scanner service.

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

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

(d) "Existing PET scanner" means an operational PET scanner used to provide PET services on the date an application is submitted to the Department.

(e) "Existing PET scanner service" means an operational PET scanner service providing PET scanner services at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service on the date an application is submitted to the Department.

(f) "Health service area" or "HSA" means the groups of counties listed in Appendix A.

(g) "Hospital" means a health facility licensed under Part 215 of the Code.

(h) "Host site" means the geographic address at which a mobile PET scanner is authorized by CON to provide mobile PET scanner services.

(i) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C.1396 to 1396g and 1396i to 1396u.

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

(k) "Mobile PET scanner" means a PET scanner unit and transporting equipment operated by a central service coordinator that serves two or more host sites.

(l) "Mobile PET scanner network" means the route (i.e., all host sites) that the central service coordinator is authorized to serve under CON.

(m) "Patient visit" means a single session utilizing a PET scanner during which 1 or more PET procedures are performed.

(n) "Pediatric patient" means any patient less than 18 years of age.

(o) "PET procedure" means the acquisition of a single image or image sequence involving a single injection of tracer.

(p) "PET scan" means one (1) or more PET procedures performed during a single patient visit.

(q) "PET scanner" means an FDA-approved full or partial ring scanner or coincidence system that has a crystal at least 5/8-inch thick, techniques to minimize or correct for scatter and/or randoms, and digital detectors and iterative reconstruction. Further, the term does include PET/COMPUTED

55 **TOMOGRAPHY (CT) AND FDA-APPROVED PET/MAGNETIC RESONANCE IMAGING (MRI) scanner**
 56 **hybrids. If the PET/CT scanner HYBRID will be used for ~~computed tomography (CT)~~ scans only in**
 57 **conjunction with the PET scan, then no separate CON is required for that CT use. IF THE FDA-**
 58 **APPROVED PET/MRI SCANNER HYBRID WILL BE USED FOR MRI SCANS ONLY IN CONJUNCTION**
 59 **WITH THE PET SCAN, THEN NO SEPARATE CON IS REQUIRED FOR THAT MRI USE.** The term
 60 does not include single-photon emission computed tomography systems (SPECT), x-ray CT systems,
 61 magnetic resonance, ultrasound computed tomographic systems, gamma cameras modified for either
 62 non-coincidence or coincidence imaging, or similar technology.

63 (r) "PET scanner services" or "PET services" means either the utilization of a PET unit(s) at one
 64 site in the case of a fixed PET service or at each host site in the case of a mobile PET service.

65 (s) "SPECT" means single photon emission computed tomography.

66
 67 (2) The definitions in Part 222 shall apply to these standards.
 68

69 **Section 3. Requirements to initiate a PET scanner service**

70
 71 Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as
 72 applicable to the proposed project.

73
 74 (1) The applicant shall demonstrate the proposed site provides the following services and
 75 specialties:

76 (a) nuclear medicine services as documented by a certificate from the US Nuclear Regulatory
 77 Commission,

78 (b) single photon emission computed tomography (SPECT) services,

79 (c) computed tomography (CT) scanning services,

80 (d) magnetic resonance imaging (MRI) services,

81 (e) cardiac catheterization services,

82 (f) open heart surgery,

83 (g) thoracic surgery,

84 (h) cardiology,

85 (i) oncology,

86 (j) radiation oncology,

87 (k) neurology,

88 (l) neurosurgery, and

89 (m) psychiatry.

90
 91 (2) If the proposed site does not provide any of the services listed in subsection (1) on-site, the
 92 applicant shall provide written contracts or agreements with a hospital(s) located within the same
 93 planning area or 25-mile radius of the proposed site for the services not provided.
 94

95 (3) The applicant shall demonstrate the proposed site has an on-site source of
 96 radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals,
 97 the applicant shall provide a written contract or agreement that demonstrates a reliable supply of
 98 radiopharmaceuticals.
 99

100 (4) An applicant proposing to initiate a fixed PET scanner service with its first PET scanner shall
 101 project 2,600 PET data units or shall demonstrate all of the following:

102 (a) The applicant is currently a host site being served by one or more mobile PET scanner
 103 services.

104 (b) The applicant has performed:

105 (i) 1,700 PET equivalents in the most recent 12-month period verifiable by the Department for a
 106 host site in a metropolitan statistical area county, or

107 (ii) 1,500 PET equivalents in the most recent 12-month period verifiable by the Department for a
 108 host site in a rural or micropolitan statistical area county.

109 (c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a
 110 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a
 111 rural or micropolitan statistical area.

112 (d) The applicant agrees to cease operation as a host site and not become a host site for at least
 113 12 months from the date the fixed PET scanner becomes operational. **THIS REQUIREMENT SHALL**
 114 **NOT APPLY IF THE APPLICANT IS INSTALLING AN FDA-APPROVED PET/MRI SCANNER HYBRID.**
 115

116 (5) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET
 117 scanner shall project 2,100 PET data units.

118 (a) Of the 2,100 PET data units, the applicant shall project a minimum of 360 PET data units within
 119 a 20-mile radius of each proposed host site for planning area 1, or 240 PET data units per host site for
 120 any other planning area, for the proposed service.

121 (b) The application for the mobile PET scanner service is accompanied by at least two host site
 122 applications.

123 (c) Each applicant provides a route schedule for the proposed mobile PET scanner service.

124 (d) The applicant provides a draft contract for services between the proposed host site and central
 125 service coordinator.

126
 127 (6) An applicant proposing to initiate a host site on a proposed or existing mobile PET scanner
 128 service shall demonstrate the following:

129 (a) The applicant provides a proposed route schedule.

130 (b) The applicant provides a draft contract for services between the proposed host site and central
 131 service coordinator.

132 (c) The applicant has not initiated fixed PET scanner services under subsection 3(4) within the
 133 most recent 12-month period as of the date the application is submitted to the Department.

134 (d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates
 135 predominantly outside of Michigan shall demonstrate 240 PET data units from planning area 6.
 136

137 (7) An applicant proposing to initiate PET scanner services as an existing host site on a different
 138 mobile PET scanner service shall demonstrate the following:

139 (a) The applicant provides a proposed route schedule.

140 (b) The applicant provides a draft contract for services between the proposed host site and central
 141 service coordinator.

142 (c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the
 143 Department from an existing mobile PET scanner service at the existing host site.
 144

145 **Section 4. Requirements to replace an existing PET scanner(s) or PET scanner service**

146
 147 Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the
 148 service to a new site. An upgrade to software or components of an existing scanner does not constitute
 149 replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET
 150 scanner service shall demonstrate the following, as applicable to the proposed project.

151
 152 (1) An applicant proposing to replace a PET scanner(s) shall demonstrate each of the following:

153 (a) The replacement scanner(s) is the same type (fixed or mobile) as the scanner(s) to be
 154 replaced.

155 (b) The scanner(s) to be replaced is fully depreciated according to generally accepted accounting
 156 principles or either of the following:

157 (i) The existing scanner(s) poses a threat to the safety of the patients.

158 (ii) The replacement scanner(s) offers technological improvements that enhance quality of care,
 159 increase efficiency, and reduce operating costs and patient charges.

160 (c) The applicant agrees that the PET scanner(s) to be replaced will be removed from service on
 161 or before beginning operation of the replacement scanner(s).
 162

163 (2) An applicant proposing to replace a fixed PET scanner service to a new site shall demonstrate
164 the following:

165 (a) The proposed site is within a 10-mile radius of the existing site for a metropolitan statistical
166 area county or a 25-mile radius for a rural or micropolitan statistical area county.

167 (b) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the
168 most recent 12-month period verifiable by the Department.

169 (c) The existing fixed PET scanner service has been in operation for at least 36 months as of the
170 date of the application submitted to the Department.

171 **Section 5. Requirements to expand a PET scanner service**

172
173
174 Sec. 5. An applicant proposing to expand a PET scanner service shall demonstrate the following, as
175 applicable to the proposed project. This section does not apply to dedicated research, dedicated
176 pediatric, or positron emission mammography (PEM) scanners.

177
178 (1) An applicant proposing to add a fixed PET scanner(s) to an existing fixed PET scanner service
179 shall demonstrate the following:

180 (a) 1,900 PET equivalents were performed per existing and approved fixed PET scanner(s) in the
181 most recent 12-month period verifiable by the Department for an applicant in a metropolitan statistical
182 area county, or

183 (b) 1,700 PET equivalents were performed per existing and approved fixed PET scanner(s) in the
184 most recent 12-month period verifiable by the Department for an applicant in a rural or micropolitan
185 statistical area county.

186 (c) The additional PET scanner(s) shall be located at the same site.

187
188 (2) An applicant proposing to add a mobile PET scanner(s) to an existing mobile PET scanner
189 service shall demonstrate the following:

190 (a) 2,000 PET equivalents were performed per existing and approved mobile scanner(s) in the
191 most recent 12-month period verifiable by the Department for an applicant serving at least one existing
192 host site in a metropolitan statistical area county, or

193 (b) 1,800 PET equivalents were performed per existing and approved scanner(s) in the most
194 recent 12-month period verifiable by the Department for an applicant serving only host sites in rural or
195 micropolitan statistical area counties.

196
197 (3) An applicant proposing to add a fixed PET scanner to an existing fixed PET scanner service
198 that also receives mobile PET scanner services shall demonstrate the following:

199 (a) The applicant is currently a host site being served by one or more mobile PET scanner
200 services.

201 (b) The applicant has performed:

202 (i) An average of 1,900 pet equivalents for the host site and each of the existing and approved
203 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a
204 metropolitan statistical area county, or

205 (ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved
206 fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a rural or
207 micropolitan statistical area county.

208 (c) The applicant agrees to cease operation as a host site and not become a host site for at least
209 12 months from the date the fixed scanner becomes operational.

210 **Section 6. Requirements to acquire a PET scanner service or scanner(s)**

211
212
213 Sec. 6. Acquiring a PET scanner service and its scanner(s) means obtaining possession and
214 control by contract, ownership, lease, or other comparable arrangement and renewal of lease for an
215 existing fixed or mobile PET scanner. An applicant proposing to acquire a PET scanner service shall
216 demonstrate the following, as applicable to the proposed project.

217
218 (1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner
219 service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its
220 scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in
221 this section.

222
223 (2) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall
224 demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents
225 per scanner in the most recent 12-month period verifiable by the Department.

226
227 (3) An applicant proposing to acquire an existing host site shall demonstrate that the existing host
228 site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

229
230 (4) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall
231 demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

232

233 **Section 7. Requirements for a dedicated research fixed PET scanner**

234

235 Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for
236 exclusive research use shall demonstrate the following:

237

238 (1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or
239 more of the scans) for research purposes only.

240

241 (2) The dedicated research PET scanner shall operate under a protocol approved by the
242 applicant's Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR
243 46.

244

245 (3) The applicant has access to a cyclotron for accelerating charged particles to high energies by
246 means of electromagnetic fields.

247

248 (4) The proposed site can have no more than three dedicated research fixed PET scanners
249 approved under this Section.

250

251 **Section 8. Requirements for a dedicated pediatric PET scanner**

252

253 Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to
254 expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

255

256 (1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or
257 more of the scans) for patients under 18 years of age.

258

259 (2) The applicant shall demonstrate the existing site provided the following for the most recent
260 calendar year or a continuous 12-month period at the time the application is submitted to the Department:

261 (a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,

262 (b) at least 5,000 pediatric (< 18 years old) surgeries, and

263 (c) at least 50 new pediatric cancer cases on its cancer registry.

264

265 (3) The applicant shall have an active medical staff at the time the application is submitted to the
266 Department that includes physicians who are fellowship-trained in the following pediatric specialties:

267 (a) radiology (at least two staff members)

268 (b) anesthesiology

269 (c) cardiology

270 (d) critical care

- 271 (e) gastroenterology
- 272 (f) hematology/oncology
- 273 (g) neurology
- 274 (h) neurosurgery
- 275 (i) orthopedic surgery
- 276 (j) pathology
- 277 (k) pulmonology
- 278 (l) surgery
- 279 (m) neonatology

280

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

- 283 (a) bone marrow transplant program
- 284 (b) sedation program
- 285 (c) open heart program

286

287 (5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a
 288 PET scanner service with a dedicated pediatric fixed PET scanner.

289

290 (6) The proposed site can have no more than two dedicated pediatric fixed PET scanners
 291 approved under this section.

292

293 **Section 9. Requirements for a positron emission mammography (PEM) scanner**

294

295 Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service
 296 shall demonstrate the following, as applicable to the proposed project.

297

298 (1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall
 299 demonstrate the following:

- 300 (a) The applicant is certified through the American College of Radiology (ACR) as a Breast
 301 Imaging Center of Excellence (BICOE) at the time the application is submitted to the Department.
- 302 (b) The applicant has a fixed PET scanner service and has performed 1,000 PET equivalents per
 303 scanner at the site in the most recent 12-month period verifiable by the Department, or the applicant
 304 operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with
 305 a facility that has a fixed PET scanner service.

306 (c) The proposed site can have no more than one fixed PEM scanner approved under this section.

307

308 (2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner
 309 service shall demonstrate the following:

310 (a) The central service coordinator application for a mobile PEM scanner shall be accompanied by
 311 at least five (5) companion host site applications for initiation of mobile PEM scanner services. The
 312 proposed host sites have not received mobile PEM scanner services within the most recent 12-month
 313 period.

314 (b) The applicant has performed an average of 500 PET equivalents per scanner on the existing
 315 mobile PET network in the most recent 12-month period verifiable by the Department.

316 (c) The applicant provides a route schedule for the proposed mobile PEM scanner service.

317 (d) The applicant provides a draft contract for PEM services between the proposed host sites and
 318 central service coordinator.

319 (e) The proposed network can have no more than one mobile PEM scanner approved under this
 320 section.

321

322 (3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate
 323 mobile PEM scanner services as a host site shall demonstrate the following:

324 (a) The applicant is certified through the ACR as a BICOE site at the time the application is

325 submitted to the Department.

326 (b) The applicant has a fixed PET scanner site or host site and has performed 100 PET
327 equivalents in the most recent 12-month period verifiable by the Department, or the applicant operates a
328 comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that
329 has a fixed or mobile PET scanner service.

330 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

331 (d) The applicant provides a draft contract for PEM services between the host site and central
332 service coordinator.

333

334 (4) An applicant proposing to add an existing PEM scanner host site to an existing mobile PEM
335 scanner service shall demonstrate the following:

336 (a) The host site has performed mobile PEM scanner service within the most recent 12-month
337 period as of the date an application is submitted to the Department.

338 (b) The proposed site is certified through the ACR as a BICOE site at the time the application is
339 submitted to the Department.

340 (c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

341 (d) The applicant provides a draft contract for PEM services between the host site and central
342 service coordinator.

343

344 **Section 10. Requirement for Medicaid participation**

345

346 Sec. 10. An applicant shall provide verification of Medicaid participation. An applicant that is a new
347 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
348 to the Department within (6) months from the offering of services if a CON is approved.

349

350 **Section 11. Project delivery Requirements and terms of approval for all applicants**

351

352 Sec. 11. An applicant shall agree that, if approved, the PET scanner services shall be delivered in
353 compliance with the following terms of approval.

354

355 (1) Compliance with these standards.

356

357 (2) Compliance with the following quality assurance requirements:

358 (a) A PET scanner service shall be staffed so that screening of requests for and interpretation of
359 PET procedures will be carried out by a physician(s) with appropriate training and familiarity with the
360 appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be
361 examined. For purposes of evaluating this subsection, the Department shall consider it prima facie
362 evidence as to the training of the physician(s) if the physician is board certified or board qualified in
363 nuclear medicine or nuclear radiology. However, an applicant may submit, and the Department may
364 accept, other evidence that the physician(s) is qualified to operate the PET service/scanner. The
365 physician(s) must be on-site or available through telecommunication capabilities to participate in the
366 screening of patients for PET procedures and to provide other consultation services.

367 (b) The PET scanner service shall include the following personnel, employed directly or on a
368 contractual basis: a technologist with training in PET scanning and a physicist. The physicist must be
369 board certified or eligible for certification by the American Board of Radiology or an equivalent
370 organization.

371 (c) The PET scanner service shall have a physician on-site or immediately available to the PET
372 scanner service at all times when patients are undergoing PET procedures.

373 (d) The applicant maintains the services and specialties as set forth in Section 3(1) through 3(4).

374

375 (3) Compliance with the following access to care requirements:

376 (a) The PET scanner service shall accept referrals for PET scanner services from all appropriately
377 licensed practitioners.

378 (b) The PET scanner service shall participate in Medicaid at least 12 consecutive months within

379 the first two years of operation and continue to participate annually thereafter.

380 (c) The PET scanner service shall not deny PET scanner services to any individual based on
381 ability to pay or source of payment.

382 (d) The operation of and referral of patients to the PET scanner service shall be in conformance
383 with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

384

385 (4) Compliance with the following monitoring and reporting requirements:

386 (a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during
387 the second 12 months of operations, and annually thereafter. This requirement shall be waived during
388 review of applications under sections 4(1) and 6(4), if applicable. In meeting these requirements, an
389 applicant shall not include any PET scans performed on a PET scanner used exclusively for research
390 approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8,
391 or for a PEM scanner approved pursuant to Section 9.

392 (b) The PET scanner service shall participate in a data collection system established and
393 administered by the Department or its designee. The data may include, but are not limited to, clinical
394 scan data, annual budget and cost information, operating schedules, through-put schedules,
395 demographic and diagnostic information, and the volume of care provided to patients from all payor
396 sources. The applicant shall provide the required data on a separate basis for each separate and distinct
397 site, PET scanner, or PET scanner service as required by the Department, in a format established by the
398 Department. The Department may elect to verify the data through on-site review of appropriate records.

399 (c) The PET scanner service shall provide the Department with timely notice of the proposed
400 project implementation consistent with applicable statute and promulgated rules.

401

402 (5) Compliance with the following dedicated research PET scanner requirements, if applicable:

403 (a) The capital and operating costs relating to the dedicated research PET scanner shall be
404 charged only to a specific research account(s) and not to any patient or third- party payor.

405 (b) The dedicated research pet scanner shall not be used for any purposes other than as approved
406 by the Institutional Review Board.

407 (c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for
408 research purposes only.

409

410 (6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:

411 (a) The dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for
412 patients under 18 years of age.

413 (b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty
414 programs as set forth in the section.

415

416 (7) Compliance with the following PEM scanner requirements, if applicable:

417 (a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the
418 Department.

419

420 (8) Compliance with the following mobile PET scanner requirements, if applicable:

421 (a) The central service coordinator for a mobile PET scanner service shall notify the Department
422 30 days prior to dropping an existing host site.

423 (b) Each host site must have at least one physician who is board certified or board eligible in
424 nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for
425 establishing patient examination and infusion protocol, and providing for the interpretation of scans
426 performed.

427 (c) Each host site shall provide a properly prepared parking pad for the mobile PET scanner unit, a
428 waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an
429 enclosed canopy or an enclosed corridor).

430 (d) A mobile PET scanner service shall operate under a contractual agreement that includes the
431 provision of PET services at each host site on a regularly scheduled basis.

432

433 (9) The agreements and assurances required by this section shall be in the form of a certification
434 agreed to by the applicant or its authorized agent.
435

436 **Section 12. Methodology for computing the projected PET data units**
437

438 Sec. 12. An applicant being reviewed under Section 3 shall apply the methodology set forth in this
439 section in computing the projected number of PET data units.
440

441 (1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the
442 requirements of Section 13.

443 (a) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes
444 C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes (9590-9729), melanoma
445 (morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411,
446 C470 or C490 excluding C440-C444 (skin of head and neck), and additional codes approved by national
447 coverage determination]. Use the name "combined" for this grouping.

448 (b) Multiply the number resulting from the calculation in "combined" cancer cases identified in
449 subsection (1)(a) by 0.8, which is the estimated probability that a "combined" cancer case will require a
450 PET scan.

451 (c) Multiply the number resulting from the calculation in subsection (1)(b) by 2.5, which is the
452 estimated number of PET scans needed for each patient requiring a PET scan.
453

454 (2) Identify the number of diagnosis-specific new cancer cases documented in accord with the
455 requirements of section 13.

456 (a) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the
457 estimated probability that a breast cancer case will require a PET scan.

458 (b) Multiply the number resulting from the calculation in subsection (2)(a) by 1.0, which is the
459 estimated number of PET scans needed for each patient requiring a PET scan.
460

461 (3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the
462 requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic
463 cardiac catheterization will require a PET scan.
464

465 (4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41,
466 345.51, 345.61, 345.71, 345.81, or 345.91) identified in accord with the requirements of Section 16 by
467 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require
468 a PET scan. Multiply the number resulting from the calculation in subsection (3) by 1.0, which is the
469 estimated number of PET scans needed for each patient requiring a PET scan.
470

471 (5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the
472 total number of projected PET data units.
473

474 (6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is
475 proposing to serve only planning area 6 to determine the total number of projected PET data units.
476

477 (7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is
478 proposing to serve only planning area 5 to determine the total number of projected PET data units.
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Section 13. Commitment of diagnosis-specific new cancer cases

Sec. 13. An applicant proposing to use diagnosis-specific new cancer cases shall demonstrate all of the following:

(1) Only those cancer diagnoses identified in Section 12(1) and 12(2) shall be included.

(2) Each entity contributing diagnosis-specific new cancer case data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnosis-specific cancer cases being committed to the application and that states no current or future diagnosis-specific new cancer case data will be used in support of any other application for a PET unit for a period of five (5) years from the date of start of operations of the approved PET scanner service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(a) For fixed PET scanner services, the geographic location of each entity contributing diagnosis-specific new cancer case data is in the same planning area as the proposed PET service.

(b) For mobile PET scanner services, the geographic location of each entity contributing diagnosis-specific new cancer case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(c) No entity contributing diagnosis-specific new cancer case data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service.

(3) No entity currently operating or approved to operate a PET scanner service shall contribute diagnosis-specific new cancer cases.

(4) The Department may not consider a withdrawal of diagnosis-specific new cancer case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been issued unless the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 14. Documentation of diagnosis-specific new cancer case data

Sec. 14. An applicant required to document volumes of diagnosis-specific new cancer cases shall submit, as part of its application at the time it is submitted to the Department, documentation from the Division for Vital Records and Health Statistics verifying the number of diagnosis-specific new cancer cases provided in support of the application for the most recent calendar year for which verifiable data are available from the state registrar. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department. Diagnosis-specific new cancer case data supporting an application under these standards shall be submitted to the Division for Vital Records and Health Statistics using a format and media specified in instructions from the Department of Community Health.

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Section 15. Commitment and documentation of diagnostic cardiac catheterization data

Sec. 15. An applicant proposing to use diagnostic cardiac catheterization data shall demonstrate all of the following:

(1) Each entity contributing diagnostic cardiac catheterization data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of diagnostic cardiac catheterization cases (sessions) committed to the application and that states no current or future diagnostic cardiac catheterization data will be used in support of any other application for a PET unit for the duration of the PET service for which data are being committed for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

(a) For fixed PET scanner services, the geographic location of each entity contributing diagnostic cardiac catheterization data is in the same planning area as the proposed PET unit/service.

(b) For mobile PET scanner services, the geographic location of each entity contributing diagnostic cardiac catheterization case data in the planning area(s) for which the proposed PET service contains a proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical area counties or 25-mile radius for metropolitan statistical area counties.

(c) No entity contributing diagnostic cardiac catheterization data has previously committed or is committing data to another service that is less than five (5) years from the start of operations of that service.

(d) The diagnostic cardiac catheterization case data is from the most recently completed report(s) of the annual survey produced by the Department, and the contributing entity has CON approval to provide diagnostic cardiac catheterization services.

(2) No entity currently operating or approved to operate a PET scanner service shall contribute diagnostic cardiac catheterization case data.

(3) The Department may not consider a withdrawal of diagnostic cardiac catheterization case data during the 120-day application review cycle following the date on which the Department review of the application commences or after a proposed decision to approve the application has been denied unless the application is denied, withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing body resolution that contains the specific CON application number to which the data were originally committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in which the governing body authorized the withdrawal of the data, the governing body president's signature, and the date of the signature.

Section 16. Commitment and documentation of intractable epilepsy data

Sec. 16. An applicant proposing to use intractable epilepsy cases shall demonstrate all of the following:

(1) Each entity contributing intractable epilepsy data provides, as part of the application at the time it is submitted to the Department, a signed governing body resolution that identifies the number of intractable epilepsy cases committed to the application and that states no current or future intractable epilepsy case data will be used in support of any other application for a PET unit for the duration of the PET service for which the data are being committed for a period of five (5) years from the date of start of operations of the approved PET service for which data are being committed. If the required documentation for this subsection is not submitted with the application on the designated application date, the application will be deemed filed on the first applicable designated application date after all required documentation is received by the Department.

586 (a) For fixed PET scanner services, the geographic location of each entity contributing intractable
587 epilepsy case data is in the same planning area as the proposed PET unit/service.

588 (b) For mobile PET scanner services, the geographic location of each entity contributing intractable
589 epilepsy case data in the planning area(s) for which the proposed PET scanner service contains a
590 proposed host site or within a 75-mile radius of the proposed host site for rural and micropolitan statistical
591 area counties or 25-mile radius for metropolitan statistical area counties.

592 (c) No entity contributing intractable epilepsy case data has previously committed or is committing
593 data to another service that is less than five (5) years from the start of operations of that service.

594 (d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base
595 (MIDB) available to the Department.

596

597 (2) No entity currently operating or approved to operate a scanner shall contribute intractable
598 epilepsy case data.

599

600 (3) The Department may not consider a withdrawal of intractable epilepsy case data during the
601 120-day application review cycle following the date on which the Department review of the application
602 commences or after a proposed decision to approve the application unless the application is denied,
603 withdrawn, or expired. The withdrawal must be submitted to the Department in the form of a governing
604 body resolution that contains the specific CON application number to which the data were originally
605 committed, the legal applicant entity, the committing entity, the type of data, the date of the meeting in
606 which the governing body authorized the withdrawal of the data, the governing body president's
607 signature, and the date of the signature.

608

609 **Section 17. Methodology for computing PET equivalents**

610

611 Sec. 17. PET equivalents shall be calculated as follows:

612

TABLE 1	
PET EQUIVALENTS	
Scan Category	Weight
Simple ¹	0.75
Standard ²	1.0
Complex ³	1.5
¹ Brain and single cardiac scans. ² Mid-skull to mid-thigh scans. ³ Inpatient, radiation treatment when patient position device is used, cardiac rest/stress perfusion and metabolism, standard study with additional limited scan, pediatric, and total body scans.	

613

614 **Section 18. Department inventory of PET scanners**

615

616 Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner
617 services annually.

618

619 **Section 19. Comparative reviews; effect on prior planning policies**

620

621 Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative
622 review. These CON review standards supersede and replace the CON standards for PET scanner
623 services approved by the CON Commission on **December 12, 2006** **September 22, 2011** and effective
624 **March 8, 2007** **November 21, 2011**.

625

APPENDIX A

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Counties assigned to each health service area are as follows:

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

APPENDIX B

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Counties by Health service areas assigned to each planning area are as follows:

PLANNING AREA 1**COUNTIES**

HSA 1	Livingston	Monroe	St. Clair
	Macomb	Oakland	Washtenaw
	Wayne		

PLANNING AREA 2

HSA 2	Clinton	Hillsdale	Jackson
	Eaton	Ingham	Lenawee
HSA 3	Barry	Calhoun	St. Joseph
	Berrien	Cass	Van Buren
	Branch	Kalamazoo	

PLANNING AREA 3

HSA 4	Allegan	Mason	Newaygo
	Ionia	Mecosta	Oceana
	Kent	Montcalm	Osceola
	Lake	Muskegon	Ottawa

PLANNING AREA 4

HSA 5	Genesee	Lapeer	Shiawassee
HSA 6	Arenac	Huron	Roscommon
	Bay	Iosco	Saginaw
	Clare	Isabella	Sanilac
	Gladwin	Midland	Tuscola
	Gratiot	Ogemaw	

PLANNING AREA 5

HSA 7	Alcona	Crawford	Missaukee
	Alpena	Emmet	Montmorency
	Antrim	Gd Traverse	Oscoda
	Benzie	Kalkaska	Otsego
	Charlevoix	Leelanau	Presque Isle
	Cheboygan	Manistee	Wexford

PLANNING AREA 6

HSA 8	Alger	Gogebic	Mackinac
	Baraga	Houghton	Marquette
	Chippewa	Iron	Menominee
	Delta	Keweenaw	Ontonagon
	Dickinson	Luce	Schoolcraft

APPENDIX C

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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

CERTIFICATE OF NEED
1st Quarter Compliance Report to the CON Commission
 October 1, 2011 through September 30, 2012 (FY 2012)

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

MCL 333.22247

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

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

(a) Revoke or suspend the certificate of need.

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

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

(d) Request enforcement action under section 22253.

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

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

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

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

Activity Report

Follow Up: In accordance with Administrative Rules 325.9403 and 325.9417, the Department tracks approved Certificates of Need to determine if proposed projects have been implemented in accordance with Part 222. By rule, applicants are required to either implement a project within one year of approval or execute an enforceable contract to purchase the covered equipment or start construction, as applicable. In addition, an applicant must install the equipment or start construction within two years of approval.

Activity	1 st Quarter	Year-to-Date
Approved projects requiring 1-year follow up	113	113
Approved projects contacted on or before anniversary date	77	77
Approved projects completed on or before 1-year follow up	68%	68%
CON approvals expired due to noncompliance with Part 222	12	12
Total follow up correspondence sent	177	177
Total approved projects still ongoing	327	

Compliance Report to CON Commission
FY 2012 – 1st Quarter Report
Page 2

Compliance: In accordance with Section 22247 and Rule 9419, the Department performs compliance checks on approved and operational Certificates of Need to determine if projects have been implemented, or if other applicable requirements have been met, in accordance with Part 222 of the Code.

The Department has taken the following actions:

- Opened compliance investigation of temp MRI unit operating beyond CON approved timeline.
- After a statewide review of the Open Heart Surgery data based on the 2010 Annual Survey, the Department opened 6 compliance investigations of Open Heart Surgery programs not meeting the approved volume requirement. A brief overview of the OHS data is as follows:
 - 300 Cases per year – there are 10 programs required to meet 300 cases per year.
 - Two (2) programs met the volume requirement
 - Four (4) programs did not meet the volume requirement, all 4 were not eligible for a volume check in 2010
 - One (1) program did not meet the volume requirement and is under a settlement agreement from previous compliance action
 - Three (3) programs did not meet the volume requirement and compliance investigations have been initiated
 - 200 Cases per year – there are 10 programs required to meet 200 cases per year.
 - Seven (7) programs met the volume requirement
 - Three (3) programs did not meet the volume requirement and compliance investigations have been initiated
 - Grandfathered – there are 13 programs with no volume requirement.
 - Ten (10) programs performed more than 300 cases
 - Two (2) programs performed fewer than 300 cases, but more than 200 cases
 - One (1) program performed fewer than 200 cases
- After a statewide review of the Psychiatric Beds and Services data based on the 2010 Annual Survey, the Department opened 14 compliance investigations of adult and child/adolescent psychiatric programs not meeting the approved occupancy rates. A brief overview of the psychiatric services data is as follows:
 - 60% average occupancy rate for adult beds and 40% average occupancy rate for child/adolescent beds – there are 16 adult programs and 4 child/adolescent programs operating under these requirements.
 - Fourteen (14) adult programs met the average occupancy rate
 - Two (2) adult programs did not meet the average occupancy rate, both programs were not eligible for a compliance check in 2010
 - Four (4) child/adolescent programs met the average occupancy rate
 - 85% average occupancy rate for adult beds and 75% average occupancy rate for child/adolescent beds – there are 11 adult programs and 2 child/adolescent programs operating under these requirements.

- One (1) adult program met the average occupancy rate
- Ten (10) adult programs did not meet the average occupancy rate and compliance investigations have been initiated
- One (1) child/adolescent program met the average occupancy rate
- One (1) child/adolescent program did not meet the average occupancy rate and a compliance investigation has been initiated
- 85% average occupancy rate for both adult and child/adolescent beds – there are 5 adult programs and 1 child/adolescent program operating under these requirements.
 - One (1) adult program met the average occupancy rate
 - Four (4) adult program did not meet the average occupancy rate and compliance investigations have been initiated
 - One (1) child/adolescent program did not meet the average occupancy rate and a compliance investigation has been initiated
- No Volume Requirements – there are 12 adult programs and 1 child/adolescent program approved under standards without an occupancy rate requirement.
 - Nine (9) adult programs with occupancy rate below 59.9%
 - Three (3) adult programs with occupancy rate between 60% and 84.9%
 - One (1) child/adolescent program with an occupancy rate between 60% and 84.9%
- Grandfathered – there are 17 adult programs and 2 child/adolescent programs with no occupancy rate requirements.
 - Five (5) adult programs with occupancy rate below 59.9%
 - Eleven (11) adult programs with occupancy rate between 60% and 84.9%
 - One (1) adult program with an occupancy rate above 85%
 - Two (2) child/adolescent programs with occupancy rate below 59.9%

CERTIFICATE OF NEED
1st Quarter Program Activity Report to the CON Commission
 October 1, 2011 through September 30, 2012 (FY 2012)

This quarterly report is designed to assist the CON Commission in monitoring and assessing the operations and effectiveness of the CON Program Section in accordance with Section 22215(1)(e) of the Public Health Code, 1978 PA 368.

Measures

Administrative Rule R325.9201 requires the Department to process a Letter of Intent within 15 days upon receipt of a Letter of Intent.

Activity	1 st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	114	N/A	114	N/A
Letters of Intent Processed within 15 days	114	100%	114	100%
Letters of Intent Processed Online	114	100%	114	100%

Administrative Rule R325.9201 requires the Department to request additional information from an applicant within 15 days upon receipt of an application, if additional information is needed.

Activity	1 st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	97	N/A	97	N/A
Applications Processed within 15 Days	97	100%	97	100%
Applications Incomplete/More Information Needed	51	53%	51	53%
Applications Filed Online*	90	99%	90	92%
Application Fees Received Online*	19	21%	19	20%

* Number/percent is for only those applications eligible to be filed online, potential comparative and comparative applications are not eligible to be filed online, and emergency applications have no fee.

Administrative rules R325.9206 and R325.9207 require the Department to issue a proposed decision for completed applications within 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

Activity	1 st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	35	100%	35	100%
Substantive Applications	22	100%	22	100%
Comparative Applications	0	N/A	0	N/A

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	1 st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	1	100%	1	100%
Decisions Issued within 10 workings Days	1	100%	1	100%

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	1 st Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	18	100%	18	100%

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

Activity	1 st Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	1 st Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	46	N/A	46	N/A
FOIA Requests Processed on Time	46	100%	46	100%
Number of Applications Viewed Onsite	2	N/A	2	N/A

FOIA – Freedom of Information Act.

**MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED PROGRAM
ANNUAL ACTIVITY REPORT**

**October 2010 through September 2011
(FY2011)**

**Michigan Department of
Community Health**



*Rick Snyder, Governor
Olga Dazzo, Director*

<http://www.michigan.gov/con>

MDCH is an Equal Opportunity Employer, Services and Program Provider.

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EXECUTIVE SUMMARY

One of the Michigan Department of Community Health's ("MDCH" or "Department") duties under Part 222 of the Public Health Code, MCL 333.22221(b), is to report to the Certificate of Need ("CON") Commission annually on the Department's performance under this Part. This is the Department's 23rd report to the Commission and covers the period beginning October 1, 2010 through September 30, 2011 ("FY 2011"). Data contained in this report may differ from prior reports due to updates subsequent to each report's publishing date.

Administration

The Department through its Planning and Access to Care Section provides support for the CON Commission ("Commission") and its Standards Advisory Committees ("SAC"). The Commission is responsible for setting review standards and designating the list of covered services. The Commission may utilize a SAC to assist in the development of proposed CON review standards, which consists of a 2/3 majority of experts in the subject area. Further, the Commission, if determined necessary, may submit a request to the Department to engage the services of consultants or request the Department to contract with an organization for professional and technical assistance and advice or other services to assist the Commission in carrying out its duties and functions.

The Department through its CON Evaluation Section manages and reviews all incoming letters of intent, applications and amendments. These functions include determining if a CON is required for a proposed project as well as providing the necessary application materials when applicable. In addition, the Section is responsible for monitoring implementation of approved projects as well as the long term compliance with the terms and conditions of approvals.

During FY 2011, the Evaluation Section continued its work to move the program into the digital age. Staff continued to improve the online application and management information system (CON e-Serve). The first module was released in 2006. Today, the vast majority of Letters of Intent, CON applications, and amendments are filed online.

In April 2008, the Section released its first Michigan Atlas of Licensed Health Facilities in collaboration with the Michigan State University Department of Geography. This fiscal year many new maps were created including 30-60 minute service level health care access maps for all CON covered services. This map allows us to view where service is largely available and where there is service need in our State.

The utilization data comes from an online survey system developed in collaboration with the Southeastern Michigan Health Association (SEMHA). This online system has greatly reduced the amount of Department staff time necessary to collect annual utilization data from approved facilities while assuring timely preparation of data reports for the Commission for policy and standards development. We have improved the quality of data this fiscal year by conducting extensive data checks, and follow ups on submitted data.

In this fiscal year we have continued to make enhancements to data quality criteria within the online MRI Validator, which verifies and stores the MRI utilization data. We have improved timeliness of data submissions through increased monitoring and achieved 100% submission rates. In addition, the application module, which processes new applications and verifies physician commitments, has been fully developed and is now functional in the online MRI Validator.

These four initiatives have greatly increased the availability of CON related information and data to improve and streamline the review process, better inform policy makers, and enhance community knowledge about Michigan's health care system.

CON Required

In accordance with MCL 333.22209, a person or entity is required to obtain a certificate of need, unless elsewhere specified in Part 222, for any of the following activities:

- a) Acquire an existing health facility or begin operation of a health facility.
- b) Make a change in the bed capacity of a health facility.
- c) Initiate, replace, or expand a covered clinical service.
- d) Make a covered capital expenditure.

CON Application Process

To apply for a CON, the following steps must be completed:

- Letter of Intent filed and processed prior to submission of an application,
- CON application filed on appropriate date as defined in the CON Administrative Rules,
- Application reviewed by the Evaluation Section,
- Issuance of Proposed Decision by the Policy and Planning Administration,
 - Appeal if applicant disagrees with the Proposed Decision issued,
- Issuance of the Final Decision by the MDCH Director.

There are three types of CON review: nonsubstantive, substantive individual, and comparative. The Administrative Rules for the CON program establish time lines by which the Department must issue a proposed decision on each CON application. The proposed decision for a nonsubstantive review must be issued within 45 days of the date the review cycle begins, 120 days for substantive individual, and 150 days for comparative reviews.

FY 2011 in Review

In FY 2011, there were 441 Letters of Intent received resulting in 318 applications filed for CON review and approval, including two (2) emergency applications. In addition, the Department received 83 amendments to previously approved applications. In total, the Department approved 324 proposed projects resulting in approximately \$4,315,769,812 of new capital expenditures into Michigan's healthcare system.

As required by Administrative Rules, the Department was timely in processing Letters of Intent, pending CON applications and issuing its decisions on pending applications. These measures along with the other information contained in this report aid the Commission in its duties as set forth in Part 222 of the Public Health Code.

The CON Commission also reviewed and revised three (3) different review standards: Bone Marrow Transplantation (BMT) Services, Magnetic Resonance Imaging (MRI) Services, and Nursing Home and Hospital long-Term Care Unit Beds and Addendum for special Population Groups (NH-HLTCU).

This report is filed by the Department in accordance with MCL 333.2221(f). The report presents information about the nature of these CON applications and decisions as well as the Commission's actions during the reporting period. Several tables include benchmarks for timely processing of applications and issuing decisions as set forth in the CON Administrative Rules. Note that the data presented represents some applications that were carried over from last fiscal year while others may be carried over into next fiscal year.

HISTORICAL OVERVIEW OF MICHIGAN'S CERTIFICATE OF NEED PROGRAM

- 1972 Legislation was introduced in the Michigan legislature to enact the Certificate of Need (CON) program. The Michigan CON program became effective on April 1, 1973.
- 1974 Congress passed the National Health Planning and Resources Development Act (PL 93-641) including funding incentives that encouraged states to establish a CON program. The purpose of the act was to facilitate recommendations for a national health planning policy. It encouraged state planning for health services, manpower, and facilities. And, it authorized financial assistance for the development of resources to implement that policy. Congress repealed PL 93-641 and certificate of need in 1986. At that time, federal funding of the program ceased and states became totally responsible for the cost of maintaining CON.
- 1988 The goal of the program is to balance cost, quality, and access issues and ensure that only needed services are developed in Michigan. However, the program's ability to meet these goals was significantly diluted by the fact that most application denials were overturned in the courts. In order to address this, Michigan's CON Reform Act of 1988 was passed to develop a clear, systematic standards development process and reduce the number of services requiring a CON.
- Prior to the 1988 CON Reform Act, the Department found that the program was not serving the needs of the state optimally. It became clear that many found the process to be excessively unclear and unpredictable. To strengthen CON, the 1988 Act established a specific process for developing and approving standards used in making CON decisions. The review standards establish how the need for a proposed project must be demonstrated. Applicants know before filing an application what specific requirements must be met.
- The Act also created the CON Commission. The CON Commission, whose membership is appointed by the Governor, is responsible for approving CON review standards. The Commission also has the authority to revise the list of covered clinical services subject to CON review. However, the CON sections inside the Department are responsible for day-to-day operations of the program, including supporting the Commission and making decisions on CON applications consistent with the review standards.
- 1993 Amendments to the 1988 Act required ad hoc committees to be appointed by the Commission to provide expert assistance in the formation of the review standards.
- 2002 Amendments to the 1988 Act expanded the CON Commission to 11 members, eliminated the previous ad hoc committees, and established the use of standard advisory committees or other private consultants/organizations for professional and technical assistance.
- Present* The CON program is now more predictable so that applicants can reasonably assess, before filing an application, whether a project will be approved. As a result, there are far fewer appeals of Department decisions. Moreover, the 1988 amendments appear to have reduced the number of unnecessary applications, i.e., those involving projects for which a need cannot be demonstrated.

The standards development process now provides a public forum for consideration of cost, quality, and access and involves organizations representing purchasers, payers, providers, consumers, and experts in the subject matter. The process has resulted in CON review standards that are legally enforceable, while assuring that standards can be revised promptly in response to the changing health-care environment.

ADMINISTRATION OF THE CERTIFICATE OF NEED PROGRAM

Commission The Commission is an 11-member body. The Commission, appointed by the Governor and confirmed by the Senate, is responsible for approving CON review standards used by the Department to make decisions on individual CON applications. The Commission also has the authority to revise the list of covered clinical services subject to CON review. Appendix I is a list of the CON commissioners for FY2011.

NEWTAC The New Technology Advisory Committee is a standing committee responsible for advising the Commission on the new technologies, including medical equipment and services that have not yet been approved by the federal Food and Drug Administration for commercial use.

SAC Standards Advisory Committees (“SAC”) may be appointed by and report to the CON Commission. The SACs advise the Commission regarding creation of, or revisions to, the standards. The committees are composed of a 2/3 majority of experts in the subject matter and include representatives of organizations of health-care providers, professionals, purchasers, consumers, and payers.

MDCH The Michigan Department of Community Health is responsible for administering the CON program and providing staffing support for the Commission. This includes promulgating applicable rules, processing and rendering decisions on applications, and monitoring and enforcing the terms and conditions of approval. These functions are within the Bureau of Policy and Planning Administration.

Policy Section The Policy Section within the Bureau provides professional and support staff assistance to the Commission and its committees in the development of new and revised standards. Staff support includes researching issues related to specific standards, preparing draft standards, and performing functions related to both Commission and committee meetings.

Evaluation Section The Evaluation Section also within the Bureau has operational responsibility for the program, including providing assistance to applicants prior to and throughout the CON process. The section is responsible for reviewing all Letters of Intent and applications as prescribed by the Administrative Rules. Staff determines if a proposed project requires a CON. If a CON is required, staff identifies the appropriate application forms for completion by the applicant and submission to the Department. The application review process includes the assessment of each application for compliance with all applicable statutory requirements and CON review standards, and preparation of a Program and Finance report documenting the analysis and findings. These findings are used by the Director to make a final decision to approve or deny a project.

In addition to the application reviews, the Section reviews requests for amendments to approved CONs as allowed by the Rules. Amendment requests involve a variety of circumstances, including changes in how an approved project is financed and authorization for cost overruns. The Section is also responsible for monitoring the implementation of approved projects as well as the long-term compliance with the terms and conditions of approvals.

The Section also provides the Michigan Finance Authority (“MFA”) information when healthcare entities request financing through MFA bond issues and Hospital Equipment Loan Program (“HELP”) loans. This involves advising on whether a CON is required for the item(s) that will be bond financed.

CERTIFICATE OF NEED PROCESS

The following discussion briefly describes the steps an applicant follows in order to apply for a Certificate of Need.

<i>Letter of Intent</i>	An applicant must file an LOI with the Department and, if applicable, the regional CON review agency. The CON Evaluation Section identifies for an applicant all the necessary application forms required based on the information contained in the LOI.
<i>Application</i>	An applicant files on or before the designated application date an application with the Department and, if applicable, the regional review agency. The Evaluation Section reviews an application to determine if it is complete. If not complete, additional information is requested. The review cycle starts after an application is deemed complete or received in accordance with the Administrative Rules.
<i>Review Types and Time Frames</i>	There are three review types: nonsubstantive, substantive individual and comparative. Nonsubstantive reviews involve projects such as replacement of covered equipment or changes in ownership that do not require a full review. Substantive individual reviews involve projects that require a full review but are not subject to comparative review as specified in the applicable CON review standards. Comparative reviews involve situations where two or more applicants are competing for a resource limited by a CON review standard, such as hospital and nursing home beds. The maximum review time frames for each review type, from the date an application is deemed complete or received until a proposed decision is issued, are: 45 days for nonsubstantive, 120 for substantive individual and 150 days for comparative reviews. The comparative review time frame includes an additional 30-day period for determining if a comparative review is necessary. Whenever this determination is made, the review cycle begins for comparative reviews.
<i>Review Process</i>	The Evaluation Section reviews the application. Each application is reviewed separately unless part of a comparative review. Each application review includes a program and finance report documenting the Department's analysis and findings of compliance with the statutory review criteria, as set forth in Section 22225 of the public health code and the applicable CON review standards.
<i>Proposed Decision</i>	The Policy and Planning Administration in which the Evaluation Section resides issues a proposed decision to the applicant within the required time frame. This decision is binding unless reversed by the Department Director or appealed by the applicant. The applicant must file an appeal within 15 days of receipt of the proposed decision if the applicant disagrees with the proposed decision or its terms and conditions. In the case of a comparative review, a single decision is issued for all applications in the same comparative group.
<i>Final Decision</i>	If the proposed decision is not appealed, a final decision is made by the Director of the Department of Community Health in accordance with MCL 333.22231. If a hearing on the proposed decision is requested, the final decision by the Director is not issued until completion of the hearing and any filing of exceptions to the proposed decision by the Michigan Administrative Hearing System. A final decision by the Director may be appealed to the applicable circuit court.

LETTERS OF INTENT

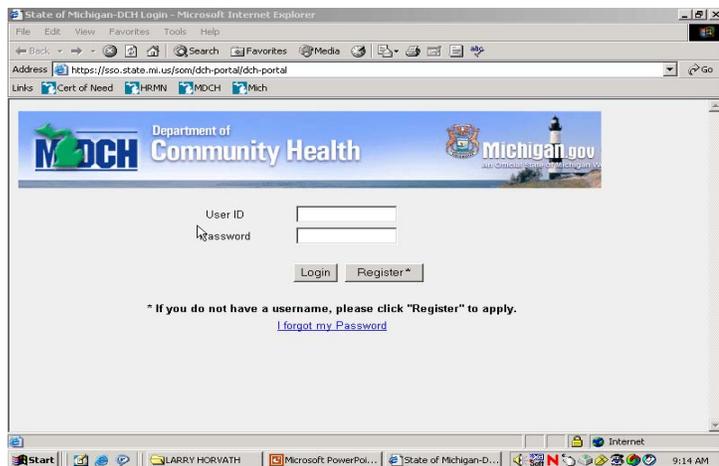
The CON Administrative Rules, specifically Rule 9201, provides that Letters of Intent (“LOIs”) must be processed within 15 days of receipt. Processing an LOI includes entering data in the management information system, verifying historical facility information, and obtaining proof of authorization to do business in Michigan. This information determines the type of review for the proposed project, and the Department then notifies the applicant of applicable application forms to be completed.

Table 1 provides an overview of the number of Letters of Intent received and processed in accordance with the above-referenced Rule.

TABLE 1			
LETTERS OF INTENT RECEIVED AND PROCESSED WITHIN 15 DAYS			
FY2007 - FY2011			
	LOIs Received	Processed within 15 Days	Percent Processed within 15 Days
FY2007	582	579	99%
FY2008	521	517	99%
FY2009	335	333	99%
FY2010	435	435	100%
FY2011	441	438	99%

In FY 2010, all LOIs were processed in a timely manner as required by Rule and available for public viewing on the online application system. The online system allows for faster processing of LOIs and subsequent applications by the Evaluation Section, as well as modifying these applications by applicants when needed.

In 2006, Michigan became the first state to have an online application and information system. Today 100% of all Letters of Intent and more than 95% of all applications are submitted on-line.



TYPES OF CERTIFICATE OF NEED APPLICATION REVIEWS

The Administrative Rules also establish three types of project reviews: nonsubstantive, substantive, and comparative. The Rules specify the time frames by which the Bureau must issue its proposed decision related to a CON application. The time allowed varies based on the type of review.

Nonsubstantive

Nonsubstantive reviews involve projects that are subject to CON review but do not warrant a full review. The following describes type of projects that are potentially eligible for nonsubstantive review:

- Acquire an existing health facility;
- Replace a health facility within the replacement zone and below the covered capital expenditure;

- Add a host site to an existing mobile network/route that does not require data commitments;
- Replace or upgrade a covered clinical equipment; or
- Acquire or relocate an existing freestanding covered clinical service.

The Rules allow the Bureau up to 45 days from the date an application is deemed complete to issue a proposed decision. Reviewing these types of proposed projects on a nonsubstantive basis allows an applicant to receive a decision in a timely fashion while still being required to meet current CON requirements, including quality assurance standards.

Substantive Individual

Substantive individual review projects require a full review but are not subject to comparative review and not eligible for nonsubstantive review. An example of a project reviewed on a substantive individual basis is the initiation of a covered clinical service such as computed tomography (CT) scanner services. The Bureau must issue its proposed decision within 120 days of the date a substantive individual application is deemed complete or received.

Comparative

Comparative reviews involve situations where two or more applications are competing for a limited resource such as hospital or nursing home beds. A proposed decision for a comparative review project must be issued by the Bureau no later than 120 days after the review cycle begins. The cycle begins when the determination is made that the project requires comparative review. According to the Rules, the Department has the additional 30 days to determine if, in aggregate, all of the applications submitted on a window date exceed the current need. A comparative window date is one of the three dates during the year on which projects subject to comparative review must be filed. Those dates are the first working day of February, June, and October.

Section 22229 established the covered services and beds that were subject to comparative review. Pursuant to Part 222, the CON Commission may change the list subject to comparative review.

Figure 1 delineates services/beds subject to comparative review.

<i>FIGURE 1: Services/Beds Subject to Comparative Review in FY2011</i>	
Neonatal Intensive Care Unit	Nursing Home Beds for Special Population Groups
Hospital Beds	Psychiatric Beds
Hospital Beds (HIV)	Transplantations (excluding Pancreas)
Nursing Home/HLTCU Beds	

Note: See individual CON review standards for more information.

Table 2 shows the number of applications received by the Department by review type.

TABLE 2 <i>APPLICATIONS RECEIVED BY REVIEW TYPE</i> <i>FY2007 - FY2011</i>					
	FY2007	FY2008	FY2009	FY2010	FY2011
<i>Nonsubstantive*</i>	170	183	115	144	166
<i>Substantive Individual</i>	135	165	78	131	122
<i>Comparative</i>	15	37	26	22	28
TOTALS	320	385	219	297	316

Note: Does not include emergency CON applications.

*Includes swing bed applications.

Table 3 provides a summary of applications received and processed in accordance with Rule 9201. The Rule requires the Evaluation Section to determine if additional information is needed within 15 days of receipt of an application. Processing of applications includes: updating the management information system, verifying submission of required forms, and determining if other information is needed in response to applicable Statutes and Standards.

TABLE 3 <i>APPLICATIONS RECEIVED AND PROCESSED WITHIN 15 DAYS</i> <i>FY2007 - FY2011</i>					
	FY2007	FY2008	FY2009	FY2010	FY2011
Applications Received	320	388	220	303	318
Processed within 15 Days	320	387	219	303	315
Percent Processed within 15 Days	100%	100%	100%	100%	99%

Note: Includes emergency CON and swing bed applications.

Table 4 provides an overview of the average number of days taken by the Evaluation Section to complete reviews by type.

TABLE 4 <i>AVERAGE NUMBER OF DAYS IN REVIEW CYCLE BY REVIEW TYPE</i> <i>FY2007- FY2011</i>					
	FY2007	FY2008	FY2009	FY2010	FY2011
Nonsubstantive	37	40	38	37	31
Substantive Individual	126	116	113	113	110
Comparative	132	151	260*	153	117

Note: Average review cycle accounts for extensions requested by applicants.

* In FY 2009, the average days for comparative review applications increased substantially due to multiple revisions to the nursing homes review standards.

EMERGENCY CERTIFICATES OF NEED

Table 5 shows the number of emergency CONs issued. The Department is authorized by Section 22235 of the Public Health Code to issue emergency CONs when applicable. Rule 9227 permits up to 10 working days to determine if an emergency application is eligible for review under Section 22235. Although it is not required by Statute, the Bureau attempts to issue emergency CON decision to the Director for final review and approval within 10 days from receipt of request.

TABLE 5 <i>EMERGENCY CON DECISIONS ISSUED</i> <i>FY2007 - FY2011</i>					
	FY2007	FY2008	FY2009	FY2010	FY2011
Emergency CONs Issued	5	3	1	4	2
Percent Issued within 10 Working Days	100%	67%	100%	100%	100%

PROPOSED DECISIONS

Part 222 establishes a 2-step decision making process for CON applications that includes both a proposed decision and final decision. After an application is deemed complete and reviewed by the Evaluation Section, a proposed decision is issued by the Bureau to the applicant and the Department Director according to the time frames established in the Rules.

Table 6 shows the number of proposed decisions by type issued within the applicable time frames set forth in the Administrative Rules 325.9206 and 325.9207: 45 days for nonsubstantive, 120 days for substantive, and 150 days for comparative reviews.

TABLE 6 PROPOSED DECISIONS ISSUED FY2007- FY2011						
	Nonsubstantive		Substantive		Comparative	
	Issued	Within 45 days	Issued	Within 120 days	Issued	Within 150 days
<i>FY2007</i>	152	99%	162	98%	15	100%
<i>FY2008</i>	176	99%	145	99%	6	50%
<i>FY2009</i>	130	100%	114	99%	20	90%
<i>FY2010</i>	123	99%	103	100%	17	100%
<i>FY2011</i>	180	100%	129	100%	34	100%

Table 7 compares the number of proposed decisions by decision type made.

TABLE 7 COMPARISON OF PROPOSED DECISIONS BY DECISION TYPE FY2007- FY2011					
	Approved	Approved w/ Conditions	Disapproved	Percent Disapproved	TOTAL
<i>FY2007</i>	263	60	10	3%	333
<i>FY2008</i>	282	50	5	2%	337
<i>FY2009</i>	240	25	19	7%	284
<i>FY2010</i>	212	27	7	3%	246
<i>FY2011</i>	298	30	15	6%	343

Note: Not all proposed decisions issued in a given year will have a final decision in the same year.

If a proposed decision is disapproved, an applicant may request an administrative hearing that suspends the time frame for issuing a final decision. After a proposed disapproval is issued, an applicant may also request that the Department consider new information. The Administrative Rules allow an applicant to submit new information in response to the areas of noncompliance identified by the Department's analysis of an application and the applicable statutory requirements to satisfy the requirements for approval.

FINAL DECISIONS

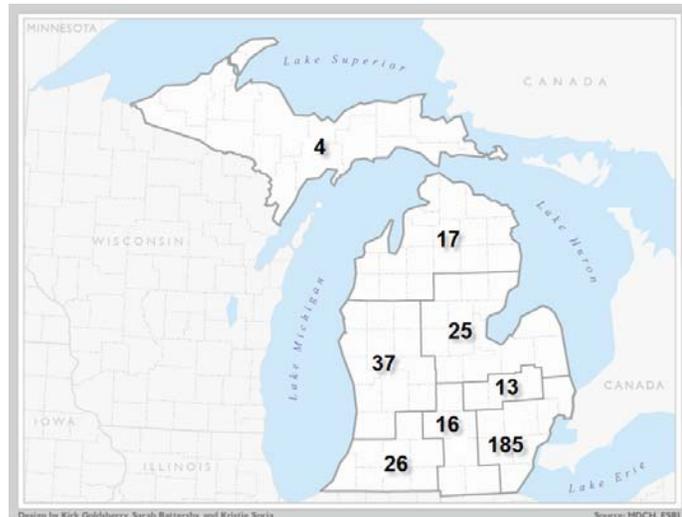
The Director issues a final decision on a CON application following either a proposed decision or the completion of a hearing, if requested, on a proposed decision. Pursuant to Section 22231(1) of the Public Health Code, the Director may issue a decision to approve an application, disapprove an application, or approve an application with conditions or stipulations. If an application is approved with conditions, the conditions must be explicit and relate to the proposed project. In addition, the conditions must specify a time period within which the conditions shall be met, and that time period cannot exceed one year after the date the decision is rendered. If approved with stipulations, the requirements must be germane to the proposed project and agreed to by the applicant.

This section of the report provides a series of tables summarizing final decisions for each of the review thresholds for which a CON is required. It should be noted that some tables will not equal other tables, as many applications fall into more than one category.

Table 8 and Figure 2 display the number of final decisions issued.

Figure 2
FY 2011 FINAL DECISIONS ISSUED
BY HEALTH SERVICE AREAS

TABLE 8	
FINAL DECISIONS	
ISSUED	
FY2007- FY2011	
FY2007	319
FY2008	354
FY2009	271
FY2010	269
FY2011	323



Note: Figure does not include 2 out-state decisions.

Table 9 summarizes final decisions by review categories defined in MCL 333.22209(1) and as summarized below:

Acquire, Begin Operation of, or Replace a Health Facility

Under Part 222, a health facility is defined as a general hospital, hospital long-term care unit, psychiatric hospital or unit, nursing home, freestanding surgical outpatient facility (FSOF), and health maintenance organization under limited circumstances. This category includes projects to construct or replace a health facility, as well as projects involving the acquisition of an existing health facility through purchase or lease.

Change in Bed Capacity

This category includes projects to increase in the number of licensed hospital, nursing home, or psychiatric beds; change the licensed use; and relocate existing licensed beds from one geographic location to another without an increase in the total number of beds.

Covered Clinical Services

This category includes projects to initiate, replace, or expand a covered clinical service: neonatal intensive care services, open heart surgery, extrarenal organ transplantation, extracorporeal shock wave lithotripsy, megavoltage radiation therapy, positron emission tomography, surgical services, cardiac catheterization, magnetic resonance imaging services, computed tomography scanner services, and air ambulance services.

Covered Capital Expenditures

This category includes capital expenditure project in a clinical area of a licensed health facility that is equal to or above the threshold set forth in Part 222. Typical examples of covered capital expenditure projects include construction, renovation, or the addition of space to accommodate increases in patient treatment or care areas not already covered. As of January 1, 2011, the covered capital expenditure threshold was \$2,957,500. The threshold is updated every January.

TABLE 9 FINAL DECISIONS ACTIVITY CATEGORY FY2007 - FY2011					
<i>Approved</i>	FY2007	FY2008	FY2009	FY2010	FY2011
<i>Acquire, Begin, or Replace a Health Facility</i>	51	71	49	44	43
<i>Change in Bed Capacity</i>	29	20	37	43	54
<i>Covered Clinical Services</i>	237	228	190	192	212
<i>Covered Capital Expenditures</i>	30	30	35	39	78
<i>Disapproved</i>					
<i>Acquire, Begin, or Replace a Health Facility</i>	2	2	1	5	0
<i>Change in Bed Capacity</i>	1	1	2	13	0
<i>Covered Clinical Services</i>	1	2	0	2	1
<i>Covered Capital Expenditures</i>	0	1	0	9	0

Note: Totals above may not match Final Decision totals because applications may include multiple categories.

Table 10 provides a comparison of the total number of final decisions and total project costs by decision type.

TABLE 10 COMPARISON OF FINAL DECISIONS BY DECISION TYPE FY2007 - FY2011				
	Approved	Approved With Conditions	Disapproved	TOTALS
<i>Number of Final Decisions</i>				
FY2007	257	58	4	319
FY2008	291	59	4	354
FY2009	240	27	3	271
FY2010	225	29	15	269
FY2011	299	25	1	325
<i>Total Project Costs</i>				
FY2007	\$1,577,574,167	\$325,128,269	\$ 1,765,604	\$1,904,468,040
FY2008	\$2,794,327,552	\$719,560,182	\$26,055,809	\$3,539,943,543
FY2009	\$ 791,637,143	\$317,924,357	\$ 931,675	\$1,110,493,175
FY2010	\$ 712,964,774	\$ 82,921,512	\$36,912,278	\$ 832,798,564
FY2011	\$4,237,317,904	\$ 78,451,908	\$ 96,000	\$4,315,865,812

Note: Final decisions include emergency CON applications.

CERTIFICATE OF NEED ACTIVITY SUMMARY COMPARISON

Table 11 provides a comparison for various stages of the CON process.

TABLE 11				
CON ACTIVITY COMPARISON				
FY2007 - FY2011				
	Number of Applications	Difference from Previous Year	Total Project Costs	Difference from Previous Year
<i>Letters of Intent Submitted</i>				
<i>FY2007</i>	582	4%	\$3,316,323,030	5%
<i>FY2008</i>	521	(10%)	\$3,032,871,348	(9%)
<i>FY2009</i>	335	(36%)	\$ 851,958,151	(72%)
<i>FY2010</i>	435	30%	\$1,675,525,170	97%
<i>FY2011</i>	441	1%	\$4,104,907,789	144%
<i>Applications Submitted</i>				
<i>FY2007</i>	320	(16%)	\$3,097,185,206	15%
<i>FY2008</i>	388	21%	\$2,577,833,078	(17%)
<i>FY2009</i>	219	(44%)	\$ 604,642,399	(77%)
<i>FY2010</i>	303	38%	\$1,503,768,132	149%
<i>FY2011</i>	318	5%	\$3,896,990,034	159%
<i>Final Decisions Issued</i>				
<i>FY2007</i>	319	(8%)	\$1,904,468,040	(21%)
<i>FY2008</i>	354	11%	\$3,539,943,543	86%
<i>FY2009</i>	271	(23%)	\$1,110,493,175	(69%)
<i>FY2010</i>	269	(1%)	\$ 832,798,564	(25%)
<i>FY2011</i>	325	21%	\$4,315,865,812	418%

Note: Final decisions Issued include Emergency CONs and swing bed applications.

AMENDMENTS

The Rules allow an applicant to request to amend an approved CON for projects that are not complete. The Department has the authority to decide when an amendment is appropriate or when the proposed change is significant enough to require a separate application. Typical reasons for requesting amendments include:

- **Cost overruns.** The Rules allow the actual cost of a project to exceed the approved amount by 15 percent of the first \$1 million and 10 percent of all costs over \$1 million. Fluctuations in construction costs can cause projects to exceed approved amounts.
- **Changes in the scope of a project.** An example is the addition of construction or renovation required by regulatory agencies to correct existing code violations that an applicant did not anticipate in planning the project.
- **Changes in financing.** Applicants may decide to pursue a financing alternative better than the financing that was approved in the CON.

Rule 9413 permits that the review period for a request to amend a CON-approved project be no longer than the original review period.

TABLE 12 provides a summary of amendment requests received by the Department and the time required to process and issue a decision.

TABLE 12
AMENDMENTS RECEIVED AND DECISIONS ISSUED
FY2007 - FY2011

	FY2007	FY2008	FY2009	FY2010	FY2011
<i>Amendments Received</i>	61	68	90	85	83
<i>Amendment Decisions Issued</i>	61	71	91	87	76
<i>Percent Issued within Required Time Frame</i>	98%	71%	93%	98%	99%

NEW CAPACITY

Table 13 provides a comparison of existing covered services, equipment and facilities already operational to new capacity approved in FY 2011. One hundred and fourteen (114) of the 324 approvals in FY 2011 were for new or additional capacity. The remaining approvals were for replacement equipment, renovations and other capital expenditures.

TABLE 13
COVERED CLINICAL SERVICES AND BEDS
FY2011

Covered Clinical Services/Beds	Existing Sites	Existing Units/Beds	New Sites	New Units/Beds
<i>Air Ambulances</i>	11	14	1	1
<i>Cardiac Catheterization Services</i>	65	200	3	5
<i>Open Heart Surgical Services</i>	34	N/A	0	0
<i>Surgical Services</i>	249	1,360	3	20
<i>CT Scanners Services</i>	309	405	18	16
<i>MRI Services</i>	260	219	23	10
<i>PET Services</i>	76	26	1	0
<i>Lithotripsy Services</i>	76	11	10	0
<i>MRT Services</i>	65	124	0	4
<i>Transplant Services</i>	7	N/A	0	0
<i>Hospitals</i>	174	26,271	2*	105
<i>NICU Services</i>	22	621	0	6
<i>Short-term Nursing (Swing Beds)</i>	33	309	0	0
<i>Nursing Homes/HLTCU</i>	462	48,460	11	1078
<i>Psychiatric Hospitals/Units</i>	62	2,245	0	16

Note: Table 13 does not account for facilities closed, services or equipment no longer operational, or beds delicensed and returned to the various bed pools.

* Both projects in this category approved to initiate LTACH hospital at an existing hospital site. No new hospitals were approved.

COMPLIANCE ACTIONS

There were 341 projects requiring follow-up for FY 2011 based on the Department's Monthly Follow-up/Monitoring Report as shown in **Table 14**.

TABLE 14
FOLLOW UP AND COMPLIANCE ACTIONS
FY2007 - FY2011

	FY2007	FY2008	FY2009	FY2010	FY2011
<i>Projects Requiring Follow-up</i>	413	417	379	326	341
<i>Approved CONs Expired</i>	24	88	155	217	80
<i>Compliance Orders Issued</i>	2	1	4	0	0

Note: CONs are expired due to non-compliance with terms and conditions of approval or when the recipient has notified the Department that either the approved-project was not implemented or the site is no longer providing the covered service/beds.

ANALYSIS OF CERTIFICATE OF NEED PROGRAM FEES AND COSTS

Section 20161(3) sets forth the fees to be collected for CON applications. The fees are based on total project costs and are set forth in **Figure 3**.

FIGURE 3
CON APPLICATION FEES

Total Project Costs	CON Application Fee
\$0 to \$500,000	\$1,500
\$500,001 to \$4,000,000	\$5,500
\$4,000,001 and above	\$8,500

Table 15 analyzes the number of applications by fee assessed.

TABLE 15
NUMBER OF CON APPLICATIONS BY FEE
FY2007 - FY2011

CON Fee	FY2007	FY2008	FY2009	FY2010	FY2011
\$ 0*	6	4	1	6	2
\$1,500	75	128	103	113	104
\$5,500	141	151	76	107	101
\$8,500	98	109	39	77	110
TOTALS	320	392	219	303	317

Note: Table 15 may not match fee totals in Table 16, as Table 16 accounts for refunds, overpayments, MFA funding, etc.

* No fees are required for emergency CON and swing beds applications.

Table 16 provides information on CON program costs and source of funds.

TABLE 16
CON PROGRAM
COST AND REVENUE SOURCES FOR FY2007- FY2011

	FY2007	FY2008	FY2009	FY2010	FY2011
<i>Program Cost</i>	\$1,741,300	\$1,960,655	\$1,871,395	\$1,972,254	\$1,902,658
<i>Fees/Funding</i>	\$1,688,000	\$1,742,926	\$1,095,048	\$1,423,451	\$1,715,588
<i>Fees % of Costs</i>	97%	89%	59%	72%	90%

Source: MDCH Budget and Finance Administration.

CERTIFICATE OF NEED COMMISSION ACTIVITY

During FY2011, the CON Commission revised the review standards for Bone Marrow Transplantation (BMT) Services, Magnetic Resonance Imaging (MRI) Services, and Nursing Home and Hospital long-Term Care Unit Beds and Addendum for special Population Groups (NH-HLTCU).

The revisions to the CON review standards for BMT Services received final approval by the CON Commission on September 23, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective December 3, 2010. The final language changes include the following:

- Modified Section 4 to extend the time period to obtain a Prospective Payment System (PPS) exemption for a cancer hospital.
- Other technical changes.

The revisions to the CON review standards for MRI Services received final approval by the CON Commission on December 15, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective March 11, 2011. The final language changes include the following:

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

The revisions to the CON review standards for NH-HLTCU received final approval by the CON Commission on December 15, 2010 and were forwarded to the Governor and legislature. Neither the Governor nor the legislature took a negative action within 45 days; therefore, the revisions became effective March 11, 2011. The final language changes include the following:

- Under Section 1, modified the language consistent with recent changes in other CON review standards.
- Under Section 2, removed unnecessary definitions.
- Under Section 10(2), revised to provide greater emphasis on Medicaid participation.
- Under Section 10(3), revised to give a higher weight for Medicare participation versus licensed-only beds.
- Under Section 10(4), revised to deduct points from providers with a negative track record of compliance with state and federal regulations.
- Under Section 10(5), revised and added points for culture change models.
- Under Section 10(6), reduced the number of categories to receive points for “applicant’s cash.”
- Under Section 10(7), added HLTCU and revised points.
- Added Section 10(8) to award points for air conditioning.

- Under Section 10(9), revised by giving more points for private rooms with adjoining sink, toilet, and shower to encourage a more home-like environment.
- Added Section 10(10) to award points for projects that result in small nursing homes/HLTCUs.
- Added Section 10(11) to award points for providing audited financial statements to assure financial viability of the applicant and project.
- Added Section 10(12) to award points to encourage new construction to house new beds.
- Added Section 10(13) to award points for not operating any 3- or 4-bed wards.
- Added Section 10(14) to award points if the existing or proposed NH/HLTCU is on or readily accessible to an existing or proposed public transportation route.
- Added Section 10(15) to award points for technological innovation.
- Under Section 10(16), modified the language consistent with recent changes in other CON review standards.
- Other technical changes.

APPENDIX I - CERTIFICATE OF NEED COMMISSION

James B. Falahee, Jr., JD, CON Commission Chairperson
Edward B. Goldman, JD, CON Commission Vice-Chairperson
Peter Ajluni, DO (Appointment expired and replaced by Kathleen Cowling, DO)
Bradley N. Cory
Kathleen Cowling, DO (Eff. 5/26/11 replaced Peter Ajluni, DO)
Charles M. Gayney
Robert L. Hughes
Marc D. Keshishian, MD
Brian A. Klott
Gay L. Landstrom
Suresh Mukherji, MD (Eff. 5/26/11 replaced Michael W. Young, DO)
Michael A. Sandler, MD
Michael W. Young, DO (Appointment expired and replaced by Suresh Mukherji, MD)

For a list and contact information of the current CON Commissioners, please visit our web site at www.michigan.gov/con.

CERTIFICATE OF NEED LEGAL ACTION
(3.16.12)

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<i>Medilodge of Howell v MDCH and Trilogy— Howell Health Campus</i> Livingston County Circuit Court No: 11-25961-AV	04/22/11	Application for Leave to Appeal relating to DCH's decision to remand a comparative review involving nursing home beds.	After the Circuit Court granted DCH's motion to dismiss, Medilodge filed an application for leave to appeal with the Michigan Court of Appeals. The COA has not ruled on the application.
<i>Metro Health Hospital – CON Application: 10-1026 MAHS</i>	01/07/11	Metro Health requested a hearing relating to DCH's 11/20/10 proposed decision to deny Metro Health's application for open heart surgery services and cardiac and catheterization services.	DCH's filed its Motion for Summary Disposition and Metro Health responded. At the request of the parties, this matter is being held in abeyance pending settlement discussions. A status conference will be held on April 3, 2012 to determine if more time is needed.

CERTIFICATE OF NEED LEGAL ACTION
(3.16.12)

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<p><i>Monroe County – Compare Group #95-0216</i></p> <p><u>Includes:</u> <i>Mercy Memorial – CON App # 11-0039</i> <i>Fountain View – CON App # 11-0018</i> <i>Medilodge of Monroe – CON App # 11-0030</i></p>	11/14/11	<p>Monroe County – Comparative Review of nursing home beds – Administrative Appeal</p> <p>The three applicants are: (1) Mercy Memorial (denied applicant); (2) Fountain View (denied applicant); (3) Medilodge of Monroe (approved applicant)</p>	<p>Medilodge’s motion to dismiss was denied on 2/13/12. The Tribunal will set another pre-hearing conference to set new dates for dispositive motions and hearing.</p>

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<p><i>Oakland County – Compare Group #95-0217</i></p> <p><u>Includes:</u> <i>Medilodge of Oxford – CON App # 11-0045</i> <i>Medilodge of Clarkston – CON App # 11-0043</i> <i>Medilodge of Square Lk – CON App # 11-0041</i> <i>Regency on the Lk – CON App # 11-0033</i> <i>Manor of Farm. Hills – CON App # 11-0024</i> <i>Bloomfield Orchard – CON App # 11-0028</i> <i>Sen. Com. Of Auburn Hills – CON App # 11-0023</i> <i>Sen. Com. Of Prov. Pk. – CON App # 11-0022</i></p>	11/1/11	<p>Oakland County – Comparative Review of nursing home beds – Administrative Appeal</p> <p>The eight applicants are: (1) Medilodge of Oxford (denied applicant); (2) Medilodge of Clarkston (denied applicant); (3) Medilodge of Square Lake (denied applicant); (4) Regency on the Lake (denied applicant); (5) Manor of Farmington Hills (approved applicant); (6) Bloomfield Orchard Villa (approved applicant); (7) Senior Community Of Auburn Hills (approved applicant); (8) Senior Community of Providence Park (approved applicant)</p>	<p>MDCH’s motion for summary disposition will be filed by March 23, 2012. Response due 4/13/12 and reply due 4/20/12. The Tribunal will set a date for hearing after all briefs are filed.</p>

CERTIFICATE OF NEED LEGAL ACTION
(3.16.12)

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<p><i>Livingston County – Compare Group #95-0214</i></p> <p><u>Includes:</u> <i>Medilodge of Livingston – CON App # 11-0044</i> <i>Livingston Care Center – CON App # 11-0021</i></p>	<p>11/1/11</p>	<p>Livingston County – Comparative Review of nursing home beds – Administrative Appeal The two applicants are: (1) Medilodge of Livingston (denied applicant); (2) Livingston Care Center (approved applicant)</p>	<p>MDCH’s motion for summary disposition will be filed by April 5, 2012. Response due 4/26/12 and reply due 5/3/12. The Tribunal will set a date for hearing after all briefs are filed.</p>

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<p><i>St. Clair County – Compare Group #95-0219</i></p> <p><u>Includes:</u> <i>Medilodge of St. Clair – CON App # 11-0032</i> <i>Regency on Lk- Ft. Gratiot – CON App # 11-0034</i></p>	<p>11/1/11</p>	<p>St. Clair County – Comparative Review of nursing home beds – Administrative Appeal The two applicants are: (1) Medilodge of St. Clair (denied applicant); (2) Regency on the Lake-Fort Gratiot (approved applicant)</p>	<p>MDCH’s motion for summary disposition will be filed by April 27, 2012. Response due 5/18/12 and reply due 5/25/12. The Tribunal will set a date for hearing after all briefs are filed.</p>

CERTIFICATE OF NEED LEGAL ACTION
(3.16.12)

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<i>Ausable Valley Continuing Care – CON App # 11-0017</i>	11/19/11	Oscoda County –Administrative Appeal relating to denial of CON application seeking 13 nursing home beds.	MDCH responded to AuSables’ discovery requests, including interrogatories and requests for admissions. MDCH’s motion for summary disposition will be filed by April 27, 2012. Response due 5/18/12 and reply due 5/25/12. The Tribunal will set a date for hearing after all briefs are filed.
<i>Medilodge of Pickney – CON App # 11-0189</i>	11/19/11	Livingston County – Administrative Appeal relating to denial of CON application seeking 56 nursing home beds.	MDCH’s motion for summary disposition will be filed by June 15, 2012. Response due 7/6/12 and reply due 7/13/12. The Tribunal will set a date for hearing after all briefs are filed.

CERTIFICATE OF NEED LEGAL ACTION
(3.16.12)

<u>Case Name</u>	<u>Date Opened</u>	<u>Case Description</u>	<u>Status</u>
<i>Beaumont Hospital v DCH – Oakland County Circuit Court No. 12-125141-CZ</i>	2/28/12	Beaumont filed a five count complaint for declaratory judgment, injunctive and other relief. The counts allege, among other things, APA violations, a due process violation and promissory estoppel. Beaumont seeks an order declaring that its CON to construct a proton beam megavoltage radiation center remains in full force and effect, enjoining MDCH from terminating or otherwise revoking the CON, costs and attorneys' fees.	MDCH filed its answer and discovery requests.

CON Leg Action; report 3.16.12

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2011												2012											
	J*	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A	M	J*	J	A	S*	O	N	D*
Bone Marrow Transplantation Services										PH			•R		D (Tabled 1/31/12)									
Heart/Lung and Liver Transplantation Services										PH			•R	•	•R—	•	•P	•▲F						
Hospital Beds and Addendum for HIV Infected Individuals	•R	•S	•S	•S		■	■	■	■	■	■	•R—	•	•P	•▲F									
Magnetic Resonance Imaging (MRI) Services	•	•	•R	•	•	•R—	•P	•	•▲F	PH•	•	•	•R	•	•R—S	•S	•PS	•▲F■	■	■	■	■	■	■
Open Heart Surgery Services**	•R	Pending CCSAC							D	•	•	•	•S	•S	•S	■	■	■	■	■	■	■	•	•R—
Pancreas Transplantation Services										PH			•R				•	•	•	•	•R—			
Positron Emission Tomography (PET) Scanner Services	•R	•	•R	•	•	•R—	•P	•	•▲F				•	•	•R—	•	•P	•▲F						
Psychiatric Beds and Services										PH			•R						•	•	•	•	•	•R—
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																		A						
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
CON Annual Activity Report FY 2011												•	•	•	•R									
2-year Report to Joint Legislative Committee (JLC)																								R

- KEY**
- - Receipt of proposed standards/documents, proposed Commission action
 - * - Commission meeting
 - - Staff work/Standard advisory committee meetings
 - ▲ - Consider Public/Legislative comment
 - ** - Current in-process standard advisory committee or Informal Workgroup
 - - Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
 - A - Commission Action
 - C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
 - D - Discussion
 - F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
 - M - Monitor service or new technology for changes
 - P - Commission public hearing/Legislative comment period
 - PH - Public Hearing for initial comments on review standards
 - R - Receipt of report
 - S - Solicit nominations for standard advisory committee or standing committee membership

For Approval March 29, 2012

Updated March 26, 2012

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, Policy & Planning, Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	August 12, 2010	2013
Bone Marrow Transplantation Services	December 3, 2010	2015
Cardiac Catheterization Services	February 27, 2012	2014
Computed Tomography (CT) Scanner Services	February 27, 2012	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	2015
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2014
Magnetic Resonance Imaging (MRI) Services	November 21, 2011	2015
Megavoltage Radiation Therapy (MRT) Services/Units	November 21, 2011	2014
Neonatal Intensive Care Services/Beds (NICU)	August 12, 2010	2013
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2013
Open Heart Surgery Services	February 25, 2008	2014
Pancreas Transplantation Services	November 5, 2009	2015
Positron Emission Tomography (PET) Scanner Services	November 21, 2011	2014
Psychiatric Beds and Services	November 5, 2009	2015
Surgical Services	February 27, 2012	2014
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2013

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

**A Public Comment Period 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.