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

Thursday June 14, 2012

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order @ 9:46 a.m., and Commissioners and staff introduced themselves.

A. Members Present:

Gail J. Clarkson RN, Medilodge
James B. Falahee, Jr., JD, Chairperson
Charles Gayney
Robert Hughes
Marc Keshishian, MD, Vice-Chairperson
Brian Klott
Gay L. Landstrom, RN in at 9:50 a.m.
Suresh Mukherji, MD
Kathleen Cowling, DO

B. Members Absent

Edward B. Goldman
Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Jessica Austin
Melanie Brim
Tulika Bhattacharya
Scott Blakeney
Natalie Kellogg
Brenda Rogers

II. Review of Agenda

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

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of March 29, 2012

Motion by Commissioner Cowling, seconded by Commissioner Klott, to approve the minutes of March 29, 2012 as presented. Motion Carried.

V. Open Heart Surgery Standard Advisory Committee (OHSSAC) - Status Report

Chairperson Falahee announced that the OHSSAC interim report provided by Dr. Sell will be posted on the web site (see Attachment A).

Discussion followed.

VI. Heart/Lung, and Liver (HLL) Transplantation Services - May 1, 2012 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the hearing and proposed language for final action including the proposed technical amendment to the HLL Transplantation Standards (see Attachments B & C).

A. Public Comment:

None

B. Commission Discussion

Discussion followed.

C. Commission Final Action:

Motion by Commissioner Gayney, seconded by Commissioner Klott, to approve the modified language and move it forward to the Joint Legislative Committee (JLC) and Governor for the 45-day review period. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

VII. Hospital Beds - May 1, 2012 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the hearing and proposed language for final action (See attachments D & E).

A. Public Comment

None.

B. Commission Discussion

None.

D. Commission Final Action

Motion by Vice-Chairperson Keshishian, seconded by Commissioner Cowling, to approve the proposed language and move it forward to the JLC and Governor for the 45-day review period. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

VIII. Magnetic Resonance Imaging (MRI) Services - May 1, 2012 Public Hearing Summary & Report

Ms. Rogers gave an overview of the hearing and proposed language for final action and explained the technical amendments (see Attachments F & G).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Mukherji, seconded by Commissioner Landstrom, to approve the proposed language as presented and move it forward to the JLC and Governor for the 45-day review period. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstained.

IX. Pancreas Transplantation Services - May 1, 2012 Public Hearing Summary & Report

Ms. Rogers gave a brief summary of the public hearing comments (see Attachment H).

A. Public Comment

Dr. Michael Sandler, Henry Ford Health System

B. Commission Discussion

Discussion followed.

C. Commission Final Action

Motion by Commissioner Landstrom, seconded by Commissioner Hughes, to approve the de-regulation of Pancreas Transplantation Services and move the recommendation forward to the JLC and Governor. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

Motion by Commissioner Cowling, seconded by Commissioner Klott to make the de-regulation effective date directly following the 45-day review period. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

X. Positron Emission Tomography (PET) Scanner Services - May 1, 2012 Public Hearing Summary & Report

Ms. Rogers gave an overview of the hearing and proposed language for final action (see Attachments I & J).

A. Public Comment

None

B. Commission Discussion

None.

C. Commission Final Action

Motion by Commissioner Mukherji, seconded by Commissioner Gayney, to approve the proposed language and move it on to the JLC and Governor for the 45-day review period. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

XI. Megavoltage Radiation Therapy (MRT) Discussion

Commissioner Keshishan explained his rationale for initiating another workgroup to review the MRT Standards.

Motion by Vice-Chairperson Keshishian, seconded by Commissioner Mukherji, to form a work group to clarify and review the full set of MRT standards. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

Vice-Chairperson Keshishian volunteered to lead the workgroup.

XII. Legislative Report

Mr. Blakeney gave a brief verbal overview of the legislative activity.

Chairperson Falahee and Commissioner Klott gave brief verbal summaries of legislative activity as it relates to CON.

XIII. Administrative Update

Mr. Blakeney gave a brief verbal update on the administration activity.

XIV. A. Planning & Access to Care Section Update

Ms. Rogers gave a verbal update on the status of the MRI SAC nominations.

B. CON Evaluation Section

1. **Compliance Report (Written Report)**
2. **Quarterly Performance Measures (Written Report)**

Ms. Bhattacharya gave an update on both compliance and quarterly performance activity (see Attachments K & L).

XV. Legal Activity Report

Mr. Potchen gave a brief status update on the legal activities (see Attachment M).

XVI. Future Meeting Dates

A. September 27, 2012
B. December 13, 2012

XVII. Public Comment

Lody Zwarensteyn, Alliance for Health
Jeffrey R. Schell, Central Michigan Stone Mgmt., L.P. (see Attachment N)
Michael Sandler, M.D. Henry Ford Health System
Melissa Cupp, Weiner Assoc.

XVIII. Review of Commission Work Plan

Ms. Rogers gave a brief overview of the Work Plan (see Attachment O).

A. Commission Discussion
None.

B. Commission Action

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to approve the work plan as presented with the addition of an MRT workgroup. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

XIX. Adjournment

Motion by Commissioner Gayney, seconded by Commissoner Klott, to adjourn the meeting @ 11:11 a.m. Motion Carried in a vote of 9- Yes, 0- No, and 0- Abstain.

Interim Report – Open Heart Surgery Standard Advisory Committee

Current status of the SAC is summarized with comments organized according to individual charges. We have just completed our third meeting, and the progress made so far has been facilitated by the formation of two subcommittees. One subcommittee has focused on Charge 2, and the other Charge 4.

Charge 1. Review and update, if necessary, the initiation and maintenance volume requirements given that OHS volumes are declining.

Currently, there are three separate volume requirements for OHS programs in the state ranging from 0 – 300 cases per year, depending upon the time at which the CON was granted for each program. The fact that OHS volumes have been steadily declining since 2000 has caused several programs to fall short of their required annual case requirement. In a presentation by the Economic Alliance of Michigan, declining OHS volumes were equated with decreasing need for OHS programs and prompted their proposal that up to ten lower volume hospitals should likely be closed. In addition, they felt that OHS program initiation volume requirements should be kept high in order to block the opening of new, unneeded OHS sites. They presented data suggesting that lower volume hospitals had significantly worse outcomes clinically; however, their numbers were found to be inaccurate due to their extrapolations. In addition, their conclusions were not supported by multiple scientific articles within the CV surgery specialty that show minimal correlation with OHS volume for an institution and clinical outcomes for CABG.

The discussion is ongoing, but hinges primarily on the questions:
a.) If institutional OHS numbers do not correlate with quality, do they need to be as high as they are for the maintenance of a program?
b.) How do you justify keeping a high initiation number if the maintenance number is not as important as once thought?

Charge 2. Review project delivery requirements to assure quality, measurability, and affordability for both the provider and consumer.

We formed a subcommittee headed by Dr. Gaetano Paone to help address this issue, and our ongoing discussions are showing that Charges 1 and 2 are really quite closely linked. A presentation by the Open Heart Coalition helped to frame the issue of how to measure and report quality in an ongoing manner. Despite the fact that the clinical indicators they selected were accepted as important, the benchmarks they suggested were felt by many on the committee to be unrealistic. This prompted a discussion of the work of the Michigan Society of Thoracic and Cardiovascular Surgeons (MSTCVS) that emphasized the complexity of measuring the quality of an OHS program. Consequently, the MSTCVS is in the process of deciding if it, as an organization, can suggest modifications to the Coalition proposal, or present a methodology that they consider to be superior. We hope to have a presentation from the MSTCVS within the next two SAC meetings.

Affordability was discussed at length, but actual cost data are not readily available. It was felt that the cost to the insurers/payers/purchasers was similar from program to program based on the similarity of Medicare payments throughout the state and the fact that commercial insurers typically follow suit with Medicare. Similarly, it was felt that direct costs to patients would be similar from hospital to hospital. This would leave the individual hospital profit margin as the primary variable in the equation. So, in essence, what we are concluding so far is that each hospital would look the same or very similar from a cost standpoint to a patient and to the payer, but hospitals may have variable profitability. In reality, the overall picture likely is not this simple, so a couple of the payers on the SAC are continuing to look into this matter.

Charge 3. Review and update, if necessary, the methodologies to assure they accurately reflect community need for OHS services.

We have had minimal discussion of this topic so far. On the surface, the calculations to project actual volume of a new program seem too complex for a SAC to revise in the limited time and with the limited resources available. We did review a 2010 population map of the state compared to a diagram showing locations of current OHS programs surrounded by calculated 30 and 60 – minute driving radiuses. This

showed no higher population center outside of the 60 – minute drive to an OHS site and is another potential indicator that there is unlikely to be current unmet need for OHS services in the state.

Charge 4. Propose standards for percutaneous insertion of heart valves.

This charge was examined by a subcommittee chaired by Dr. Al Delucia. This committee was able to reach a consensus and made the recommendation to the SAC that no CON level standards be developed for Transcatheter Aortic Valve Replacement (TAVR). A motion was made and passed to this effect at our May meeting. The recommendation was based largely on the 2012 multispecialty consensus document on TAVR published in the Annals of Thoracic Surgery (Ann Thorac Surg 2012;93:1340-1395) and the May 1, 2012 Decision Memo by the Centers for Medicare and Medicaid Services (CMS) regarding TAVR.

The opinion of the SAC was that the CMS TAVR Decision Memo constituted very strict guidelines by which OHS programs employing TAVR procedures would be reimbursed for services, and that, given the expense of the procedure, essentially no OHS program would elect to utilize this technology without reimbursement. The SAC believes that all other payers will also adopt the CMS standards regarding reimbursement. In addition, it was felt that the qualifications required of OHS programs to perform TAVR would limit the adoption of this technology to larger centers with greater aortic valve surgery experience. Further, the opinion of the SAC was that an attempt to duplicate the CMS TAVR requirements in a CON regulation would be unnecessarily complicated and may be too slow in keeping pace with potential changes in the technology and any modifications to the CMS reimbursement decision.

Charge 5. Consider any necessary technical or other changes, e.g., updates or modifications consistent with other CON review standards and the Public Health Code.

The concept of retroactive vs. prospective regulations required a lengthy discussion before members of the SAC were comfortable with their understanding. Once that point was reached, a fairly uniform

message came from the SAC members. Assuming that this SAC develops specific quality metrics, the members felt that all programs should be measured in the same way, and all should have the same reporting requirements. They felt that it made little sense to measure quality only on programs that are new, newly acquired, or low on numbers. The SAC has not moved this issue to the level of asking the CON Commission to effect this change for all programs, but it seems likely that it will make that recommendation before the SAC work is concluded. The technical change, then, would be to identify a way to allow the quality measures requirement to apply to all programs.

Respectfully submitted,

Timothy Sell, M.D.

6/13/12

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.~~

(~~a~~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.

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

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

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

(~~h~~F) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396~~r-6 and~~TO 1396~~r-8 to~~G AND 1396I TO ~~1396v~~1396U.

(~~i~~G) "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.

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

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

(~~l~~J) "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.~~

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

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

Section 3. Requirements ~~for all applicants~~TO INITIATE A HEART, HEART/LUNG OR LIVER TRANSPLANTATION SERVICE

Sec. 3. ~~(1)~~ 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).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) Except for an application pursuant to Section 3(~~5~~4) of these standards, an applicant for a heart, heart/lung or lung transplantation service shall project a minimum of 12 heart, heart/lung or lung transplantation procedures annually in the second 12-months of operation following the date on which the first heart, heart/lung or lung transplant procedure is performed and annually thereafter.

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

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

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

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

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

(d) continuously available coagulation laboratory services; and

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

Section 5. Additional requirements for liver transplantation services

Sec. 5. (1) Approval of an application proposing to provide liver transplantation services shall not result in more than three (3) liver transplantation services in the planning area. In evaluating compliance

with this subsection, an application submitted or a certificate approved pursuant to Section 3(~~5~~4) of these standards shall be considered as a single service.

(2) Except for an application pursuant to Section 3(~~5~~4) of these standards, an applicant for a liver transplantation service shall project a minimum of 12 liver transplantation procedures annually in the second 12-months of operation following the date on which the first liver transplant procedure is performed, and annually thereafter.

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

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

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

SECTION 6. REQUIREMENTS FOR MEDICAID PARTICIPATION

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

Section ~~6~~7. Review standards for comparative reviews

Sec. ~~6~~7. ~~(1)~~ Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, ~~or under these standards~~ shall be grouped and reviewed comparatively with other applications ~~in accordance with the CON rules.~~FOR PURPOSES OF THESE STANDARDS, 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.

(~~2~~1) 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.

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

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

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

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

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

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

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

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

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

(4) Submission of conflicting information in this section may result in a lower point reward. If an application contains conflicting information which could result in a different point value being awarded in this section, the Department will award points based on the lower point value that could be awarded from

conflicting information. For example, if submitted information would result in 6 points being awarded, but other conflicting information would result in 12 points being awarded, then 6 points will be awarded. If the conflicting information does not affect the point value, the Department will award points accordingly. For example, if submitted information would result in 12 points being awarded and other conflicting information would also result in 12 points being awarded, then 12 points will be awarded.

Section ~~7~~8. Project delivery requirements -- terms of approval

Sec. ~~7~~8. ~~(1)~~ An applicant shall agree that, if approved, the HLL service(s) shall be delivered in compliance with the following terms of CON approval~~:~~.

(~~a~~1) Compliance with these standards. An applicant shall immediately report to the Department any changes in key staff or other aspects of the transplantation service that may affect its ability to comply with these standards.

(~~b~~2) ~~Compliance with applicable safety and operating standards.~~

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

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

(~~ii~~A) The applicant shall comply and ~~remain~~ MAINTAIN a functionally active program ~~with the~~PURSUANT TO OPTN and its by-laws and policies.

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

(~~B~~II) The applicant must be in good standing with the OPTN.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(~~2~~5) The agreements and assurances required by this section, as applicable, shall be in the form of a certification agreed to by the applicant or its authorized agent.

Section ~~8~~9. Documentation of projections

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

Section ~~9~~10. ~~Health Service Areas~~ Effect on prior CON Review Standards; comparative reviews

Sec. 11. 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 25, 2010 and effective on MAY 28, 2010.

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

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:

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

~~**Section 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.~~

~~(21) Projects reviewed under these standards shall be subject to comparative review.~~

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

Date: May 15, 2012

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Heart/Lung and Liver (HLL) Transplantation Services, Hospital Beds (HB), Magnetic Resonance Imaging (MRI) Services, Positron Emission Tomography (PET) Scanner Services, and Pancreas Transplantation Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the HLL Transplantation Services, HB, MRI Services, PET Scanner Services, and Pancreas Transplantation Services Standards at its March 29, 2012 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed above-mentioned Standards on May 1, 2012. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from four organizations and is summarized as follows:

HLL Transplantation Services

Dennis McCafferty, Economic Alliance for Michigan (EAM)

EAM supports the position taken by the Commission that only technical changes are required to modify the Standards for consistency with other CON Standards. Other substantial changes are not needed at this time.

Richard Pietroski, Gift of Life

Gift of Life supports the technical amendment to the Standards provided by the Department, and anticipates a robust dialogue in 2015 regarding the potential deregulation of these services. Gift of Life also supports the Commission's discussion to revisit these standards through a SAC or workgroup in the future.

Hospital Beds

Dennis McCafferty, EAM

EAM supports the proposed changes in the standards. Specifically, for determining which hospitals service which communities (hospital groups) and the methodology for projecting future need of additional acute beds. EAM believes that the new provisions reducing portions of the excess licensed beds at low occupancy urban county hospitals will help improve hospital planning in the long run and serves the best interest of the citizens of Michigan.

Philip Incarnati, McLaren Health Care

McLaren does not support the proposed changes to the HB Standards for the following reasons:

- The bed need methodology recommended by the SAC and approved by the Commission essentially preserves status quo. The methodology will always result in excess beds and will never show a need for new beds in a given area. It fails to account for population shifts and makes capacity a proxy for access.
- The bed reduction language has no statistical basis and puts communities served by aging facilities, such as McLaren–Oakland in Pontiac at a disadvantage. The language further complicates a potential bed move that would position Pontiac with the appropriate number of beds and allow the people of Clarkston and surrounding communities to be served by an acute care hospital.
- Adopting the proposed language will continue to mean that the only new hospitals ever built in the State of Michigan will be approved by the Legislature or the courts and not the CON Commission. Everyone can look forward to more new, overbuilt towers at existing locations because that is the only permissible construction.
- McLaren supports simplifying the Hospital Bed standards to include the following when a hospital elects to relocate beds to a new site, it must demonstrate :
  - Financial viability with regard to the entire project
  - Conclusive positive community need assessment for both the proposed hospital site that is receiving the beds and the hospital giving up the beds
    - Significant community benefit with a financially viable plan for reuse of existing facility
    - Existing facilities cannot close to move to a new facility
  - No additional beds in Michigan
  - Maintain existing payer contracts for at least five years
  - Delicense at least 10% of existing facility’s beds

- Proposed new hospital sites may not be approved within five miles of existing acute care hospitals, nor within the same county as single community providers

Magnetic Resonance Imaging (MRI) Services

Dennis McCafferty, EAM

EAM supports the inclusion of the MRI-Guided EPI definition within the standards and the language restricting this technology to hospitals with existing MRI services that have been operational for at least 36 months and are meeting minimum volume requirements for both MRI and OHS. EAM also supports the inclusion of the PET/MRI scanner hybrid in both the MRI and PET standards.

Melissa Cupp, Wiener Assoc.

Ms. Cupp would like to suggest that the modified definition for "MRI procedure" be added to the definition of "MRI unit" rather than "MRI procedure."

"THE TERM INCLUDES FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/ MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES."

This would be consistent with how similar provisions for PET/CT hybrids are handled in the CON Standards for CT Services.

Positron Emission Tomography (PET) Scanner Services

Dennis McCafferty, EAM

EAM supports the inclusion of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures in both the MRI and PET standards.

Pancreas Transplantation Services

Dennis McCafferty, EAM

EAM would recommend that a work group be convened to review the question of deregulation. EAM strongly supported the changes made in these standards during the last review that limited this service to only higher volume kidney transplant centers. EAM requests that quality assurance issues be addressed by a workgroup considering deregulation of this service.

Richard Pietroski, Gift of Life

Gift of Life supports the action taken to eliminate regulation for Pancreas Transplantation Services. The duplication of a state level program is no longer cost effective nor can it provide the scope of oversight that is performed by the Organ Procurement and Transplantation Network (OPTN).

There is continued federal regulation of organ transplant centers by the Department of Health and Human Services through both the OPTN and the Centers for Medicare and Medicaid Services (CMS).* The national OPTN requires each approved program to meet rigid criteria for establishing a transplant program (OPTN Bylaws: Attachment I - Criteria for Transplant Program Designation), and ongoing requirements for timely patient-level data submission (OPTN Policy 7.0: Data Submission Requirements). Furthermore, each center undergoes a robust analysis for transplant and outcome data under the federal Scientific Registry for Transplant Recipients (http://www.srtr.org/). Center specific data are refreshed every six months, and statistically analyzed to identify underperforming programs which trigger a quality review by the OPTN.

*References:

Policies and Bylaws. Department of Health and Human Services: Organ Procurement and
Transplantation Network. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp
http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp
Federal Register. Department of Health and Human Services: Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 482, 488, and 498: *Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants*.
http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf

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)A~~A 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

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

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

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

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

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

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

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

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

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

(~~f~~G) "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~~H) "Common ownership or control" means a hospital that is owned by, is under common control of, or has a common parent as the applicant hospital.

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

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

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

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

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

(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

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

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

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

(~~o~~P) "Health service area" OR "HSA" means the groups of counties listed in ~~Section 18~~APPENDIX A.

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

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

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

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

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

(~~t~~U) "Host hospital" means a licensed and operating hospital, which delicenses hospital beds, and which leases patient care space and other space within the physical plant of the host hospital, to allow a~~long-term (acute) care~~LTAC hospital, or alcohol and substance abuse hospital, to begin operation.

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

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

(~~w~~X) "Long-term (acute) care hospital" OR "LTAC HOSPITAL" means a hospital has been approved to participate in the Title XVIII (Medicare) program as a prospective payment system (PPS) exempt hospital in accordance with 42 CFR Part 412.

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

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

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

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

~~(bb)~~ "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.

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

~~the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.~~

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

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

(~~ff~~DD) "Obstetrics patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 15 through 44 with drgs 370 through 375 (obstetrical discharges).

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

(~~hh~~FF) "Pediatric patient days of care" means inpatient days of care for patients in the applicant's Michigan Inpatient Data Base data ages 0 through 14 excluding normal newborns.

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

(~~jj~~HH) "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 or these Standards.

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

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

(~~mm~~JJ) "Remaining patient days of care" means total inpatient days of care in the applicant's Michigan Inpatient Data Base data minus obstetrics patient days of care and pediatric patient days of care.

(~~nn~~KK) "Replace~~ment~~ beds ~~in a hospital~~" means ~~hospital beds that meet all of the following conditions; (i) an equal or greater number of hospital beds are currently licensed to the applicant at the licensed site at which the proposed replacement beds are currently licensed; (ii)~~A CHANGE IN THE LOCATION OF THE LICENSED HOSPITAL, OR THE REPLACEMENT OF A PORTION OF THE LICENSED BEDS AT THE SAME LICENSED SITE. ~~the~~ The hospital beds ~~are proposed for replacement~~WILL BE in new physical plant space being developed in new construction or in newly acquired space (purchase, lease, donation, etc.) ~~; and (iii) the hospital beds to be replaced will be located in~~WITHIN the replacement zone.

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

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

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

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

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

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

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

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

Section 3. Hospital ~~subareas~~GROUPS

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

(~~i~~1) These hospital ~~subarea~~GROUP~~s,~~ and the assignments of hospitals to ~~subarea~~HOSPITAL GROUP~~s,~~ shall be updated BY THE DEPARTMENT EVERY FIVE YEARS OR~~,~~ at the direction of the Commission~~, starting in May 2003, to be completed no later than November 2003~~. ~~Thereafter, at the direction of the Commission, the updates shall occur no later than two years after the official date of the federal decennial census, provided that:~~THE METHODOLOGY DESCRIBED IN "~~A~~NEW METHODOLOGY FOR DEFINING HOSPITAL GROUPS" BY PAUL L. DELAMATER, ASHTON M. SHORTRIDGE, AND JOSEPH P. MESSINA, 2011 SHALL BE USED AS FOLLOWS:

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

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

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

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

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

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

~~P_i = Population of zip code i.~~

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

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

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

~~then $\overline{R}_j = \frac{\sum_{i \in Ij} P_i (d_{ij}/D_i)}{\sum_{i \in Ij} P_i}$~~ GROUP HOSPITALS INTO CLUSTERS USING THE K-MEANS CLUSTERING ALGORITHM WITH INITIAL CLUSTER CENTERS PROVIDED BY A WARDS HIERARCHICAL CLUSTERING METHOD. ITERATE OVER ALL CLUSTER SOLUTIONS FROM 2 TO THE NUMBER OF HOSPITALS (*n*) MINUS 1.

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

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

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

ANALYIS, INCLUDING WARD'S METHOD; ONE EXAMPLE IS: G. GAN, C. MA, & J. WU (2007) DATA CLUSTERING: THEORY, ALGORITHMS, AND APPLICATIONS (ASA-SIAM SERIES ON STATISTICS AND APPLIED PROBABILITY). SOCIETY FOR INDUSTRIAL AND APPLIED MATHEMATICS (SIAM), 466 P.

(~~v~~F) ~~If there is only a single applicant, then the assignment procedure is complete. If there are additional applicants, then steps (iii), and (iv) must be repeated until all applicants have been assigned to an existing subarea.~~ CALCULATE THE INCREMENTAL F SCORE (F_{inc}) FOR EACH CLUSTER SOLUTION (i) BETWEEN 3 AND *n*-1 LETTING:

r^2_i = r^2 OF SOLUTION i

r^2_{i-1} = r^2 OF SOLUTION i-1

k_i = NUMBER OF CLUSTERS IN SOLUTION i

k_{i-1} = NUMBER OF CLUSTERS IN SOLUTION i-1

n = TOTAL NUMBER OF HOSPITALS

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

(G) SELECT CANDIDATE SOLUTIONS BY FINDING THOSE WITH PEAK VALUES IN F_{inc} SCORES SUCH THAT $F_{inc,\,i}$ IS GREATER THAN BOTH $F_{inc,\,i-1}$ AND $F_{inc,\,i+1}$.

(H) REMOVE ALL CANDIDATE SOLUTIONS IN WHICH THE LARGEST SINGLE CLUSTER CONTAINS MORE THAN 20 HOSPITALS.

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

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

(K) RENAME HOSPITAL GROUPS AS FOLLOWS:

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

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

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

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

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

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

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

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

(D) CALCULATE THE DISTANCE ($D_{K,S}$) BETWEEN THE PROPOSED NEW SITE AND EACH EXISTING HOSPITAL GROUP

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

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

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

(3) The ~~Commission~~ DEPARTMENT shall amend ~~Appendix A~~ THE HOSPITAL GROUPS to reflect: (a) approved new licensed site(s) assigned to a specific hospital ~~subarea~~GROUP; (b) hospital closures; and (c) licensure action(s) as appropriate.

(~~3~~4) As directed by the Commission, new ~~sub-area~~HOSPITAL GROUP assignments established according to subsection (1)~~(a)(i)~~ shall supersede ~~Appendix A~~ THE PREVIOUS SUBAREA/HOSPITAL GROUP ASSIGNMENTS and shall be ~~included as an amended appendix to these standards~~POSTED ON THE STATE OF MICHIGAN CON WEB SITE effective on the date determined by the Commission.

Section 4. Determination of the needed hospital bed supply

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

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

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

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

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

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

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

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

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

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

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

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

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

~~if the planning year is a leap year). Round each ADC to a whole number. This will give three ADC computations per limited access area or subarea, as applicable.~~

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

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

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

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

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

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

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

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

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

Section 5. Bed Need

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

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

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

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

(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~~LTAC 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~~LTAC hospital applicant described in this subsection does not meet the Title XVIII requirements of the Social Security Act for exemption from PPS as aN ~~long-term (acute) care~~LTAC 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 aN ~~long-term (acute) care~~LTAC 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~~LTAC hospital. In the event that the host hospital applies for a CON to acquire the ~~long-term (acute) care~~LTAC hospital [including the beds leased by the host hospital to the ~~long-term (acute) care~~LTAC hospital] within six months following the termination of the lease with the ~~long-term (acute) care~~LTAC 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~~LTAC hospital to the host hospital's medical/surgical licensed capacity and the application meets all other

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

(B) Delicensure of the hospital beds; or

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

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

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

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

(f) The proposed project to begin operation of a new hospital, under this subsection, shall constitute a change in bed capacity under Section 1(~~3~~2) of these standards.

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

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

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

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

(i) In the ~~subarea~~HOSPITAL GROUP PURSUANT TO SECTION 8(2)(A), or

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

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

(b) 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.

(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:

(I) AS OF THE DATE OF THE APPLICATION, CALCULATE THE ADJUSTED PATIENT DAYS FOR THE MOST RECENT, CONSECUTIVE 36-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .40.

(II) DIVIDE THE RESULT OF SUBSECTION (I) BY 1095 (OR 1096, IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE RECEIVING HOSPITAL.

(III) SUBTRACT THE RECEIVING HOSPITAL'S TOTAL NUMBER OF LICENSED BEDS AND APPROVED BEDS FROM THE RESULT OF SUBSECTION (II). THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE ADDED TO THE RECEIVING HOSPITAL.

(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.

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

(F) The proposed project to add new hospital beds, under this subsection, shall constitute a change in bed capacity under Section 1(~~3~~2) of these standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(d) The new beds in a hospital in a limited access area shall result in a hospital of at least 100 beds in a metropolitan statistical area county or 50 beds in a rural or micropolitan statistical area county. If the

bed need for a limited access area, as shown in Appendix ~~E~~D, is less, then that will be the minimum number of beds for a new hospital under this provision. If an applicant for new beds in a hospital under this provision simultaneously applies for status as a critical access hospital, the minimum hospital size shall be that number allowed under state/federal critical access hospital designation.

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

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

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

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

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

Section 7. Requirements for approval ~~--~~TO replace~~ment~~ beds ~~in a hospital in a replacement zone~~

Sec. 7. (1) If the application involves the development of a new licensed site, an applicant proposing TO replace~~ment~~ beds in a hospital WITHin the replacement zone shall demonstrate that the new beds in a hospital shall result in a hospital of at least 200 beds in a metropolitan statistical area county or ~~50~~ 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.

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

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

(4) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(A) THE APPLICANT'S ~~shall propose to (i) replace an equal or lesser number of beds currently licensed to the applicant at the licensed site at which the proposed replacement beds are located, and (ii) that the proposed new licensed site is in the replacement zone.~~ HOSPITAL SHALL HAVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE.

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

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

(II) DIVIDE THE RESULT OF SUBSECTION (I) ABOVE BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 25,

WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE LICENSED HOSPITAL SITE AFTER THE REPLACEMENT.

(C) SUBSECTION (4)(A) AND (B) SHALL NOT APPLY TO EXCLUDED HOSPITALS.

(~~3~~5) An applicant proposing replacement beds in the replacement zone shall not be required to be in compliance with the needed hospital bed supply ~~set forth in Appendix C~~ if the application meets all other applicable CON review standards and agrees and assures to comply with all applicable project delivery requirements.

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

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

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

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

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

(3) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(A) THE SOURCE HOSPITAL SHALL HAVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE.

(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:

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

(II) DIVIDE THE RESULT OF SUBSECTION (I) BY 1095 (OR 1096 IF THE 36-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE SOURCE HOSPITAL SITE AFTER THE RELOCATION.

(C) SUBSECTIONS (3)(A) AND (B) SHALL NOT APPLY TO EXCLUDED HOSPITALS.

(4) A SOURCE HOSPITAL SHALL APPLY FOR MULTIPLE RELOCATIONS ON THE SAME APPLICATION DATE, AND THE APPLICATIONS CAN BE COMBINED TO MEET THE CRITERIA OF (3)(B) ABOVE. A SEPARATE APPLICATION SHALL BE SUBMITTED FOR EACH PROPOSED RELOCATION.

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

(~~4~~6) The relocated beds shall be licensed to the receiving hospital and will be counted in the inventory for the applicable ~~subarea~~HOSPITAL GROUP.

(~~5~~7) The relocation of beds under this section shall not be subject to a mileage limitation.

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

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

(~~a~~1) Compliance with these standards.

(2) Compliance with the following quality assurance standards:
(A) The applicant shall assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:
(A) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.
(B) The applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
(i) Not deny services to any individual based on ability to pay or source of payment.
(ii) Maintain information by source of payment to indicate the volume of care from each payor and non-payor source provided annually.
(iii) Provide services to any individual based on clinical indications of need for the services.

(4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:
(A) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75 percent over the last 12-month period in the three years after the new beds are put into operation, and for each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a minimum of 75 percent average annual occupancy for the revised licensed bed complement.
(B) The applicant must submit documentation acceptable and reasonable to the Department, within 30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-month period after the new beds are put into operation and for each subsequent calendar year, within 30 days after the end of the year.
(~~D~~C) The applicant shall participate in a data collection SYSTEM established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information, OPERATING SCHEDULES, THROUGH-PUT SCHEDULES, and demographic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.
(~~E~~D) The applicant shall participate and submit data to the Michigan Inpatient Data Base (MIDB). The data shall be submitted to the Department or its designee.
(~~F~~E) The applicant shall provide the Department with ~~a notice stating the date the hospital beds are placed in operation and such~~ TIMELY notice ~~shall be submitted to the Department~~OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.
~~(b) Compliance with applicable operating standards.~~
~~(i) An applicant approved pursuant to Section 6(4) must achieve a minimum occupancy of 75 percent over the last 12-month period in the three years after the new beds are put into operation, and for each subsequent calendar year, or the number of new licensed beds shall be reduced to achieve a minimum of 75 percent average annual occupancy for the revised licensed bed complement.~~
~~(ii) The applicant must submit documentation acceptable and reasonable to the Department, within 30 days after the completion of the 3-year period, to substantiate the occupancy rate for the last 12-month period after the new beds are put into operation and for each subsequent calendar year, within 30 days after the end of the year.~~
~~(c) Compliance with the following quality assurance standards:~~
~~(i) The applicant shall provide the Department with a notice stating the date the hospital beds are placed in operation and such notice shall be submitted to the Department consistent with applicable statute and promulgated rules.~~
~~(ii) The applicant shall assure compliance with Section 20201 of the Code, being Section 333.20201 of the Michigan Compiled Laws.~~

~~(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information and demographic, diagnostic, morbidity, and mortality information, as well as the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each licensed site; in a format established by the Department, and in a mutually agreed upon media. The Department may elect to verify the data through on-site review of appropriate records.~~

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

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

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

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

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

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

(~~2~~5) The agreements and assurances required by this section shall be in the form of a certification agreed to by the applicant or its authorized agent.

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

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

Section 11. Department inventory of beds

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

Section 12. Effect on prior planning policies; comparative reviews

Sec. 12. (1) These CON review standards supersede and replace the CON standards for hospital beds approved by the CON Commission on December ~~12~~9, ~~2006~~ 2008 and effective March ~~8~~2, ~~2007~~2009.

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

Section 13. Additional requirements for applications included in comparative reviews

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

(2) Each application in a comparative review group shall be individually reviewed to determine whether the application is a qualifying project. If the Department determines that two or more competing applications are qualifying projects, it shall conduct a comparative review. The Department shall approve those qualifying projects which, when taken together, do not exceed the need, as defined in Section

22225(1) of the Code, and which have the highest number of points when the results of subsection (3) are totaled. If two or more qualifying projects are determined to have an identical number of points, then the Department shall approve those qualifying projects that, when taken together, do not exceed the need in the order in which the applications were received by the Department based on the date and time stamp placed on the applications by the department in accordance with rule 325.9123.

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

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

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

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

percentile rank	points awarded
87.5 – 100	20 pts
75.0 – 87.4	15 pts
62.5 – 74.9	10 pts
50.0 – 61.9	5 pts
less than 50.0	0 pts

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

(c) A qualifying project shall be awarded points as set forth in the following table in accordance with its impact on inpatient capacity. If an applicant proposes to close a hospital(s), points shall only be awarded if (i) closure of that hospital(s) does not create a bed need in any ~~subarea~~HOSPITAL GROUP as a result of its closing; (ii) the applicant stipulates that the hospital beds to be closed shall not be transferred to another location or facility; and (iii) the utilization (as defined by the average daily census over the previous 24-month period prior to the date that the application is submitted) of the hospital to be closed is at least equal to 50 percent of the size of the proposed hospital (as defined by the number of proposed new licensed beds).

Impact on Capacity	Points Awarded

Closure of hospital(s)	25 pts
Closure of hospital(s) which creates a bed need	-15 pts

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

Percent	Points Awarded
% of market share	% of market share served x 30 (total pts. awarded)

The source for calculations under this criterion is the MIDB.

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

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

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

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

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

50.0 – 59.9	5 pts

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

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

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

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

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

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

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

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

The source for calculations under this criterion is the MIDB.

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

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

time of proposed site awarded)

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

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

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

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

Section ~~16~~15. Requirements for approval -- acquisition of a hospital

Sec. ~~16~~15. (1) An applicant proposing to acquire a hospital shall not be required to be in compliance with the needed hospital bed supply ~~set forth in Appendix C~~ for the ~~subarea~~HOSPITAL GROUP in which the hospital subject to the proposed acquisition is assigned if the applicant demonstrates that all of the following are met:

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

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

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

(d) if the application is to acquire a hospital, which was proposed in a prior application to be established as a~~n long-term (acute) care~~LTAC hospital ~~(LTAC)~~ and which received CON approval, the applicant also must meet the requirements of Section 6(2). Those hospitals that received such prior approval are so identified ~~in Appendix A~~BON THE DEPARTMENT INVENTORY OF BEDS.

(2) THE APPLICANT SHALL COMPLY WITH THE FOLLOWING REQUIREMENTS, AS APPLICABLE:

(A) THE EXISTING LICENSED HOSPITAL SHALL HAVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE.

(B) IF THE EXISTING LICENSED HOSPITAL DOES NOT HAVE AN AVERAGE ADJUSTED OCCUPANCY RATE OF 40 PERCENT OR ABOVE, THE APPLICANT SHALL AGREE TO ALL OF THE FOLLOWING:

(I) THE HOSPITAL TO BE ACQUIRED WILL ACHIEVE AN ANNUAL ADJUSTED OCCUPANCY OF AT LEAST 40% DURING ANY CONSECUTIVE 12-MONTH PERIOD BY THE END OF THE THIRD YEAR OF OPERATION AFTER COMPLETION OF THE ACQUISITION. ANNUAL ADJUSTED OCCUPANCY SHALL BE CALCULATED AS FOLLOWS:

(A) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD FOR WHICH VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT.

(B) DIVIDE THE NUMBER OF ADJUSTED PATIENT DAYS CALCULATED IN (A) ABOVE BY 365 (OR 366 IF A LEAP YEAR).

(C) IF THE HOSPITAL TO BE ACQUIRED DOES NOT ACHIEVE AN ANNUAL ADJUSTED OCCUPANCY OF AT LEAST 40 PERCENT, AS CALCULATED IN (B) ABOVE, DURING ANY CONSECUTIVE 12-MONTH PERIOD BY THE END OF THE THIRD YEAR OF OPERATION AFTER COMPLETION OF THE ACQUISITION, THE APPLICANT SHALL RELINQUISH SUFFICIENT BEDS AT THE EXISTING HOSPITAL TO RAISE ITS ADJUSTED OCCUPANCY TO 60 PERCENT. THE REVISED NUMBER OF LICENSED BEDS AT THE HOSPITAL SHALL BE CALCULATED AS FOLLOWS:

(I) CALCULATE THE NUMBER OF ADJUSTED PATIENT DAYS DURING THE MOST RECENT, CONSECUTIVE 12-MONTH PERIOD WHERE VERIFIABLE DATA IS AVAILABLE TO THE DEPARTMENT, AND DIVIDE BY .60.

(II) DIVIDE THE RESULT OF SUBSECTION (I) ABOVE BY 365 (OR 366 IF THE 12-MONTH PERIOD INCLUDES A LEAP YEAR) AND ROUND UP TO THE NEXT WHOLE NUMBER OR 25, WHICHEVER IS LARGER. THIS IS THE MAXIMUM NUMBER OF BEDS THAT CAN BE LICENSED AT THE EXISTING LICENSED HOSPITAL SITE AFTER ACQUISITION.

(D) SUBSECTION (2) SHALL NOT APPLY TO EXCLUDED HOSPITALS.

Section ~~17~~16. Requirements for approval – all applicants

Sec. ~~17~~16. (1) An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

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

(3) THE APPLICANT CERTIFIES THAT THE HEALTH FACILITY FOR THE PROPOSED PROJECT HAS NOT BEEN CITED FOR A STATE OR FEDERAL CODE DEFICIENCY WITHIN THE 12 MONTHS PRIOR TO THE SUBMISSION OF THE APPLICATION. IF A STATE CODE DEFICIENCY HAS BEEN ISSUED, THE APPLICANT SHALL CERTIFY THAT A PLAN OF CORRECTION FOR CITED STATE DEFICIENCIES AT THE HEALTH FACILITY HAS BEEN SUBMITTED AND APPROVED BY THE BUREAU OF HEALTH SYSTEMS WITHIN THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS. IF A FEDERAL CODE DEFICIENCY HAS BEEN ISSUED, THE APPLICANT SHALL CERTIFY THAT A PLAN OF CORRECTION FOR CITED FEDERAL DEFICIENCIES AT THE HEALTH FACILITY HAS BEEN SUBMITTED AND APPROVED BY THE CENTERS FOR MEDICARE AND MEDICAID SERVICES. IF CODE DEFICIENCIES INCLUDE ANY UNRESOLVED DEFICIENCIES STILL OUTSTANDING WITH THE DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS OR THE CENTERS FOR MEDICARE AND MEDICAID SERVICES THAT ARE THE BASIS FOR THE DENIAL, SUSPENSION, OR REVOCATION OF AN APPLICANT'S HEALTH FACILITY LICENSE, POSES AN IMMEDIATE JEOPARDY TO THE HEALTH AND SAFETY OF PATIENTS, OR MEETS A FEDERAL CONDITIONAL DEFICIENCY LEVEL, THE PROPOSED PROJECT CANNOT BE APPROVED WITHOUT APPROVAL FROM THE BUREAU OF HEALTH SYSTEMS OR, IF APPLICABLE, THE CENTERS FOR MEDICARE AND MEDICAID SERVICES.

APPENDIX A

~~**Section 18. Health service areas**~~

~~Sec. 18.~~ Counties assigned to each ~~of the~~ health service area~~s~~ 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

APPENDIX A

CON REVIEW STANDARDS FOR HOSPITAL BEDS

HOSPITAL SUBAREA ASSIGNMENTS

Revised 11/19/08

Health Service Area	Sub 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)

Health Service Area	Sub 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.

APPENDIX A (continued)

Health Service Area	Sub 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 Heallth 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.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
4 – West (continued)			
	4F	Carson City Hospital (Fac #59-0010)	Carson City
	4F	Gratiot Medical Center (Fac #29-0010)	Alma
	4G	Hackley Hospital (Fac #61-0010)	Muskegon
	4G	Mercy General Health Partners (Sherman) (Fac #61-0020)	Muskegon
	4G	Mercy General Health Partners (Oak) (Fac #61-0030)	Muskegon
	4G	Lifecare Hospitals of Western MI (LTAC - Fac #61-0052)*	Muskegon
	4G	Select Specialty Hospital – Western MI (LTAC - Fac #61-0051)*	Muskegon
	4G	North Ottawa Community Hospital (Fac #70-0010)	Grand Haven
	4H	Spectrum Health – Blodgett Campus (Fac #41-0010)	E. Grand Rapids
	4H	Spectrum Health Hospitals (Fac #41-0040)	Grand Rapids
	4H	Spectrum Health – Kent Community Campus (Fac #41-0090)	Grand Rapids
	4H	Mary Free Bed Hospital & Rehab Ctr (Fac #41-0070)	Grand Rapids
	4H	Metro Health Hospital (Fac #41-0060)	Wyoming
	4H	Saint Mary's Health Care (Fac #41-0080)	Grand Rapids
	4I	Sheridan Community Hospital (A) (Fac #59-0030)	Sheridan
	4I	Spectrum Health United Memorial – United Campus (Fac #59-0060)	Greenville
	4J	Holland Community Hospital (Fac #70-0020)	Holland
	4J	Zeeland Community Hospital (Fac #70-0030)	Zeeland
	4K	Ionia County Memorial Hospital (A) (Fac #34-0020)	Ionia
	4L	Allegan General Hospital (A) (Fac #03-0010)	Allegan
5 – GLS			
	5A	Memorial Healthcare (Fac #78-0010)	Owosso
	5B	Genesys Regional Medical Center – Health Park (Fac #25-0072)	Grand Blanc
	5B	Hurley Medical Center (Fac #25-0040)	Flint
	5B	Mclaren Regional Medical Center (Fac #25-0050)	Flint
	5B	Select Specialty Hospital-Flint (LTAC - Fac #25-0071)*	Flint
	5C	Lapeer Regional Medical Center (Fac #44-0010)	Lapeer
6 – East			
	6A	West Branch Regional Medical Center (Fac #65-0010)	West Branch
	6A	Tawas St. Joseph Hospital (Fac #35-0010)	Tawas City
	6B	Central Michigan Community Hospital (Fac #37-0010)	Mt. Pleasant

*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.

APPENDIX A (continued)

Health Service Area	Sub Area	Hospital Name	City
6 – East (continued)			
	6C	MidMichigan Medical Center-Clare (Fac #18-0010)	Clare
	6D	Mid-Michigan Medical Center - Gladwin (A) (Fac #26-0010)	Gladwin
	6D	Mid-Michigan Medical Center - Midland (Fac #56-0020)	Midland
	6E	Bay Regional Medical Center (Fac #09-0050)	Bay City
	6E	Bay Regional Medical Center - West (Fac #09-0020)	Bay City
	6E	Bay Special Care (LTAC - Fac #09-0010)*	Bay City
	6E	St. Mary's Standish Community Hospital (A) (Fac #06-0020)	Standish
	6F	Select Specialty Hospital – Saginaw (LTAC - Fac #73-0062)*	Saginaw
	6F	Covenant Medical Center – Cooper (Fac #73-0040)	Saginaw
	6F	Covenant Medical Center – N Michigan (Fac #73-0030)	Saginaw
	6F	Covenant Medical Center – N Harrison (Fac #73-0020)	Saginaw
	6F	Healthsource Saginaw (Fac #73-0060)	Saginaw
	6F	St. Mary's of Michigan Medical Center (Fac #73-0050)	Saginaw
	6F	Caro Community Hospital (Fac #79-0010)	Caro
	6F	Hills and Dales General Hospital (Fac #79-0030)	Cass City
	6G	Harbor Beach Community Hospital (A) (Fac #32-0040)	Harbor Beach
	6G	Huron Medical Center (Fac #32-0020)	Bad Axe
	6G	Scheurer Hospital (A) (Fac #32-0030)	Pigeon
	6H	Deckerville Community Hospital (A) (Fac #76-0010)	Deckerville
	6H	Mckenzie Memorial Hospital (A) (Fac #76-0030)	Sandusky
	6I	Marlette Regional Hospital (Fac #76-0040)	Marlette
7 - Northern Lower			
	7A	Cheboygan Memorial Hospital (Fac #16-0020)	Cheboygan
	7B	Charlevoix Area Hospital (Fac #15-0020)	Charlevoix
	7B	Mackinac Straits Hospital (A) (Fac #49-0030)	St. Ignace
	7B	Northern Michigan Hospital (Fac #24-0030)	Petoskey
	7C	Rogers City Rehabilitation Hospital (Fac #71-0030)	Rogers City
	7D	Otsego Memorial Hospital (Fac #69-0020)	Gaylord
	7E	Alpena General Hospital (Fac #04-0010)	Alpena
	7F	Kalkaska Memorial Health Center (A) (Fac #40-0020)	Kalkaska

*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.

APPENDIX A (continued)

Health Service Area	Sub 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

~~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

Health Service Area	SA No.	Bed Need
6 - EAST		
	6A	96
	6B	62
	6C	42
	6D	181
	6E	321
	6F	820
	6G	48
	6H	16
	6I	22
7 - NORTHERN LOWER		
	7A	38
	7B	200
	7C	19
	7D	35
	7E	102
	7F	392
	7G	64
	7H	59
	7I	36
8 - UPPER PENINSULA		
	8A	30
	8B	12
	8C	22
	8D	12
	8E	54
	8F	93
	8G	226
	8H	53
	8I	7
	8J	9
	8K	11
	8L	51

OCCUPANCY RATE TABLE

Adult Medical/Surgical

HOSPITAL GROUP PROJECTED BED ADC			ADJUSTED BedsBed RANGE	
ADC >= LOW	ADC< HIGH	Occup	StartBEDS_LOW	StopBEDS_HIGH
30	3031	0.60%	50	<=5052
3132	3235	0.6061%	5253	5258
3236	3439	0.6162%	5359	5653
3540	3745	0.6263%	5764	6072
3846	4150	0.6364%	6172	6579
4251	4658	0.6465%	6679	7290
4759	5067	0.6566%	7390	77102
5168	5677	0.6667%	78102	85115
5778	6388	0.6768%	86115	94130
6489	70101	0.6869%	95129	103147
71102	79117	0.6970%	104146	114168
80118	89134	0.7071%	115167	126189
90135	100154	0.7172%	127188	140214
101155	114176	0.7273%	141213	157242
115177	130204	0.7374%	158240	177276
131205	149258	0.7475%	178274	200344
150259	172327	0.7576%	201341	227431
173328	200424	0.7677%	228426	261551
201425	234561	0.7778%	262545	301720
235562	276760	0.7879%	302712	350963
277761	327895	0.7980%	351952	4101119
328	391	0.80	411	484
392	473	0.81	485	578
474	577	0.82	579	696
578	713	0.83	697	850
714	894	0.84	851	894
895		0.85	>=1054	

Pediatric Beds

ADC >	ADC<=	Occup	Beds Start	Beds Stop
	30	0.50		<=5 0
30	33	0.50	61	66
34	40	0.51	67	79
41	46	0.52	80	88
47	53	0.53	89	100
54	60	0.54	101	111
61	67	0.55	112	121
68	74	0.56	122	131
75	80	0.57	132	139
81	87	0.58	140	149
88	94	0.59	150	158
95	101	0.60	159	167
102	108	0.61	168	175
109	114	0.62	176	182
115	121	0.63	183	190
122	128	0.64	191	198
129	135	0.65	199	206
136	142	0.66	207	213
143	149	0.67	214	220
150	155	0.68	221	226
156	162	0.69	227	232
163	169	0.70	233	239
170	176	0.71	240	245
177	183	0.72	246	252
184	189	0.73	253	256
190	196	0.74	257	>=26 3
197		0.75		

Obstetric Beds

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

Obstetric Beds cont.

ADC >	ADC<=	Occup	Beds Start	Beds Stop
115	121	0.63	183	190
122	128	0.64	191	198
129	135	0.65	199	206
136	142	0.66	207	213
143	149	0.67	214	220
150	155	0.68	221	226
156	162	0.69	227	232
163	169	0.70	233	239
170	176	0.71	240	245
177	183	0.72	246	252
184	189	0.73	253	256

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

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LIMITED ACCESS AREAS

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

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

(NEEDS TO BE UPDATED WHEN BED NEED IS RUN.)

Sources:

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

2) Section 4 of these standards

3) Michigan State University
   Department of Geography
   2011 Planning Year Hospital Bed Need Calculations
   August 28, 2008

(SOURCES MAY NEED UPDATING)

MICHIGAN DEPARTMENT OF PUBLIC HEALTH
OFFICE OF HEALTH AND MEDICAL AFFAIRS

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

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

Section 1. Applicability; definitions

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

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

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

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

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

Section 2. Requirements for approval; change in bed capacity

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

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

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

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

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

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

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

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

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

~~Section 4. Comparative reviews~~

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

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

Date: May 15, 2012

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Heart/Lung and Liver (HLL) Transplantation Services, Hospital Beds (HB), Magnetic Resonance Imaging (MRI) Services, Positron Emission Tomography (PET) Scanner Services, and Pancreas Transplantation Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the HLL Transplantation Services, HB, MRI Services, PET Scanner Services, and Pancreas Transplantation Services Standards at its March 29, 2012 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed above-mentioned Standards on May 1, 2012. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from four organizations and is summarized as follows:

HLL Transplantation Services

Dennis McCafferty, Economic Alliance for Michigan (EAM)

EAM supports the position taken by the Commission that only technical changes are required to modify the Standards for consistency with other CON Standards. Other substantial changes are not needed at this time.

Richard Pietroski, Gift of Life

Gift of Life supports the technical amendment to the Standards provided by the Department, and anticipates a robust dialogue in 2015 regarding the potential deregulation of these services. Gift of Life also supports the Commission's discussion to revisit these standards through a SAC or workgroup in the future.

Hospital Beds

Dennis McCafferty, EAM

EAM supports the proposed changes in the standards. Specifically, for determining which hospitals service which communities (hospital groups) and the methodology for projecting future need of additional acute beds. EAM believes that the new provisions reducing portions of the excess licensed beds at low occupancy urban county hospitals will help improve hospital planning in the long run and serves the best interest of the citizens of Michigan.

Philip Incarnati, McLaren Health Care

McLaren does not support the proposed changes to the HB Standards for the following reasons:

- The bed need methodology recommended by the SAC and approved by the Commission essentially preserves status quo. The methodology will always result in excess beds and will never show a need for new beds in a given area. It fails to account for population shifts and makes capacity a proxy for access.
- The bed reduction language has no statistical basis and puts communities served by aging facilities, such as McLaren–Oakland in Pontiac at a disadvantage. The language further complicates a potential bed move that would position Pontiac with the appropriate number of beds and allow the people of Clarkston and surrounding communities to be served by an acute care hospital.
- Adopting the proposed language will continue to mean that the only new hospitals ever built in the State of Michigan will be approved by the Legislature or the courts and not the CON Commission. Everyone can look forward to more new, overbuilt towers at existing locations because that is the only permissible construction.
- McLaren supports simplifying the Hospital Bed standards to include the following when a hospital elects to relocate beds to a new site, it must demonstrate :
  - Financial viability with regard to the entire project
  - Conclusive positive community need assessment for both the proposed hospital site that is receiving the beds and the hospital giving up the beds
    - Significant community benefit with a financially viable plan for reuse of existing facility
    - Existing facilities cannot close to move to a new facility
  - No additional beds in Michigan
  - Maintain existing payer contracts for at least five years
  - Delicense at least 10% of existing facility’s beds

- Proposed new hospital sites may not be approved within five miles of existing acute care hospitals, nor within the same county as single community providers

Magnetic Resonance Imaging (MRI) Services

Dennis McCafferty, EAM

EAM supports the inclusion of the MRI-Guided EPI definition within the standards and the language restricting this technology to hospitals with existing MRI services that have been operational for at least 36 months and are meeting minimum volume requirements for both MRI and OHS. EAM also supports the inclusion of the PET/MRI scanner hybrid in both the MRI and PET standards.

Melissa Cupp, Wiener Assoc.

Ms. Cupp would like to suggest that the modified definition for "MRI procedure" be added to the definition of "MRI unit" rather than "MRI procedure."

"THE TERM INCLUDES FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/ MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES."

This would be consistent with how similar provisions for PET/CT hybrids are handled in the CON Standards for CT Services.

Positron Emission Tomography (PET) Scanner Services

Dennis McCafferty, EAM

EAM supports the inclusion of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures in both the MRI and PET standards.

Pancreas Transplantation Services

Dennis McCafferty, EAM

EAM would recommend that a work group be convened to review the question of deregulation. EAM strongly supported the changes made in these standards during the last review that limited this service to only higher volume kidney transplant centers. EAM requests that quality assurance issues be addressed by a workgroup considering deregulation of this service.

Richard Pietroski, Gift of Life

Gift of Life supports the action taken to eliminate regulation for Pancreas Transplantation Services. The duplication of a state level program is no longer cost effective nor can it provide the scope of oversight that is performed by the Organ Procurement and Transplantation Network (OPTN).

There is continued federal regulation of organ transplant centers by the Department of Health and Human Services through both the OPTN and the Centers for Medicare and Medicaid Services (CMS).* The national OPTN requires each approved program to meet rigid criteria for establishing a transplant program (OPTN Bylaws: Attachment I - Criteria for Transplant Program Designation), and ongoing requirements for timely patient-level data submission (OPTN Policy 7.0: Data Submission Requirements). Furthermore, each center undergoes a robust analysis for transplant and outcome data under the federal Scientific Registry for Transplant Recipients (http://www.srtr.org/). Center specific data are refreshed every six months, and statistically analyzed to identify underperforming programs which trigger a quality review by the OPTN.

*References:

Policies and Bylaws. Department of Health and Human Services: Organ Procurement and
Transplantation Network. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp
http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp
Federal Register. Department of Health and Human Services: Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 482, 488, and 498: *Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants*.
http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf

MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

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

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

Section 1. Applicability

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

Section 2. Definitions

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

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

(b) "Actual MRI adjusted procedures" or "MRI adjusted procedures," means the number of MRI procedures, adjusted in accordance with the applicable provisions of Section ~~13~~15, 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).

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

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

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

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

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

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

(p) "Health service area" or "HSA" means the geographic areas set forth in Section ~~19~~21.

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

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

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

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

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

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

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

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

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

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

(z) "MRI adjusted procedure" means an MRI visit, at an existing MRI service, that has been adjusted in accordance with the applicable provisions of Section ~~13~~15.

(aa) "MRI database" means the database, maintained by the Department pursuant to Section ~~12~~-14 of these standards, that collects information about each MRI visit at MRI services located in Michigan.

(BB) "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.

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

procedure or a procedure conducted by an MRI unit at a site participating with an approved diagnostic radiology residency program, under a research protocol approved by an IRB. The capital and operating costs related to the research use are charged to a specific research account and not charged to or collected from third-party payors or patients. ~~THE TERM INCLUDES FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES.~~ The term does not include a procedure conducted by an MRI unit approved pursuant to Section 8(1).

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

(~~dd~~EE) "MRI unit" means the magnetic resonance system consisting of an integrated set of machines and related equipment necessary to produce the images and/or spectroscopic quantitative data from scans INCLUDING FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES. The term does not include MRI simulators used solely for treatment planning purposes in conjunction with an MRT unit.

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

(~~ff~~GG) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396~~r-6~~ TO ~~and~~1396~~r-8~~G ~~to~~ AND 1396I TO ~~1396v~~1396U.

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

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

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

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

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

(~~ll~~MM) "Planning area" means

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

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

(iii) in the case of a proposed mobile MRI service or unit meeting the requirement of Section ~~13~~15(2)(d), the health service area in which all the proposed mobile host sites will be located.

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

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

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

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

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

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

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

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

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

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

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

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

(~~vv~~WW) "Site" means

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

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

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

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

(~~yy~~ZZ) "Unadjusted MRI scan" means an MRI procedure performed on a single anatomical site as defined by the MRI database and that is not adjusted pursuant to the applicable provisions of Section ~~13~~15.

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

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

(ii) involves a capital expenditure related to the MRI equipment of less than $750,000 in any consecutive 24-month period.

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

Section 3. Requirements to initiate an MRI service

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(6) The applicant shall demonstrate that the available MRI adjusted procedures from the "Available MRI Adjusted Procedures List" or the adjusted procedures from the "MRI Service Utilization List," as

applicable, are from the most recently published MRI lists as of the date an application is deemed submitted by the Department.

Section 4. Requirements to replace an existing MRI unit

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

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

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

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

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

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

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

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

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

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

Section 5. Requirements to expand an existing MRI service

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

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

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

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

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

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

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

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

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

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

(c) Each existing MRI unit to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section ~~12~~ 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

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

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

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

(d) Each existing MRI unit at the service from which a unit is to be relocated performed at least the applicable minimum number of MRI adjusted procedures set forth in Section ~~12~~ 14 based on the most recently published MRI Service Utilization List as of the date an application is deemed submitted by the Department.

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

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

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

(a) For the first application proposing to acquire an existing fixed or mobile MRI service on or after July 1, 1997, the existing MRI service and its unit(s) to be acquired shall not be required to be in compliance with the volume requirements applicable to a seller/lessor on the date the acquisition occurs. The MRI service shall be operating at the applicable volume requirements set forth in Section ~~12~~ 14 of these standards in the second 12 months after the effective date of the acquisition, and annually thereafter.

(b) For any application proposing to acquire an existing fixed or mobile MRI service and its unit(s), except the first application approved pursuant to subsection (a), an applicant shall be required to document that the MRI service and its unit(s) to be acquired is operating in compliance with the volume requirements set forth in Section ~~12~~ 14 of these standards applicable to an existing MRI service on the date the application is submitted to the Department.

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

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

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

Section 8. Requirements to establish a dedicated research MRI unit

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

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

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

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

Section 9. Requirements to establish a dedicated pediatric MRI unit

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

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

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

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

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

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

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

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

Section 10. 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.

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

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

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

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

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

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

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

SEC. 11. AN APPLICANT PROPOSING TO INITIATE, REPLACE, OR ACQUIRE A HOSPITAL BASED MRI-GUIDED EPI 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.

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

(4) THE PROPOSED MRI-GUIDED EPI UNIT MUST BE LOCATED IN A CARDIAC CATHETERIZATION LAB CONTAINING A FLOUROSCOPY UNIT WITH AN ADJOINING ROOM CONTAINING AN MRI SCANNER. THE ROOMS SHALL CONTAIN A PATIENT TRANSFER SYSTEM ALLOWING FOR TRANSFER OF THE PATIENT BETWEEN THE CARDIAC CATHETERIZATION LAB AND THE MRI UNIT, UTILIZING ONE OF THE FOLLOWING:
(A) MOVING THE PATIENT TO THE MRI SCANNER, OR
(B) INSTALLING THE MRI SCANNER ON A SLIDING GANTRY TO ALLOW THE PATIENT TO REMAIN STATIONARY.

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

(A) THE PATIENT HAS BEEN ADMITTED TO AN INPATIENT UNIT; OR

(B) THE PATIENT IS HAVING THE STUDY PERFORMED ON AN OUTPATIENT BASIS AS FOLLOWS:

(I) IS IN NEED OF GENERAL ANESTHESIA OR DEEP SEDATION AS DEFINED BY THE AMERICAN SOCIETY OF ANESTHESIOLOGISTS, OR

(II) HAS AN IMPLANTABLE CARDIAC DEVICE.

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

(7) 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. REQUIREMENTS FOR APPROVAL OF AN FDA-APPROVED PET/MRI SCANNER HYBRID FOR INITIATION, EXPANSION, REPLACEMENT, AND ACQUISITION

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

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

(2) THE APPLICANT AGREES TO OPERATE THE FDA-APPROVED PET/MRI SCANNER HYBRID IN ACCORDANCE WITH ALL APPLICABLE PROJECT DELIVERY REQUIREMENTS SET FORTH IN SECTION ~~13~~14 OF THESE STANDARDS.

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

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

Section ~~11~~13. Requirements for all applicants

Sec. ~~11~~13. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of services if a CON is approved.

Section ~~12~~14. Project delivery requirements – terms of approval

Sec. ~~12~~14. (1) An applicant shall agree that, if approved, MRI services, whether fixed or mobile, shall be delivered and maintained in compliance with the following:

(a) Compliance with these standards.

(b) Compliance with applicable safety and operating standards.

(c) Compliance with the following quality assurance standards:

(i) An applicant shall develop and maintain policies and procedures that establish protocols for assuring the effectiveness of operation and the safety of the general public, patients, and staff in the MRI service.

(ii) An applicant shall establish a schedule for preventive maintenance for the MRI unit.

(iii) An applicant shall provide documentation identifying the specific individuals that form the MRI team. At a minimum, the MRI team shall consist of the following professionals:

(A) Physicians who shall be responsible for screening of patients to assure appropriate utilization of the MRI service and taking and interpretation of scans. At least one of these physicians shall be a board-certified radiologist.

(B) An appropriately trained MRI technician who shall be responsible for taking an MRI scan.

(C) An MRI physicist/engineer available as a team member on a full-time, part-time, or contractual basis.

(iv) An applicant shall document that the MRI team members have the following qualifications:

(A) Each physician credentialed to interpret MRI scans meets the requirements of each of the following:

(1) The physician is licensed to practice medicine in the State of Michigan.

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

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

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

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

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

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

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

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

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

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

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

(i) MRI units shall be operating at a minimum average annual utilization during the second 12 months of operation, and annually thereafter, as applicable:

(A) 6,000 MRI adjusted procedures per unit for fixed MRI services unless compliant with (1) or (2),

(1) 4,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(ii) and is the only fixed MRI unit at the current site,

(2) 3,000 MRI adjusted procedures for the fixed MRI unit initiated pursuant to Section 3(2)(b)(iii) and is the only fixed MRI unit at the hospital site licensed under part 215 of the code,

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

(C) 3,500 MRI adjusted procedures per unit for dedicated pediatric MRI units.

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

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

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

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

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

(iii) The applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, operating schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources, as well as other data requested by the Department or its designee and approved by the Commission. The applicant shall provide the required data in a format established by the Department and in a mutually agreed upon media no later than 30 days following the last day of the quarter for which data are being reported to the Department. An applicant shall be considered in violation of this term of approval if the required data are not submitted to the Department within 30 days following the last day of the quarter for which data are being reported. The Department may elect to verify the data through on-site review of appropriate records. Data for an MRI unit approved pursuant to Section 8(1), Section 9, ~~or~~ Section 10, OR SECTION 11 shall be reported separately.

For purposes of Section 10, the data reported shall include, at a minimum, how often the IMRI unit is used and for what type of services, i.e., intra-operative or diagnostic. FOR PURPOSES OF SECTION 11, THE DATA REPORTED SHALL INCLUDE, AT A MINIMUM, HOW OFTEN THE MRI-GUIDED EPI UNIT IS USED AND FOR WHAT TYPE OF SERVICES, I.E., ELECTROPHYSIOLOGY OR DIAGNOSTIC.

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

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

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

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

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

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

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

Section ~~13~~15. MRI procedure adjustments

Sec. ~~13~~15. (1) The Department shall apply the following formula, as applicable, to determine the number of MRI adjusted procedures that are performed by an existing MRI service or unit:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section ~~14~~16. Documentation of actual utilization

Sec. ~~14~~16. Documentation of the number of MRI procedures performed by an MRI unit shall be substantiated by the Department utilizing data submitted by the applicant in a format and media specified by the Department and as verified for the 12-month period reported on the most recently published "MRI Service Utilization List" as of the date an application is deemed submitted by the Department. The number of MRI procedures actually performed shall be documented by procedure records and not by application of the methodology required in Section ~~15~~17. The Department may elect to verify the data through on-site review of appropriate records.

Section ~~15~~17. Methodology for computing the number of available MRI adjusted procedures

Sec. ~~15~~17. (1) The number of available MRI adjusted procedures required pursuant to Section 3 shall be computed in accordance with the methodology set forth in this section. In applying the methodology, the following steps shall be taken in sequence, and data for the 12-month period reported on the most recently published "Available MRI Adjusted Procedures List," as of the date an application is deemed submitted by the Department, shall be used:

(a) Identify the number of actual MRI adjusted procedures performed by each existing MRI service as determined pursuant to Section ~~13~~15.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section ~~16~~18. Procedures and requirements for commitments of available MRI adjusted procedures

Sec. ~~16~~18. (1) If one or more host sites on a mobile MRI service are located within the planning area of the proposed site, the applicant may access available MRI adjusted procedures from the entire mobile MRI service.

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

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

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

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

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

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

(a) A committing doctor certifies that 100% of his or her available MRI adjusted procedures for each specified MRI service, calculated pursuant to Section ~~15~~17, is being committed and specifies the CON application number for the MRI unit to which the data commitment is made. A doctor shall not be required to commit available MRI adjusted procedures from all MRI services to which his or her patients are referred for MRI services but only from those MRI services specified by the doctor in the data commitment form provided by the Department and submitted by the applicant in support of its application.

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

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

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

(i) The approved CON is withdrawn or expires.

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

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

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

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

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

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

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

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

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

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

(a) on or after the date an application is deemed submitted by the Department.

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

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

Section ~~17~~19. Lists published by the Department

Sec. ~~17~~19. (1) On or before May 1 and November 1 of each year, the Department shall publish the following lists:

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

(i) The number of actual MRI adjusted procedures;

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

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

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

(i) The number of available MRI adjusted procedures;

(ii) The name, address, and license number of each referring doctor, identified in Section ~~15~~17(1)(c)(v), whose patients received MRI services at that MRI service; and

(iii) The number of available MRI adjusted procedures performed on patients referred by each referring doctor, identified in Section ~~15~~17(1)(c)(v), and if any are committed to an MRI service. This number shall be calculated in accordance with the requirements of Section ~~15~~17(1). A referring doctor may have fractional portions of available MRI adjusted procedures.

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

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

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

(3) In publishing the lists pursuant to subsections (a) and (b), if an MRI service has not reported data in compliance with the requirements of Section ~~12~~14, the Department shall indicate on both lists that the MRI service is in violation of the requirements set forth in Section ~~12~~14, and no data will be shown for that service on either list.

Section ~~18~~20. Effect on prior CON Review Standards; Comparative reviews

Sec. ~~18~~20. (1) These CON review standards supersede and replace the CON Review Standards for MRI Services approved by the CON Commission on ~~December 15, 2010~~September 22, 2011 and effective ~~March 11~~November 21, 2011.

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

Section ~~19~~21. Health Service Areas

Sec. ~~19~~21. Counties assigned to each of the health service areas are as follows:

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

APPENDIX A

CON REVIEW STANDARDS FOR MRI SERVICES

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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

Date: May 15, 2012

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Heart/Lung and Liver (HLL) Transplantation Services, Hospital Beds (HB), Magnetic Resonance Imaging (MRI) Services, Positron Emission Tomography (PET) Scanner Services, and Pancreas Transplantation Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the HLL Transplantation Services, HB, MRI Services, PET Scanner Services, and Pancreas Transplantation Services Standards at its March 29, 2012 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed above-mentioned Standards on May 1, 2012. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from four organizations and is summarized as follows:

HLL Transplantation Services

Dennis McCafferty, Economic Alliance for Michigan (EAM)

EAM supports the position taken by the Commission that only technical changes are required to modify the Standards for consistency with other CON Standards. Other substantial changes are not needed at this time.

Richard Pietroski, Gift of Life

Gift of Life supports the technical amendment to the Standards provided by the Department, and anticipates a robust dialogue in 2015 regarding the potential deregulation of these services. Gift of Life also supports the Commission's discussion to revisit these standards through a SAC or workgroup in the future.

Hospital Beds

Dennis McCafferty, EAM

EAM supports the proposed changes in the standards. Specifically, for determining which hospitals service which communities (hospital groups) and the methodology for projecting future need of additional acute beds. EAM believes that the new provisions reducing portions of the excess licensed beds at low occupancy urban county hospitals will help improve hospital planning in the long run and serves the best interest of the citizens of Michigan.

Philip Incarnati, McLaren Health Care

McLaren does not support the proposed changes to the HB Standards for the following reasons:

- The bed need methodology recommended by the SAC and approved by the Commission essentially preserves status quo. The methodology will always result in excess beds and will never show a need for new beds in a given area. It fails to account for population shifts and makes capacity a proxy for access.
- The bed reduction language has no statistical basis and puts communities served by aging facilities, such as McLaren–Oakland in Pontiac at a disadvantage. The language further complicates a potential bed move that would position Pontiac with the appropriate number of beds and allow the people of Clarkston and surrounding communities to be served by an acute care hospital.
- Adopting the proposed language will continue to mean that the only new hospitals ever built in the State of Michigan will be approved by the Legislature or the courts and not the CON Commission. Everyone can look forward to more new, overbuilt towers at existing locations because that is the only permissible construction.
- McLaren supports simplifying the Hospital Bed standards to include the following when a hospital elects to relocate beds to a new site, it must demonstrate :
  - Financial viability with regard to the entire project
  - Conclusive positive community need assessment for both the proposed hospital site that is receiving the beds and the hospital giving up the beds
    - Significant community benefit with a financially viable plan for reuse of existing facility
    - Existing facilities cannot close to move to a new facility
  - No additional beds in Michigan
  - Maintain existing payer contracts for at least five years
  - Delicense at least 10% of existing facility’s beds

- Proposed new hospital sites may not be approved within five miles of existing acute care hospitals, nor within the same county as single community providers

Magnetic Resonance Imaging (MRI) Services

Dennis McCafferty, EAM

EAM supports the inclusion of the MRI-Guided EPI definition within the standards and the language restricting this technology to hospitals with existing MRI services that have been operational for at least 36 months and are meeting minimum volume requirements for both MRI and OHS. EAM also supports the inclusion of the PET/MRI scanner hybrid in both the MRI and PET standards.

Melissa Cupp, Wiener Assoc.

Ms. Cupp would like to suggest that the modified definition for "MRI procedure" be added to the definition of "MRI unit" rather than "MRI procedure."

"THE TERM INCLUDES FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/ MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES."

This would be consistent with how similar provisions for PET/CT hybrids are handled in the CON Standards for CT Services.

Positron Emission Tomography (PET) Scanner Services

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EAM supports the inclusion of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures in both the MRI and PET standards.

Pancreas Transplantation Services

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EAM would recommend that a work group be convened to review the question of deregulation. EAM strongly supported the changes made in these standards during the last review that limited this service to only higher volume kidney transplant centers. EAM requests that quality assurance issues be addressed by a workgroup considering deregulation of this service.

Richard Pietroski, Gift of Life

Gift of Life supports the action taken to eliminate regulation for Pancreas Transplantation Services. The duplication of a state level program is no longer cost effective nor can it provide the scope of oversight that is performed by the Organ Procurement and Transplantation Network (OPTN).

There is continued federal regulation of organ transplant centers by the Department of Health and Human Services through both the OPTN and the Centers for Medicare and Medicaid Services (CMS).* The national OPTN requires each approved program to meet rigid criteria for establishing a transplant program (OPTN Bylaws: Attachment I - Criteria for Transplant Program Designation), and ongoing requirements for timely patient-level data submission (OPTN Policy 7.0: Data Submission Requirements). Furthermore, each center undergoes a robust analysis for transplant and outcome data under the federal Scientific Registry for Transplant Recipients (http://www.srtr.org/). Center specific data are refreshed every six months, and statistically analyzed to identify underperforming programs which trigger a quality review by the OPTN.

*References:

Policies and Bylaws. Department of Health and Human Services: Organ Procurement and
Transplantation Network. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp
http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp
Federal Register. Department of Health and Human Services: Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 482, 488, and 498: *Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants*.
http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf

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Date: May 15, 2012

TO: Brenda Rogers

FROM: Natalie Kellogg

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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 TOMOGRAPHY (CT) AND FDA-APPROVED PET/MAGNETIC RESONANCE IMAGINING (MRI) scanner

hybrids. If the PET/CT scanner HYBRID will be used for ~~computed tomography (~~CT~~)~~ scans only in conjunction with the PET scan, then no separate CON is required for that CT use. 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. The term does not include single-photon emission computed tomography systems (SPECT), x-ray CT systems, magnetic resonance, ultrasound computed tomographic systems, gamma cameras modified for either non-coincidence or coincidence imaging, or similar technology.

(r) "PET scanner services" or "PET services" means either the utilization of a PET unit(s) at one site in the case of a fixed PET service or at each host site in the case of a mobile PET service.

(s) "SPECT" means single photon emission computed tomography.

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

Section 3. Requirements to initiate a PET scanner service

Sec. 3. An applicant proposing to initiate PET scanner services shall demonstrate the following, as applicable to the proposed project.

(1) The applicant shall demonstrate the proposed site provides the following services and specialties:

(a) nuclear medicine services as documented by a certificate from the US Nuclear Regulatory Commission,

(b) single photon emission computed tomography (SPECT) services,

(c) computed tomography (CT) scanning services,

(d) magnetic resonance imaging (MRI) services,

(e) cardiac catheterization services,

(f) open heart surgery,

(g) thoracic surgery,

(h) cardiology,

(i) oncology,

(j) radiation oncology,

(k) neurology,

(l) neurosurgery, and

(m) psychiatry.

(2) If the proposed site does not provide any of the services listed in subsection (1) on-site, the applicant shall provide written contracts or agreements with a hospital(s) located within the same planning area or 25-mile radius of the proposed site for the services not provided.

(3) The applicant shall demonstrate the proposed site has an on-site source of radiopharmaceuticals. If the proposed site does not provide an on-site source of radiopharmaceuticals, the applicant shall provide a written contract or agreement that demonstrates a reliable supply of radiopharmaceuticals.

(4) An applicant proposing to initiate a fixed PET scanner service with its first PET scanner shall project 2,600 PET data units or shall demonstrate all of the following:

(a) The applicant is currently a host site being served by one or more mobile PET scanner services.

(b) The applicant has performed:

(i) 1,700 PET equivalents in the most recent 12-month period verifiable by the Department for a host site in a metropolitan statistical area county, or

(ii) 1,500 PET equivalents in the most recent 12-month period verifiable by the Department for a host site in a rural or micropolitan statistical area county.

(c) The applicant shall install the fixed PET unit at the same site as the existing host site or within a 10-mile radius of the existing host site for a metropolitan statistical area county or a 25-mile radius for a rural or micropolitan statistical area.

(d) The applicant agrees to cease operation as a host site and not become a host site for at least 12 months from the date the fixed PET scanner becomes operational. THIS REQUIREMENT SHALL NOT APPLY IF THE APPLICANT IS INSTALLING AN FDA-APPROVED PET/MRI SCANNER HYBRID.

(5) An applicant proposing to initiate a mobile PET scanner service with its first mobile PET scanner shall project 2,100 PET data units.

(a) Of the 2,100 PET data units, the applicant shall project a minimum of 360 PET data units within a 20-mile radius of each proposed host site for planning area 1, or 240 PET data units per host site for any other planning area, for the proposed service.

(b) The application for the mobile PET scanner service is accompanied by at least two host site applications.

(c) Each applicant provides a route schedule for the proposed mobile PET scanner service.

(d) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

(6) An applicant proposing to initiate a host site on a proposed or existing mobile PET scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

(c) The applicant has not initiated fixed PET scanner services under subsection 3(4) within the most recent 12-month period as of the date the application is submitted to the Department.

(d) An applicant initiating a host site in HSA 8 on a mobile PET scanner service that operates predominantly outside of Michigan shall demonstrate 240 PET data units from planning area 6.

(7) An applicant proposing to initiate PET scanner services as an existing host site on a different mobile PET scanner service shall demonstrate the following:

(a) The applicant provides a proposed route schedule.

(b) The applicant provides a draft contract for services between the proposed host site and central service coordinator.

(c) 50 PET equivalents were performed in the most recent 12-month period verifiable by the Department from an existing mobile PET scanner service at the existing host site.

Section 4. Requirements to replace an existing PET scanner(s) or PET scanner service

Sec. 4. Replacing a PET scanner(s) means a change in the scanner equipment or relocation of the service to a new site. An upgrade to software or components of an existing scanner does not constitute replacement of a PET scanner. An applicant proposing to replace an existing PET scanner(s) or PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to replace a PET scanner(s) shall demonstrate each of the following:

(a) The replacement scanner(s) is the same type (fixed or mobile) as the scanner(s) to be replaced.

(b) The scanner(s) to be replaced is fully depreciated according to generally accepted accounting principles or either of the following:

(i) The existing scanner(s) poses a threat to the safety of the patients.

(ii) The replacement scanner(s) offers technological improvements that enhance quality of care, increase efficiency, and reduce operating costs and patient charges.

(c) The applicant agrees that the PET scanner(s) to be replaced will be removed from service on or before beginning operation of the replacement scanner(s).

(2) An applicant proposing to replace a fixed PET scanner service to a new site shall demonstrate the following:

(a) The proposed site is within a 10-mile radius of the existing site for a metropolitan statistical area county or a 25-mile radius for a rural or micropolitan statistical area county.

(b) The existing fixed PET scanner(s) performed 500 PET equivalents per fixed scanner in the

most recent 12-month period verifiable by the Department.

(c) The existing fixed PET scanner service has been in operation for at least 36 months as of the date of the application submitted to the Department.

Section 5. Requirements to expand a PET scanner service

Sec. 5. An applicant proposing to expand a PET scanner service shall demonstrate the following, as applicable to the proposed project. This section does not apply to dedicated research, dedicated pediatric, or positron emission mammography (PEM) scanners.

(1) An applicant proposing to add a fixed PET scanner(s) to an existing fixed PET scanner service shall demonstrate the following:

(a) 1,900 PET equivalents were performed per existing and approved fixed PET scanner(s) in the most recent 12-month period verifiable by the Department for an applicant in a metropolitan statistical area county, or

(b) 1,700 PET equivalents were performed per existing and approved fixed PET scanner(s) in the most recent 12-month period verifiable by the Department for an applicant in a rural or micropolitan statistical area county.

(c) The additional PET scanner(s) shall be located at the same site.

(2) An applicant proposing to add a mobile PET scanner(s) to an existing mobile PET scanner service shall demonstrate the following:

(a) 2,000 PET equivalents were performed per existing and approved mobile scanner(s) in the most recent 12-month period verifiable by the Department for an applicant serving at least one existing host site in a metropolitan statistical area county, or

(b) 1,800 PET equivalents were performed per existing and approved scanner(s) in the most recent 12-month period verifiable by the Department for an applicant serving only host sites in rural or micropolitan statistical area counties.

(3) An applicant proposing to add a fixed PET scanner to an existing fixed PET scanner service that also receives mobile PET scanner services shall demonstrate the following:

(a) The applicant is currently a host site being served by one or more mobile PET scanner services.

(b) The applicant has performed:

(i) An average of 1,900 pet equivalents for the host site and each of the existing and approved fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a metropolitan statistical area county, or

(ii) An average of 1,700 PET equivalents for the host site and each of the existing and approved fixed scanners in the most recent 12-month period verifiable by the Department for a host site in a rural or micropolitan statistical area county.

(c) The applicant agrees to cease operation as a host site and not become a host site for at least 12 months from the date the fixed scanner becomes operational.

Section 6. Requirements to acquire a PET scanner service or scanner(s)

Sec. 6. Acquiring a PET scanner service and its scanner(s) means obtaining possession and control by contract, ownership, lease, or other comparable arrangement and renewal of lease for an existing fixed or mobile PET scanner. An applicant proposing to acquire a PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) For the first application proposing to acquire an existing fixed, mobile, or host site PET scanner service, other than a renewal of lease, on or after November 21, 2011, the existing PET service and its scanner(s) shall not be required to be in compliance with the applicable volume requirements set forth in this section.

(2) An applicant proposing to acquire an existing fixed or mobile PET scanner service shall

demonstrate that the existing fixed or mobile scanner(s) performed an average of 500 PET equivalents per scanner in the most recent 12-month period verifiable by the Department.

(3) An applicant proposing to acquire an existing host site shall demonstrate that the existing host site has performed 50 PET equivalents in the most recent 12-month period verifiable by the Department.

(4) An applicant proposing to renew a lease for an existing fixed or mobile PET scanner(s) shall demonstrate that the renewal of the lease is more cost effective than replacing the scanner(s).

Section 7. Requirements for a dedicated research fixed PET scanner

Sec. 7. An applicant proposing to add a fixed PET scanner to an existing PET scanner service for exclusive research use shall demonstrate the following:

(1) The applicant agrees that the dedicated research PET scanner will be used primarily (70% or more of the scans) for research purposes only.

(2) The dedicated research PET scanner shall operate under a protocol approved by the applicant's Institutional Review Board, as defined by Public Law 93-348 and regulated by Title 45 CFR 46.

(3) The applicant has access to a cyclotron for accelerating charged particles to high energies by means of electromagnetic fields.

(4) The proposed site can have no more than three dedicated research fixed PET scanners approved under this Section.

Section 8. Requirements for a dedicated pediatric PET scanner

Sec. 8. An applicant proposing to initiate a PET scanner service, or add a fixed PET scanner to expand an existing PET scanner service, for dedicated pediatric PET use shall demonstrate the following:

(1) The applicant agrees that the dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for patients under 18 years of age.

(2) The applicant shall demonstrate the existing site provided the following for the most recent calendar year or a continuous 12-month period at the time the application is submitted to the Department:

(a) at least 7,000 pediatric (< 18 years old) discharges, excluding normal newborns,
(b) at least 5,000 pediatric (< 18 years old) surgeries, and
(c) at least 50 new pediatric cancer cases on its cancer registry.

(3) The applicant shall have an active medical staff at the time the application is submitted to the Department that includes physicians who are fellowship-trained in the following pediatric specialties:

(a) radiology (at least two staff members)
(b) anesthesiology
(c) cardiology
(d) critical care
(e) gastroenterology
(f) hematology/oncology
(g) neurology
(h) neurosurgery
(i) orthopedic surgery
(j) pathology
(k) pulmonology
(l) surgery
(m) neonatology

(4) The applicant shall have in operation the following pediatric specialty programs at the time the application is submitted to the Department:

(a) bone marrow transplant program

(b) sedation program

(c) open heart program

(5) The applicant meets the requirements of Section 3(1) through 3(4) if the applicant is initiating a PET scanner service with a dedicated pediatric fixed PET scanner.

(6) The proposed site can have no more than two dedicated pediatric fixed PET scanners approved under this section.

Section 9. Requirements for a positron emission mammography (PEM) scanner

Sec. 9. An applicant proposing to add a PEM scanner service to an existing PET scanner service shall demonstrate the following, as applicable to the proposed project.

(1) An applicant proposing to add a fixed PEM scanner to an existing fixed PET scanner site shall demonstrate the following:

(a) The applicant is certified through the American College of Radiology (ACR) as a Breast Imaging Center of Excellence (BICOE) at the time the application is submitted to the Department.

(b) The applicant has a fixed PET scanner service and has performed 1,000 PET equivalents per scanner at the site in the most recent 12-month period verifiable by the Department, or the applicant operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that has a fixed PET scanner service.

(c) The proposed site can have no more than one fixed PEM scanner approved under this section.

(2) An applicant proposing to add a mobile PEM scanner to an existing mobile PET scanner service shall demonstrate the following:

(a) The central service coordinator application for a mobile PEM scanner shall be accompanied by at least five (5) companion host site applications for initiation of mobile PEM scanner services. The proposed host sites have not received mobile PEM scanner services within the most recent 12-month period.

(b) The applicant has performed an average of 500 PET equivalents per scanner on the existing mobile PET network in the most recent 12-month period verifiable by the Department.

(c) The applicant provides a route schedule for the proposed mobile PEM scanner service.

(d) The applicant provides a draft contract for PEM services between the proposed host sites and central service coordinator.

(e) The proposed network can have no more than one mobile PEM scanner approved under this section.

(3) An applicant, whether an existing fixed PET scanner site or host site, proposing to initiate mobile PEM scanner services as a host site shall demonstrate the following:

(a) The applicant is certified through the ACR as a BICOE site at the time the application is submitted to the Department.

(b) The applicant has a fixed PET scanner site or host site and has performed 100 PET equivalents in the most recent 12-month period verifiable by the Department, or the applicant operates a comprehensive cancer center recognized by the National Cancer Institute and contracts with a facility that has a fixed or mobile PET scanner service.

(c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

(d) The applicant provides a draft contract for PEM services between the host site and central service coordinator.

(4) An applicant proposing to add an existing PEM scanner host site to an existing mobile PEM

scanner service shall demonstrate the following:

(a) The host site has performed mobile PEM scanner service within the most recent 12-month period as of the date an application is submitted to the Department.

(b) The proposed site is certified through the ACR as a BICOE site at the time the application is submitted to the Department.

(c) The applicant provides a proposed route schedule for the mobile PEM scanner service.

(d) The applicant provides a draft contract for PEM services between the host site and central service coordinator.

Section 10. Requirement for Medicaid participation

Sec. 10. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within (6) months from the offering of services if a CON is approved.

Section 11. Project delivery Requirements and terms of approval for all applicants

Sec. 11. An applicant shall agree that, if approved, the PET scanner services shall be delivered in compliance with the following terms of approval.

(1) Compliance with these standards.

(2) Compliance with the following quality assurance requirements:

(a) A PET scanner service shall be staffed so that screening of requests for and interpretation of PET procedures will be carried out by a physician(s) with appropriate training and familiarity with the appropriate diagnostic use and interpretation of cross-sectional images of the anatomical region(s) to be examined. For purposes of evaluating this subsection, the Department shall consider it prima facie evidence as to the training of the physician(s) if the physician is board certified or board qualified in nuclear medicine or nuclear radiology. However, an applicant may submit, and the Department may accept, other evidence that the physician(s) is qualified to operate the PET service/scanner. The physician(s) must be on-site or available through telecommunication capabilities to participate in the screening of patients for PET procedures and to provide other consultation services.

(b) The PET scanner service shall include the following personnel, employed directly or on a contractual basis: a technologist with training in PET scanning and a physicist. The physicist must be board certified or eligible for certification by the American Board of Radiology or an equivalent organization.

(c) The PET scanner service shall have a physician on-site or immediately available to the PET scanner service at all times when patients are undergoing PET procedures.

(d) The applicant maintains the services and specialties as set forth in Section 3(1) through 3(4).

(3) Compliance with the following access to care requirements:

(a) The PET scanner service shall accept referrals for PET scanner services from all appropriately licensed practitioners.

(b) The PET scanner service shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(c) The PET scanner service shall not deny PET scanner services to any individual based on ability to pay or source of payment.

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

(4) Compliance with the following monitoring and reporting requirements:

(a) The PET scanners shall be operating at an average of 500 PET equivalents per scanner during the second 12 months of operations, and annually thereafter. This requirement shall be waived during review of applications under sections 4(1) and 6(4), if applicable. In meeting these requirements, an applicant shall not include any PET scans performed on a PET scanner used exclusively for research

approved pursuant to Section 7, for a dedicated pediatric PET scanner approved pursuant to Section 8, or for a PEM scanner approved pursuant to Section 9.

(b) The PET scanner service shall participate in a data collection system established and administered by the Department or its designee. The data may include, but are not limited to, clinical scan data, annual budget and cost information, operating schedules, through-put schedules, demographic and diagnostic information, and the volume of care provided to patients from all payor sources. The applicant shall provide the required data on a separate basis for each separate and distinct site, PET scanner, or PET scanner service as required by the Department, in a format established by the Department. The Department may elect to verify the data through on-site review of appropriate records.

(c) The PET scanner service shall provide the Department with timely notice of the proposed project implementation consistent with applicable statute and promulgated rules.

(5) Compliance with the following dedicated research PET scanner requirements, if applicable:

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

(b) The dedicated research pet scanner shall not be used for any purposes other than as approved by the Institutional Review Board.

(c) The dedicated research PET scanner will be used primarily (70% or more of the scans) for research purposes only.

(6) Compliance with the following dedicated pediatric PET scanner requirements, if applicable:

(a) The dedicated pediatric PET scanner will be used primarily (70% or more of the scans) for patients under 18 years of age.

(b) Shall maintain active medical staff in the applicable pediatric specialties and pediatric specialty programs as set forth in the section.

(7) Compliance with the following PEM scanner requirements, if applicable:

(a) The PEM scanner service must maintain ACR accreditation as a BICOE site verifiable by the Department.

(8) Compliance with the following mobile PET scanner requirements, if applicable:

(a) The central service coordinator for a mobile PET scanner service shall notify the Department 30 days prior to dropping an existing host site.

(b) Each host site must have at least one physician who is board certified or board eligible in nuclear medicine or nuclear radiology on its medical staff. The physician(s) shall be responsible for establishing patient examination and infusion protocol, and providing for the interpretation of scans performed.

(c) Each host site shall provide a properly prepared parking pad for the mobile PET scanner unit, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as an enclosed canopy or an enclosed corridor).

(d) A mobile PET scanner service shall operate under a contractual agreement that includes the provision of PET services at each host site on a regularly scheduled basis.

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

Section 12. Methodology for computing the projected PET data units

Sec. 12. An applicant being reviewed under Section 3 shall apply the methodology set forth in this section in computing the projected number of PET data units.

(1) Identify the number of diagnosis-specific new cancer cases documented in accordance with the requirements of Section 13.

(a) Combine the number of cancer cases for lung (site codes C340-C349), esophagus (site codes C150-C159), colorectal (site codes C180-C209), lymphoma (morphology codes (9590-9729), melanoma

(morphology codes 8720-8790), and head & neck [site codes C000-C148, C300-C329, C410, C411, C470 or C490 excluding C440-C444 (skin of head and neck), and additional codes approved by national coverage determination]. Use the name "combined" for this grouping.

(b) Multiply the number resulting from the calculation in "combined" cancer cases identified in subsection (1)(a) by 0.8, which is the estimated probability that a "combined" cancer case will require a PET scan.

(c) Multiply the number resulting from the calculation in subsection (1)(b) by 2.5, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(2) Identify the number of diagnosis-specific new cancer cases documented in accord with the requirements of section 13.

(a) Multiply the number of breast cancer cases (site codes C500-C509) by 0.25, which is the estimated probability that a breast cancer case will require a PET scan.

(b) Multiply the number resulting from the calculation in subsection (2)(a) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(3) Multiply the number of diagnostic cardiac catheterization cases identified in accord with the requirements of Section 15 by 0.1, which is the estimated probability that a patient having a diagnostic cardiac catheterization will require a PET scan.

(4) Multiply the number of intractable epilepsy cases (ICD-9-CM codes 345.01, 345.11, 345.41, 345.51, 345.61, 345.71, 345.81, or 345.91) identified in accord with the requirements of Section 16 by 1.0, which is the estimated probability that a patient having an intractable epilepsy procedure will require a PET scan. Multiply the number resulting from the calculation in subsection (3) by 1.0, which is the estimated number of PET scans needed for each patient requiring a PET scan.

(5) Sum the numbers resulting from the calculations in subsections (1) through (4) to determine the total number of projected PET data units.

(6) Multiply the result calculated in subsection (5) above by a factor of 3.0 if the applicant is proposing to serve only planning area 6 to determine the total number of projected PET data units.

(7) Multiply the result calculated in subsection (5) above by a factor of 2.0 if the applicant is proposing to serve only planning area 5 to determine the total number of projected PET data units.

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.

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.

(a) For fixed PET scanner services, the geographic location of each entity contributing intractable

epilepsy case 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 intractable epilepsy case data in the planning area(s) for which the proposed PET scanner 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 intractable epilepsy 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.

(d) The intractable epilepsy case data is from the most recent Michigan Inpatient Data Base (MIDB) available to the Department.

(2) No entity currently operating or approved to operate a scanner shall contribute intractable epilepsy case data.

(3) The Department may not consider a withdrawal of intractable epilepsy 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 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 17. Methodology for computing PET equivalents

Sec. 17. PET equivalents shall be calculated as follows:

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.

Section 18. Department inventory of PET scanners

Sec. 18. The Department shall maintain and publicly post on its web site a list of PET scanner services annually.

Section 19. Comparative reviews; effect on prior planning policies

Sec. 19. Proposed projects reviewed under these standards shall not be subject to comparative review. These CON review standards supersede and replace the CON standards for PET scanner services approved by the CON Commission on ~~December 12, 2006~~September 22, 2011 and effective ~~March 8, 2007~~November 21, 2011.

APPENDIX A

Counties assigned to each health service area are as follows:

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

APPENDIX B

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

Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

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

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

Date: May 15, 2012

TO: Brenda Rogers

FROM: Natalie Kellogg

RE: Summary of Public Hearing Comments on Heart/Lung and Liver (HLL) Transplantation Services, Hospital Beds (HB), Magnetic Resonance Imaging (MRI) Services, Positron Emission Tomography (PET) Scanner Services, and Pancreas Transplantation Services Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the HLL Transplantation Services, HB, MRI Services, PET Scanner Services, and Pancreas Transplantation Services Standards at its March 29, 2012 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed above-mentioned Standards on May 1, 2012. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from four organizations and is summarized as follows:

HLL Transplantation Services

Dennis McCafferty, Economic Alliance for Michigan (EAM)

EAM supports the position taken by the Commission that only technical changes are required to modify the Standards for consistency with other CON Standards. Other substantial changes are not needed at this time.

Richard Pietroski, Gift of Life

Gift of Life supports the technical amendment to the Standards provided by the Department, and anticipates a robust dialogue in 2015 regarding the potential deregulation of these services. Gift of Life also supports the Commission's discussion to revisit these standards through a SAC or workgroup in the future.

Hospital Beds

Dennis McCafferty, EAM

EAM supports the proposed changes in the standards. Specifically, for determining which hospitals service which communities (hospital groups) and the methodology for projecting future need of additional acute beds. EAM believes that the new provisions reducing portions of the excess licensed beds at low occupancy urban county hospitals will help improve hospital planning in the long run and serves the best interest of the citizens of Michigan.

Philip Incarnati, McLaren Health Care

McLaren does not support the proposed changes to the HB Standards for the following reasons:

- The bed need methodology recommended by the SAC and approved by the Commission essentially preserves status quo. The methodology will always result in excess beds and will never show a need for new beds in a given area. It fails to account for population shifts and makes capacity a proxy for access.
- The bed reduction language has no statistical basis and puts communities served by aging facilities, such as McLaren–Oakland in Pontiac at a disadvantage. The language further complicates a potential bed move that would position Pontiac with the appropriate number of beds and allow the people of Clarkston and surrounding communities to be served by an acute care hospital.
- Adopting the proposed language will continue to mean that the only new hospitals ever built in the State of Michigan will be approved by the Legislature or the courts and not the CON Commission. Everyone can look forward to more new, overbuilt towers at existing locations because that is the only permissible construction.
- McLaren supports simplifying the Hospital Bed standards to include the following when a hospital elects to relocate beds to a new site, it must demonstrate :
  - Financial viability with regard to the entire project
  - Conclusive positive community need assessment for both the proposed hospital site that is receiving the beds and the hospital giving up the beds
    - Significant community benefit with a financially viable plan for reuse of existing facility
    - Existing facilities cannot close to move to a new facility
  - No additional beds in Michigan
  - Maintain existing payer contracts for at least five years
  - Delicense at least 10% of existing facility's beds

- Proposed new hospital sites may not be approved within five miles of existing acute care hospitals, nor within the same county as single community providers

Magnetic Resonance Imaging (MRI) Services

Dennis McCafferty, EAM

EAM supports the inclusion of the MRI-Guided EPI definition within the standards and the language restricting this technology to hospitals with existing MRI services that have been operational for at least 36 months and are meeting minimum volume requirements for both MRI and OHS. EAM also supports the inclusion of the PET/MRI scanner hybrid in both the MRI and PET standards.

Melissa Cupp, Wiener Assoc.

Ms. Cupp would like to suggest that the modified definition for "MRI procedure" be added to the definition of "MRI unit" rather than "MRI procedure."

"THE TERM INCLUDES FDA-APPROVED POSITRON EMISSION TOMOGRAPHY (PET)/ MRI SCANNER HYBRIDS IF USED FOR MRI ONLY PROCEDURES."

This would be consistent with how similar provisions for PET/CT hybrids are handled in the CON Standards for CT Services.

Positron Emission Tomography (PET) Scanner Services

Dennis McCafferty, EAM

EAM supports the inclusion of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures in both the MRI and PET standards.

Pancreas Transplantation Services

Dennis McCafferty, EAM

EAM would recommend that a work group be convened to review the question of deregulation. EAM strongly supported the changes made in these standards during the last review that limited this service to only higher volume kidney transplant centers. EAM requests that quality assurance issues be addressed by a workgroup considering deregulation of this service.

Richard Pietroski, Gift of Life

Gift of Life supports the action taken to eliminate regulation for Pancreas Transplantation Services. The duplication of a state level program is no longer cost effective nor can it provide the scope of oversight that is performed by the Organ Procurement and Transplantation Network (OPTN).

There is continued federal regulation of organ transplant centers by the Department of Health and Human Services through both the OPTN and the Centers for Medicare and Medicaid Services (CMS).* The national OPTN requires each approved program to meet rigid criteria for establishing a transplant program (OPTN Bylaws: Attachment I - Criteria for Transplant Program Designation), and ongoing requirements for timely patient-level data submission (OPTN Policy 7.0: Data Submission Requirements). Furthermore, each center undergoes a robust analysis for transplant and outcome data under the federal Scientific Registry for Transplant Recipients (http://www.srtr.org/). Center specific data are refreshed every six months, and statistically analyzed to identify underperforming programs which trigger a quality review by the OPTN.

*References:

Policies and Bylaws. Department of Health and Human Services: Organ Procurement and
Transplantation Network. http://optn.transplant.hrsa.gov/policiesAndBylaws/policies.asp
http://optn.transplant.hrsa.gov/policiesAndBylaws/bylaws.asp
Federal Register. Department of Health and Human Services: Centers for Medicare & Medicaid Services. 42 CFR Parts 405, 482, 488, and 498: *Medicare Program; Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants*.
http://www.cms.hhs.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf

CERTIFICATE OF NEED

2nd 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	2nd Quarter	Year-to-Date
Approved projects requiring 1-year follow up	100	213
Approved projects contacted on or before anniversary date	72	149
Approved projects completed on or before 1-year follow up	72%	70%
CON approvals expired due to noncompliance with Part 222	10	22
Total follow up correspondence sent	214	391
Total approved projects still ongoing	340	

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. The Department is in the process of collecting information to continue investigation.

- 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. The Department is in the process of collecting information to continue investigation.

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

CERTIFICATE OF NEED

2nd 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	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Letters of Intent Received	93	N/A	207	N/A
Letters of Intent Processed within 15 days	93	100%	207	100%
Letters of Intent Processed Online	93	100%	207	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	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
Applications Received	57	N/A	154	N/A
Applications Processed within 15 Days	57	100%	154	100%
Applications Incomplete/More Information Needed	37	65%	88	57%
Applications Filed Online*	46	96%	136	98%
Application Fees Received Online*	6	13%	25	18%

* 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	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Nonsubstantive Applications	53	100%	88	100%
Substantive Applications	26	100%	48	100%
Comparative Applications	3	100%	3	100%

Note: Data in this table may not total/correlate with application received table because receive and processed dates may carry over into next month/next quarter.

Measures – continued

Administrative Rule R325.9227 requires the Department to determine if an emergency application will be reviewed pursuant to Section 22235 of the Public Health Code within 10 working days upon receipt of the emergency application request.

Activity	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Emergency Applications Received	1	100%	2	100%
Decisions Issued within 10 workings Days	1	100%	2	100%

Administrative Rule R325.9413 requires the Department to process amendment requests within the same review period as the original application.

Activity	2nd Quarter		Year-to-Date	
	Issued on Time	Percent	Issued on Time	Percent
Amendments	17	100%	35	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	2nd Quarter	Year-to-Date
Refunds Issued Pursuant to Section 22231	0	0

Other Measures

Activity	2nd Quarter		Year-to-Date	
	No.	Percent	No.	Percent
FOIA Requests Received	47	N/A	93	N/A
FOIA Requests Processed on Time	47	100%	46	100%
Number of Applications Viewed Onsite	0	N/A	2	N/A

FOIA – Freedom of Information Act.

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

CERTIFICATE OF NEED LEGAL ACTION

(6.14.12)

Case Name	Date Opened	Case Description	Status
Medilodge of Howell v MDCH and Trilogy—Howell Health Campus 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.

Case Name	Date Opened	Case Description	Status
Metro Health Hospital – CON Application: 10-1026 MAHS	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.	On May 3, 2012, the ALJ held a status conference and will be issuing a decision on the Department's pending motion for summary disposition in the near future.

CERTIFICATE OF NEED LEGAL ACTION

(6.14.12)

Case Name	Date Opened	Case Description	Status
Monroe County – Compare Group #95-0216 Includes: *Mercy Memorial – CON App # 11-0039* *Fountain View – CON App # 11-0018* *Medilodge of Monroe – CON App # 11-0030*	11/14/11	Monroe County – Comparative Review of nursing home beds – Administrative Appeal The three applicants are: (1) Mercy Memorial (denied applicant); (2) Fountain View (denied applicant); (3) Medilodge of Monroe (approved applicant)	After Medilodge's motion to dismiss was denied, the ALJ set the following schedule: Motions for summary disposition must be filed by Sept. 28, 2012. Responses due 10/26/12 and replies due 11/16/12. The Tribunal will set a date for hearing after all briefs are filed.

Case Name	Date Opened	Case Description	Status
Oakland County – Compare Group #95-0217 Includes: *Medilodge of Oxford – CON App # 11-0045* *Medilodge of Clarkston – CON App # 11-0043* *Medilodge of Square Lk – CON App # 11-0041* *Regency on the Lk – CON App # 11-0033* *Manor of Farm. Hills – CON App # 11-0024* *Bloomfield Orchard – CON App # 11-0028* *Sen. Com. Of Auburn Hills – CON App # 11-0023* *Sen. Com. Of Prov. Pk. – CON App # 11-0022*	11/1/11	Oakland County – Comparative Review of nursing home beds – Administrative Appeal 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)	The ALJ issued a proposal for decision to grant MDCH's motion for summary disposition. The parties are waiting for a final decision from the Director.

CERTIFICATE OF NEED LEGAL ACTION

(6.14.12)

Case Name	Date Opened	Case Description	Status
Livingston County – Compare Group #95-0214 Includes: *Medilodge of Livingston – CON App # 11-0044* *Livingston Care Center – CON App # 11-0021*	11/1/11	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)	The ALJ issued a proposal for decision to grant MDCH's motion for summary disposition. The parties are waiting for a final decision from the Director.

Case Name	Date Opened	Case Description	Status
St. Clair County – Compare Group #95-0219 Includes: *Medilodge of St. Clair – CON App # 11-0032* *Regency on Lk- Ft. Gratiot – CON App # 11-0034*	11/1/11	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)	The ALJ issued a proposal for decision to grant MDCH's motion for summary disposition. The parties are waiting for a final decision from the Director.

Case Name	Date Opened	Case Description	Status
Ausable Valley Continuing Care – CON App # 11-0017	11/19/11	Oscoda County –Administrative Appeal relating to denial of CON application seeking 13 nursing home beds.	AuSable Valley withdrew its request for hearing and the matter has been dismissed, with prejudice.

CERTIFICATE OF NEED LEGAL ACTION

(6.14.12)

Case Name	Date Opened	Case Description	Status
Medilodge of Pickney – CON App # 11-0189	11/19/11	Livingston County – Administrative Appeal relating to denial of CON application seeking 56 nursing home beds.	Medilodge of Pinckney withdrew its request for hearing and the matter has been dismissed, with prejudice.
Case Name	Date Opened	Case Description	Status
Beaumont Hospital v DCH – Oakland County Circuit Court No. 12-125141-CZ	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.
Case Name	Date Opened	Case Description	Status
Macomb County – Compare Group #95-0225 Includes: *St. Mary's Nursing & RC– CON App # 11-0314* *Lakeside Manor Nursing & RC– CON App # 11-0306* *Shelby Twp Care Center – CON App # 11-0312*	4/25/12	Macomb County – Comparative Review of nursing home beds – Administrative Appeal The three applicants are: (1) St. Mary's Nursing & RC (approved applicant); (2) Lakeside Manor Nursing & RC (denied applicant); (3) Shelby Twp Care Center (denied applicant).	A prehearing conference was held on 6/12/12. Dates for discovery and motions were set.

Central Michigan Stone Management, L.P.
c/o Michael Beer, M.D.
1121 W. Hill Road
Flint, Michigan 48507

June 13, 2012

Representatives of the Michigan Department of Community Health and Certificate of Need Commission:

In accordance with the Certificate of Need Administrative Rules, R 325.9227, Central Michigan Stone Management, L.P. hereby submits this request for an Emergency Certificate of Need Review. The emergency basis of this review is supported primarily by the fact that numerous patients who need care in various locations around the state cannot access needed care for kidney stones. In several cases, including cases specifically reported by staff at Carson City Hospital, rather than seeking care, patients return home and simply do not receive care. In other cases, patients must suffer with stents for extended periods of time, exposing patients to serious risk of complications and extreme discomfort.

Except for the unnecessary requirements imposed by the CON Review Standards for Lithotripsy, which bear no relationship to the reality that Lithotripsy cases should be treated as an outpatient procedure, at Carson City, Hurley Medical Center, and elsewhere, patients are unnecessarily placed at risk because of the lack of access to important and needed lithotripsy service.

These facts are supported by the attached affidavit of Michael Beer, M.D., a Flint Urologist, and letters on behalf of Hurley Medical Center, Carson City Hospital, Sheridan Community Hospital, Deckerville Community Hospital, and West Branch Medical Center.

Please take immediate action to approve this Emergency Certificate of Need in accordance with Section 22235 of the Public Health Code to resolve this emergency situation, which has unnecessarily caused a lack of access to vital care.

Regards,

Jeffrey R. Schell, Esq.

On behalf of Central Michigan Stone Management, L.P.,
Hurley Medical Center, Carson City Hospital, Michigan Rural Healthcare Preservation, Inc., Tri City Urology,
Urological Associates, P.C. and patients across Michigan

AFFIDAVIT OF MICHAEL BEER, M.D.

COUNTY OF GENESEE)
) SS.
STATE OF MICHIGAN)

Michael Beer, M.D. first being duly sworn, states as follows:

1. I am a urologist practicing in Flint, Michigan;

2. The lack of lithotripsy services available in the Flint and surrounding areas, as documented by letters from hospital administrators in Flint and other areas of the state, along with the statements of urologists throughout the state, have created an emergency circumstance where patients needing care for kidney stones either simply do not get care or suffer an unreasonable and unconscionable delay in getting such services;

3. Both the healthcare providers applying for the emergency Certificate of Need to offer lithotripsy services and the community at large will suffer serious adverse effects resulting from the lack of access to care services, namely, the inability for healthcare providers to provide needed lithotripsy services to treat kidney stones within a reasonable timeline, and the lack of available kidney stone care services to the community;

4. The facilities that existed before lithotripsy services would be offered would not substantially change, except for the addition of the lithotripsy service itself, the lack of which is the fundamental cause of the emergency situation;

5. The nature of the services offered, namely the addition of a mobile service at sites that require minimal modifications, will only require temporary facilities or minimal construction that modifies existing facilities on an insubstantial basis and therefore will not preclude different disposition of longer term determinations in a subsequent application for a certificate of need not made under this section.

_____
Michael Beer, M.D.

Subscribed and sworn to me this
_____ of _____, 2012

_____
Notary Public, _____County, State of _____
My Commission Expires: _____

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

ATTACHMENT O

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	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	•	•	•	•	•	• R—	•	•P	•▲F
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	•▲	•	•P	•▲F						
Magnetic Resonance Imaging (MRI) Services	•	•	•R	•	•	•R—	•P	•	•▲F	PH•	•	•	•R	•	•R—S	•S	•PS	•▲F•S	•S	▮	▮	▮	▮	▮
Open Heart Surgery Services**	•R	Pending CCSAC							D	•	•	•	•S	•S	•S	▮	▮	▮	▮	▮	▮	▮	•	•R—
Pancreas Transplantation Services										PH			•R		—	•	•P	•▲F						
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
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 June 14, 2012

Updated June 11, 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.