

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

Tuesday January 31, 2012

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

APPROVED MINUTES

I. Call to Order

Chairperson Falahee called the meeting to order @ 9:39 a.m.

A. Members Present:

James B. Falahee, Jr., JD, Chairperson
Edward B. Goldman, Vice-Chairperson
Charles Gayney left @ 11:08 a.m.
Robert Hughes
Marc Keshishian, MD
Michael A. Sandler, MD
Kathleen Cowling, DO

B. Members Absent

Suresh Mukherji, MD
Bradley Cory
Brian Klott
Gay L. Landstrom, RN

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
Tania Rodriguez
Brenda Rogers

II. Review of Agenda

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

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of December 15, 2011

Motion by Commissioner Cowling, seconded by Commissioner Hughes, to approve the minutes of December 15, 2011 as presented. Motion Carried.

V. Heart/Lung, and Liver (HLL) Transplantation Services - October 12, 2011 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding HLL Transplantation Services (see Attachment A).

A. Public Comment:

Deidre Wilson, Blue Cross Blue Shield of MI
Jeff Punch, University of Michigan
Robert Meeker, Spectrum Health
Amy Olszewski, Gift of Life MI (see Attachment B)
Karen Kippen, Henry Ford Health System (see Attachment C)
Patrick O'Donovan, Beaumont
Dennis McCafferty, Economic Alliance of Michigan

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Hughes, seconded by Commissioner Keshishian, to keep HLL Standards under continued CON regulation and review the issue again in 2015.

Vice-Chairperson Goldman and Commissioner Sandler declared potential conflicts of interest and removed themselves from further discussion and voting.

Motion Failed in a vote of 5- Yes, 0- No, and 0- Abstained.

VI. Pancreas Transplantation Services - October 12, 2011 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding Pancreas Transplantation Services (see Attachment D).

A. Public Comment:

None

B. Commission Discussion

None

C. Commission Action:

Motion by Commissioner Sandler, seconded by Vice-Chairperson, Goldman to consider the Department's recommendation to de-regulate pancreas transplantation services and convene a work group to flush out & decide if there is merit for deregulation. Motion Carried in a vote of 7- Yes, 0- No, and 0- Abstained.

Break @ 11:08 a.m. - 11:23 a.m.

VII. Bone Marrow Transplantation(BMT) Services - October 12, 2011 Public Hearing Summary & Report

A. Public Comment:

Samuel M. Silver, University of Michigan
Joe Uberti, Karmanos Cancer Center
Patrick O' Donovan, Beaumont
Karen Kippen, Henry ford health System (see Attachment E)
Sean Gehle, Ascension Health
Robert Meeker, Spectrum Health

Ms. Rogers gave a brief overview of the Department's recommendations regarding BMT Services (See attachment F).

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Vice-Chairperson Goldman, seconded by Commissioner Cowling, to table BMT until more Commissioners are available at the next meeting. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstained.

VIII. Magnetic Resonance Imaging (MRI) Services - October 12, 2011 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding MRI Services (See attachment G).

A. Public Comment:

Karen Kippen, Henry Ford Health System - For the official record, the Commission already addressed their concerns.
Robert Meeker, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action:

Motion by Commissioner Keshishian, seconded by Vice-Chairperson Goldman, to accept the Department's recommendation and create a SAC to address stated MRI concerns as well as weighting issues, volume requirements, mobile vs fixed for replacement, aggregate MRI data vs MRI database, and any other issues identified by the Chairperson & Vice-chairperson when developing and approving the charge. PET/MRI and MRI/Electrophysiology will continue to be evaluated separately by the groups led by Commissioner Keshishian. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstain.

IX. Psychiatric Beds and Services - October 12, 2011 Public Hearing Summary & Report

Ms. Rogers gave a brief overview of the Department's recommendations regarding Psychiatric Beds and Services (See attachment H).

A. Public Comment:

Alex Luvall, Acadia Healthcare/ Pioneer Behavioral Health (see Attachment K)
Andy Ball, Kheder, Davis & Assoc.
Karen Kippen, Henry Ford Health System

B. Commission Discussion

Discussion followed.

C. Commission Action:

Motion by Commissioner Sandler, seconded by Vice-Chairperson Goldman, to form a workgroup to address Psych Bed issues including the Department's recommendations. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstain.

X. Review of Commission Work Plan

Ms. Rogers gave a brief summary of the upcoming work plan (see Attachment I).

A. Commission Discussion

Discussion followed.

B. Commission Action:

Motion by Vice-Chairperson Goldman, seconded by Commissioner Sandler, to approve the Department to make technical edits to HLL Standards consistent with other CON review standards to present at a future meeting. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstain.

Commissioner Sandler volunteered to lead the Psychiatric Beds workgroup.

Motion by Vice-Chairperson Goldman, seconded by Commissioner Sandler, to accept the Work Plan as amended, with workgroups as a first priority, the SAC(s) as a second priority, and the formation of the Pancreas workgroup and HLL technical edits as the Department can allot time. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstain.

XI. Future Meeting Dates- March 29, 2012, June 14, 2012, September 27, 2012 & December 13, 2012

A. Commission Discussion

Chairperson Falahee reviewed the upcoming meeting dates for 2012.

B. Commission Action

Motion by Vice-Chairperson Goldman, seconded by Commissioner Sandler to approve the future meeting dates. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstain.

XII. Adjournment

Motion by Commissioner Sandler, seconded by Vice-Chairperson Goldman, to adjourn the meeting at 1:09 p.m. Motion Carried in a vote of 6- Yes, 0- No, and 0- Abstain.

MDCH Recommendations for CON Standards Scheduled for 2012 Review ATTACHMENT A

Heart/Lung and Liver (HLL) Transplantation Services (Please refer to MDCH staff summary of comments for additional detail)		
Should services continue to be regulated under CON?	No.	There is no data suggesting direct relationship between quality and volume. Additionally, financial and staffing requirements dictate concentration of the services to relatively few providers.
Identified Issues	Recommended for Review	Comments
Increase the number of allowed heart/lung and liver transplant centers.	No.	The number of these types of transplants performed at the centers has remained relatively stable over the last two years (2008-2010). There are not any factors to suggest any significant increases or decreases, and are constrained by the availability of organ donations.

MDCH Staff Analysis of Heart/Lung & Liver (HLL) Transplantation Services Standards

Statutory Assignment

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

Public Hearing Testimony

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

1. *Patrick O'Donovan, Beaumont Health System:*
 - Supports the continued regulation of HLL transplantation services.
 - Recommends the Commission consider an institution specific methodology for initiation of HLL transplantation services, in lieu of comparative review.

2. *Dennis McCaffery, Economic Alliance for Michigan (EAM)*
 - Supports continued regulation of HLL transplantation services.
 - States that volume is constrained by the supply of organs available for transplantation, not upon lack of providers.
 - Supports Department-only technical changes without the formation of a SAC.

3. *Steve Szelag, University of Michigan Health System*
 - Supports continued regulation of HLL transplantation services.

- States that it is too early to objectively evaluate the effects of the prior modification in March 2010.
 - Recommends no revisions at this time and wait until the next review cycle in 2015.
4. *Robert Meeker, Spectrum Health*
- Supports continued regulation of HLL transplantation services.
 - Recommends no revisions at this time.
5. *Karen Kippen, Henry Ford Health System*
- Supports continued regulation of HLL transplantation services.
 - Recommends no revisions at this time.

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

Michigan is one of 21 states which regulate Organ Transplantation Standards within CON. In 2010, there were 61 heart transplants, 0 heart/lung transplants, 42 lung transplants, and 198 liver transplants. There are currently 3 facilities that are approved to provide all of these services within the State of Michigan.

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

HLL Transplantation Services have low capital costs. According to the most recent CON application, the facility was not close to the covered capital expenditure threshold of \$3,012,500. The capital costs to initiate this service should remain relatively low because most facilities that would seek initiation would have existing infrastructure, operating rooms, and surgical equipment to perform transplant procedures.

The operational costs involved with a functional HLL transplant program vary greatly among facilities, but all programs must include: a primary transplant surgeon, transplant physician, and transplant team composed of individuals from medicine, nursing, nutrition, social services, transplant coordination, and pharmacology with the appropriate training and experience to provide transplantation services. The Department could not obtain facility specific operating cost information. Since 2009, no new applications have been submitted to establish new HLL transplant programs.

HLL Services are provided by 3 facilities within the State of Michigan. The number of these types of transplants performed at the centers has remained relatively stable over the last three years specifically: 2008 - 305 transplants performed, 2009 - 296 transplants performed, and in 2010 - 301 transplants performed.¹ These services are restricted to programs that participate with Organ Procurement Organizations (OPOs) and are assigned geographic service areas by CMS and are obligated to serve all hospitals in their assigned area. Under these regulations, hospitals must contract with their federally designated OPO. Hospitals may not choose which OPO to work with. The contract facilitates that transplant patients receive procedures that are of the highest quality, locally accessible, and cost-effective transplant services within their community or surrounding area.²

¹ CON Annual Survey Data: 2008, 2009, 2010

² <http://www.onelegacy.org/site/docs/ConditionsOfParticipationForHospitals.pdf>

HLL Services are required to be in compliance with Medicare's requirements in order to be reimbursed for the transplant. The evaluation of a program's compliance with Medicare requirements involves several steps. CMS will obtain data from United Network for Organ Sharing (UNOS), the contractor for the Organ Procurement Transplantation Network (OPTN), and from the University of Michigan to provide background and determine compliance with the program's OPTN membership, submission of forms to OPTN, clinical experience (volume), and outcomes, as applicable. CMS will share this information with either the State Survey Agency or CMS' Contractor (depending upon the provider's location) to incorporate into their onsite evaluation of compliance with the Medicare Conditions of participation.³

The current HLL Transplantation Standards do incorporate a needs-based methodology. The existing standards only allow for three (3) HLL transplantation services within a planning area (currently defined as the state of Michigan), and the cap creates a comparative review for any applicant proposing to initiate a program. There are currently 3 facilities approved to provide HLL Transplantation Services; two located in Southeast Michigan and one located on the west side of the State. Geographic access to HLL services is not compromised by CON requirements.

There is a direct relation between quality and volume as is recognized by volume standards associated with federal approvals (e.g. CMS, OPTN). Transplant centers must meet all data submission, clinical experience, and outcome requirements to receive initial approval by CMS, and they must also perform 10 transplants over a 12-month period. The transplant center's Quality Assessment and Performance Improvement (QAPI) program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, and patient education, satisfaction, and rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.⁴

The UNOS By-Laws require Transplant Hospitals to implement and practice appropriate routine referral procedures for all potential donors. Transplant Hospitals are further expected to demonstrate compliance based upon an annual medical record review, performed in collaboration with the OPO. Centers found to be out of compliance will be reviewed by the Membership and Professional Standards Committee.⁵ In addition, this particular service is constrained by the availability of organ donations.

MDCH Staff Recommendations

- Consider deregulating HLL transplant services. The clinical services are constrained by the availability of organ donations. There is currently no indication of immediate or sustaining proliferation of these services. Quality and volume outcomes will not be affected as programs are evaluated and must comply with CMS requirements and adhere to United

³ https://www.cms.gov/CertificationandCompliance/20_Transplant.asp

⁴ <https://www.cms.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf>

⁵ <http://www.unos.org/about/index.php?topic=bylaws>

ATTACHMENT A
Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) certification.



MICHIGAN ORGAN & TISSUE DONATION PROGRAM

January 31, 2012



A.D. 2007-12-19 09:51:27

On behalf of Gift of Life Michigan, the federally designated organ procurement organization for the state of Michigan, I am submitting formal testimony pertaining to the CON Review Standards for Pancreas and Heart/Lung Transplantation Services.

Gift of Life Michigan recommends that the standards for these two sections be discontinued due to the continued federal oversight of organ transplant centers by the Department of Health and Human Services through both the Organ Procurement and Transplantation Network (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.

The CON transplant standards were developed prior to the policies of the federal OPTN. With a national, standardized, methodology in place for establishing, monitoring, and investigating center specific outcome measures, the duplication of a state level program is no longer cost effective or can provide the scope of oversight that is performed by the OPTN and SRTR.

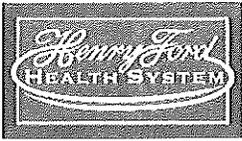
Thank you for this opportunity to comment on the Pancreas and Heart/Lung Transplantation Services Review Standards.

Richard Pietroski
Chief Executive Officer

***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>



BONE MARROW TRANSPLANT PROGRAM
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Dr. Nalini Janakiraman, M.D.
Henry Ford Health System
One Ford
Detroit, MI 48202
January 26, 2012

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

On behalf of Henry Ford Health System (HFHS), I would like to offer comments on the MDCH recommendations for Bone Marrow Transplantation (BMT) Services Standards.

HFHS strongly supports the continued regulation of Bone Marrow transplantation services and supports those regulations in their current form without revisions.

The Department suggests in their recommendations there are no concerns regarding proliferation of these services. Currently, there are four programs statewide providing these services. As evidenced by the testimony from William Beaumont Hospitals and Ascension Health, the deregulation will most certainly lead to the expansion of at least two additional programs within the tri-county region, an increase of 50%. Conversely, the MDCH survey proves that the volume of transplants performed over the last 3 years remained steady averaging 565/year. Adding more centers will spread the number of transplants performed over more sites but the demand will remain unchanged.



There are significant costs associated with creating new programs and maintaining existing programs. The Department sites cost of \$8 million dollars for maintaining and operating a BMT service. Current flat demand and appropriate access for BMT services does not support adding costs by deregulating BMT services with no demonstrable benefit for the patients.

As a transplant physician myself, I know there are a limited number of transplant physicians in Michigan. Adding more BMT programs would create constant turnover in physicians and skilled staff required to provide high quality services. This turnover is inevitable as deregulation would increase demand for personnel by 50% to staff unwarranted programs that meet no current community access need

The Department seems to justify their recommendation with the idea that FACT accreditation will ensure continued high quality and notes that all existing BMT programs in Michigan are FACT accredited. However, it is important to understand that FACT accreditation is completely voluntary without CON standards in place that require it. Without CON, there is nothing to ensure that new programs would obtain FACT accreditation or that would ensure existing programs would maintain it.

To conclude, as a member of the BMT SAC in 2009, I believe the revisions to the BMT standards, effective in March 2010 have enabled service providers to effectively meet the transplantation needs of the people of Michigan providing timely access, high quality and low cost services.

Respectfully,

Nalini Janakiraman, M.D.

Dr. Nalini Janakiraman, M.D.
Senior Staff
Director, Bone Marrow Transplant

MDCH Recommendations for CON Standards Scheduled for 2012 Review

Pancreas Transplantation Services (Please refer to the attached MDCH staff analysis for additional details)		
Should the covered service continue to be regulated?	No.	The need to regulate does not exist as the procedures continue to decrease with emerging medical technology. Quality-driven programs will continue to thrive as facilities are federally mandated to comply with the Organ Procurement Transplantation Network (OPTN) for Medicare approval to receive reimbursement.
All Identified Issues	Recommended Course of Action to Review Issues	Other/Comments
None.		Recommends no revisions at this time.

MDCH Staff Analysis of the Pancreas Transplantation Services Standards

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

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 12, 2011, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from four (4) organizations and is summarized as follows:

Patrick O'Donovan, Beaumont Health System

- Supports the continued regulation of pancreas transplantation services.
- Recommends no changes at this time.

Dennis McCafferty, Economic Alliance for Michigan (EAM)

- Supports the continued regulation of pancreas transplantation services.
- States the new standards use the number of kidney transplants performed by an institution as the surrogate for proficiency with pancreas transplants, and revising the standards to allow for additional providers is unnecessary.
- Recommends department-only technical changes without the formation of a SAC.

Steve Szelag, University of Michigan Health System

- Supports the continued regulation of pancreas transplantation services.

- Recommends no revisions at this time, as it is too early to objectively evaluate the effects of the modifications approved in March 2010, and waiting until the next review cycle in 2015.

Karen Kippen, Henry Ford Health System

- Supports the continued regulation of pancreas transplantation services.
- Recommends no changes at this time.

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

Michigan is one of 21 states which regulate Organ Transplantation Standards within CON. According to the CON Annual Survey, there were 26 pancreatic transplantation procedures performed in 2009, and 18 performed within 2010. There are currently three (3) facilities that are approved to provide these services within the State of Michigan.

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

Pancreas Transplantation Services have low capital costs. According to the most recent CON applications, none of the facilities were close to the covered capital expenditure threshold of \$2,932,500 (2009). The capital costs to initiate this service should remain relatively low because most facilities seeking initiation have existing infrastructure such as: surgical services, pre and post-operative services, staffing & existing Nephrologists and transplant surgeons to support and perform transplant procedures. The Department could not obtain facility specific operating cost information. Since 2009, no applications to establish a new pancreas transplant program have been submitted.

Pancreas Transplantation Services are provided by 3 approved programs in the State of Michigan. The number of these procedures has remained relatively low over the last few years: in 2008 - 26, 2009 - 26 and in 2010 - 18 pancreas transplants; as procedures are constrained to the availability of organ donation.¹ Pancreas allograft acceptance is markedly more selective than other solid organs. The number of pancreata recovered is insufficient to meet the demand for pancreas transplants, particularly for patients awaiting simultaneous kidney-pancreas transplant.² Pancreas Transplant Services are required to be in compliance with Medicare’s requirements in order to be reimbursed for the transplant. The evaluation of a program’s compliance with Medicare requirements involves several steps. CMS will obtain data from United Network for Organ Sharing (UNOS), the contractor for the Organ Procurement Transplantation Network (OPTN), and from the University of Michigan to provide background and determine compliance with the program’s OPTN membership, submission of forms to OPTN, clinical experience (volume), and outcomes, as applicable. CMS will share this information with either the State Survey Agency or CMS’ Contractor (depending upon the provider’s location) to incorporate into their onsite evaluation of compliance with the Medicare Conditions of participation.³

¹ CON Annual Survey Data: 2008, 2009, 2010

² <http://deepblue.lib.umich.edu/bitstream/2027.42/78607/1/j.1600-6143.2009.02996.x.pdf>

³ https://www.cms.gov/CertificationandCompliance/20_Transplant.asp

The current Pancreas Transplantation standards requires an applicant proposing to establish a new service to: project a minimum of 2 pancreas transplantation procedures annually in the second 12 months of operation following the date on which the first pancreas transplant procedure is performed, and has performed a minimum of 80 kidney transplants in the 2 most recent 12 month periods verifiable by the Department. Geographic access to Pancreas Transplantation services is not compromised by CON requirements; this particular service is constrained by the availability of organ donations.

There is a direct relation between quality and volume as is recognized by volume standards associated with federal approvals (e.g. CMS, OPTN). Transplant centers must meet all data submission, clinical experience, and outcome requirements to receive initial approval by CMS, and they must also perform 10 transplants over a 12-month period. The transplant center's Quality Assessment and Performance Improvement (QAPI) program must use objective measures to evaluate the center's performance with regard to transplantation activities and outcomes. Outcome measures may include, but are not limited to, patient and donor selection criteria, accuracy of the waiting list in accordance with the OPTN waiting list requirements, accuracy of donor and recipient matching, patient and donor management, techniques for organ recovery, consent practices, and patient education, satisfaction, and rights. The transplant center must take actions that result in performance improvements and track performance to ensure that improvements are sustained.⁴

The UNOS By-Laws require Transplant Hospitals to implement and practice appropriate routine referral procedures for all potential donors. Transplant Hospitals are further expected to demonstrate compliance based upon an annual medical record review, performed in collaboration with the OPO. Centers found to be out of compliance will be reviewed by the Membership and Professional Standards Committee.⁵ In addition, this particular service is constrained by the availability of organ donations.

MDCH Staff Recommendations

- Consider de-regulating Pancreas Transplantation Services as the need to regulate does not exist as the procedures continue to decrease due to organ availability. The key factors in the consideration of whether CON regulation is necessary for a covered service is whether the proposed regulation is necessary to assure that health services are of a high quality, provide the public access to needed health services, and are cost beneficial.
- The uses of Pancreas Transplantation Services are a specific medical treatment rather than a diagnostic procedure. Quality-driven programs will continue to thrive as all hospitals in the United States that provide pancreas transplant programs must be a member of the Organ Procurement Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS) to be Centers for Medicare and Medicaid (CMS) certified and receive reimbursement. The three facilities approved to provide pancreas transplant services within Michigan are UNOS, OPTN, and CMS certified.
- Upon review, geographical access has not been identified by the Department or public as an indicative concern for patients seeking treatment services within Michigan. Currently, there are 19 patients awaiting a pancreas transplant, per the UNOS website.

⁴ <https://www.cms.gov/CFCsAndCoPs/downloads/trancenterreg2007.pdf>

⁵ <http://www.unos.org/about/index.php?topic=bylaws>

MDCH Recommendations for CON Standards Scheduled for 2012 Review ATTACHMENT F

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

MDCH Staff Analysis of Bone Marrow Transplant Services Standards

Statutory Assignment

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

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

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

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

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

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

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

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

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

7. *Karen Kippen, Henry Ford Health System*

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

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

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

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

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

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

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

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

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

ATTACHMENT 5
The Foundation for Accreditation of Cellular Therapy (FACT) provides voluntary accreditation to clinical programs and collection and processing facilities. All Michigan BMT programs are FACT accredited. In addition, facilities that manufacture human cell, tissue, and cellular and tissue-based products, including hematopoietic stem cells obtained from peripheral and cord blood, are subject to Title 21 CFR part 1271. However, minimally manipulated bone marrow does not fall under this regulation, instead falling under the authority of the Public Health Service Act, Section 361. Minimal manipulation is defined as “processing that does not alter the relevant biological characteristics of cells or tissues.”⁴

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

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

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

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

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

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

⁶ BMT SAC Report to CON Commission, December 2009

⁷ Hematopoietic stem cell transplant

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

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

MDCH Staff Recommendations

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

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

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

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

MDCH Recommendations for CON Standards Scheduled for 2012 Review

Magnetic Resonance Imaging (MRI) Services (Please refer to the attached MDCH staff analysis for additional details)		
Should the covered service continue to be regulated?	Yes.	The regulation of MRI Services ensures appropriate utilization of each MRI to keep Michigan right-sized.
All Identified Issues	Recommended for Review	Comments
1. Consider streamlining the process for documenting actual MRI utilization & volume thresholds	Yes.	Form a standard advisory committee (SAC) to review weighting issues and volume requirements to ensure right-sizing Michigan.
2. Consider language that would allow for greater clinical use of MRI, specifically hybrid equipment	Yes.	Form a SAC to explore hybrid modalities used in conjunction with MRI's. With FDA approval, PET/MRI scanners are available for clinical use and should be examined to draft appropriate volume requirements and prevent over utilization. A discussion group, lead by Commissioner Keshishian, will be discussing and making recommendation on this issue as it relates to the PET standards pursuant to the Commission's action at its December 15, 2011 meeting.
3. Modifications to the Standards as recommended by the Department, including project delivery requirements	Yes.	Technical/editorial changes to the standards. Reduce number of project delivery requirements for approved services that are enforceable and achieve major objectives of assuring affordable, quality MRI services without overwhelming providers.
4. Consider language similar to PET and CT requiring no minimum volume for replacement or relocation	Yes.	Draft language to address threshold utilization for replacement & relocation to a new geographical site.

MDCH Staff Analysis of the Magnetic Resonance Imaging (MRI) Services Standards

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with

the established review schedule on the Commission Workplan, the (MRI Services Standards are scheduled for review in calendar year 2012.

Public Hearing Testimony

The Department held a Public Hearing to receive testimony regarding the Standards on October 12, 2011, with written testimony being received for an additional seven (7) days after the hearing. Testimony was received from six (6) organizations and is summarized as follows:

1. *Patrick O'Donovan, Beaumont Health System*
 - Supports continued regulation of MRI services.
 - Recommends the Commission consider streamlining the process for documenting actual MRI utilization (Section 14) to increase efficiency and ease applicant compliance.
2. *Azzam S. Kanaan, M.D., Southwest Michigan Imaging Center, LLC*
 - Supports continued regulation of MRI services.
 - Recommends the Department draft replacement language similar to PET and CT that address the threshold utilization concern.
 - Supports using the same language for all covered clinical equipment standards to prevent interruption or loss of service to smaller communities.
3. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
 - Supports continued regulation of MRI services.
 - Recommends the formation of a SAC to review the burdensome reporting requirements for providers.
4. *Steven Szelag, University of Michigan Health System (UMHS)*
 - Supports the continued regulation of MRI services.
 - Recommends lowering the MRI Adjusted Procedure volume threshold below the current average of 11,000.
 - Recommends exploring the benefits and the allowance of greater clinical use of MRI within a hybrid configuration. These modalities include, but should not be limited to: MRIs used in conjunction with a Linear Accelerator, Positron Emission Tomography, or an Electro-Physiology laboratory.
 - Recommends modification(s) to the replacement and relocation language, to improve "point-of service" care based on changing demographics and demand, currently it is somewhat restrictive.
 - Suggests using similar language to that of moving licensed medical/surgical beds between multiple licensed facilities under common ownership.
5. *Loren Rhoad, Alliance- HNV*
 - Supports the continued regulation of MRI services.
 - Recommends that the MRI Standards should be adjusted consistently with the policy premise articulated in the CT and PET Standards.

- Recommends reviewing the existing replacement and upgrade language, and proposes if the project costs are less than \$750,000, the entire project be considered part of the upgrade.

6. *Robert Meeker, Spectrum Health*

- Supports the continued regulation of MRI services.
- Recommends modifying the MRI data reporting system to streamline some of the processes involved, as it is overly-burdensome to both the providers and the Department.

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

Michigan is one of 22 states which regulate MRI Services within CON. The regulation of MRI Services ensures appropriate utilization of each MRI to keep Michigan right-sized. As part of the review, the Department considered the “Guiding Principles...” as follows:

The costs of initiating a fixed MRI service vary considerably, ranging from \$1,607,373 to \$4,975,000, according to CON applications dated January 1, 2010 to November 1, 2010. MRI services are ubiquitous throughout the state of Michigan, served by both mobile and fixed sites at hospitals and freestanding centers. The number of MRIs performed in the state over the past three years has declined slightly (<3 percent), as follows:

2008: 764,076
 2009: 763,195
 2010: 742,399

Despite the slight decline, MRI is a standard of care for many conditions and will likely remain so for several reasons, including high quality views and concerns about ionizing radiation usage in other imaging modalities.

MRI services are not monitored under any other agencies within the State of Michigan. Effective January 1, 2012, an outpatient MRI facility must be accredited by the American College of Radiology (ACR) in order to receive reimbursement for the technical component of the procedure under Medicare Part B.¹

In order to initiate a fixed MRI service, the proposed site must demonstrate 6,000 available adjusted procedures (3,000 in the case of a hospital with 24-hour emergency care and a minimum of 20,000 visits in the past year).

Geographic access to MRI services is not compromised by CON requirements. MRI quality is not linked to volume.

The Patient Protection and Affordable Care Act (PPACA) of 2010 contain provisions that discourage self-referral, mandating that providers furnish a list of local alternatives for the patient to choose from when receiving MRI services. In addition, prior authorization for outpatient MRI services is a requirement of many private health insurance plans, limiting the number of

¹ http://www.acr.org/accreditation/mri/m_faq.aspx

unnecessary scans performed. Accreditation through the ACR does not address cost or access. The focus is on image quality, safety practices, quality control protocols, and staff qualifications.²

Department Recommended Modifications

The Department is recommending that the Standards be reviewed and modified for clarity, administrative efficiencies, and relevance in the following instances:

- The Department recommends modifying the reporting process in order to capture actual MRI utilization. The November 2011 MRI report is the first that has reported 100% of data.
- The weighting of scans should be reviewed, through the formation of a SAC. The volume requirements for facilities that perform complex scans should be reviewed to offset patient time(s) and visit(s) for facilities that perform simple scans.
- The Department recommends forming a SAC to address the emerging MR hybrid modalities i.e.; Linear Accelerator, Positron Emission Tomography, or an Electro-Physiology laboratory. The advancement of this technology will impact the practice of many services including nuclear medicine. Patients will benefit from early detection because physicians will acquire more data simultaneously, consequently improving personalized treatment planning. The Department will assist with drafting language within the Standards to aid facilities accessibility to this new technology.
- The Department recommends technical modifications only for consistency with other CON review standards along with project delivery requirements. Project delivery requirements are those requirements that a recipient of an approved CON must comply with throughout the life of the services, or unless modified by a subsequent CON approval. Review is to assure that each requirement is measurable, comports with today's standard of care, does not duplicate other regulatory requirements already established, and have cost-effective value in achieving the goals and objectives of the program to assure affordable, quality health care services for both the consumer and provider.
- The Department recommends eliminating the volume requirement for replacement of MRI equipment, similar to the PET and CT standards. Upgrades to existing MRI equipment, without replacement of the equipment would not require CON review/approval.

² http://www.acr.org/accreditation/mri/mri_reqs.aspx

MDCH Recommendations for CON Standards Scheduled for 2012 Review

Psychiatric Beds and Services Standards (Please refer to the attached MDCH staff analysis for additional details)		
All Identified Issues	Recommended for Review	Other/Comments
Should the covered service continue to be regulated?	Yes	Psychiatric beds are not a defined covered clinical service. Therefore, deregulation is not an option pursuant to MCL 333.22215(1)(a).
Average Daily Census (ADC)	Yes	Add a clarifying step to the calculation under Section 7(3) (d); specifically subtraction of current licensed bed(s) from the ADC to produce the number of high occupancy beds to be added. This will ensure less confusion for future applicant(s) and the Department.
Update Bed Need (Section 4)	Yes	The CON Commission establishes a planning year for which inpatient psychiatric bed needs are developed and the base year for child/adolescent beds based on the most recent data available to the Department as well as the effective date of the new bed numbers. (The planning year shall be a year for which official population projections from the Department of Management and Budget are available. At this time, these projection data are not available.)
Clarify language as it relates to relocation and replacement of beds to facilities within planning areas	Yes	Add language for relocation of beds consistent with other CON Review Standards for beds.
Technical changes made by the Department	Yes	Modify the standards only for consistency with other CON Standards including the Project Delivery requirements.

MDCH Staff Analysis of the Psychiatric Beds and Services Standards

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

Public Hearing Testimony

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

1. *Patrick O'Donovan, Beaumont Health System*
 - Supports the continued regulation of psychiatric beds and services.
 - Recommends no changes at this time.
2. *Dennis McCafferty, Economic Alliance for Michigan*
 - Supports the continued regulation of psychiatric beds and services.
 - Supports department-only technical changes, and will wait to see if what, if any, issues are raised in the public hearing.
3. *Karen Kippen, Henry Ford Health System*
 - Supports the continued regulation of psychiatric beds and services.
 - Supports the creation of a SAC to review, update, and clarify:
 - Appropriate time period for calculation of average daily occupancy (adult and child; 24-month period does not allow flexibility for changes in staff and patient populations)
 - Impact of current average occupancy rate percentages on patient access and service in a changing market
 - Replacement and relocation within planning areas

MDCH Staff Recommendations

- The Department recommends adding a clarifying step to the calculation under Section 7(3) (d); specifically subtraction of current licensed bed(s) from the ADC to produce the number of high occupancy beds to be added.
- The Department recommends updating the bed need numbers for 2012. The CON Commission establishes a planning year for which inpatient psychiatric bed needs are developed and the base year for child/adolescent beds based on the most recent data available to the Department as well as the effective date of the new bed numbers. (The planning year shall be a year for which official population projections from the Department of Management and Budget are available. At this time, these projection data are not available.)
- The Department recommends adding language as it relates to relocation of beds to facilities within planning areas to be consistent with other CON Review Standards for beds.
- The Department recommends technical changes to streamline the format similar to other CON review standards including the Project Delivery requirements.
- The Department would present proposed draft standards to the Commission at a future meeting.

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											
Cardiac Catheterization Services	■	■	■	■	■	•R—	•	•	—	•	•P	•▲F												
Computed Tomography (CT) Scanner Services	■	•	—	•	•P	•▲		•	•	•	•P	•▲F												
Heart/Lung and Liver Transplantation Services										PH			•R											
Hospital Beds and Addendum for HIV Infected Individuals	•R	•S	•S	•S		■	■	■	■	■	■	•R—	•	•P	•▲F									
Magnetic Resonance Imaging (MRI) Services	•	•	•R	•	•	•R—	•P	•	•▲F	PH•	•	•	•R											
Open Heart Surgery Services	•R	Pending CCSAC							D	•	•	•												
Pancreas Transplantation Services										PH			•R											
Psychiatric Beds and Services										PH			•R											
Surgical Services	•R	•	•	•	•	•	•	•	•R—	•	•P	•▲F												
Renewal of "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need (CON) Review"																								
New Medical Technology Standing Committee	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M	•M
Commission & Department Responsibilities			M			M			M			M			M			M			M			M
CON Annual Activity Report FY 2011												•	•	•	•R									

- KEY**
- - Receipt of proposed standards/documents, proposed Commission action
 - * - Commission meeting
 - - Staff work/Standard advisory committee meetings
 - ▲ - Consider Public/Legislative comment
 - ** - Current in-process standard advisory committee or Informal Workgroup
 - - Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work
 - A - Commission Action
 - C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
 - D - Discussion
 - F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
 - M - Monitor service or new technology for changes
 - P - Commission public hearing/Legislative comment period
 - PH - Public Hearing for initial comments on review standards
 - R - Receipt of report
 - S - Solicit nominations for standard advisory committee or standing committee membership

For Approval December 15, 2011

Updated December 7, 2011

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

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

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	August 12, 2010	2013
Bone Marrow Transplantation Services	December 3, 2010	2012
Cardiac Catheterization Services	February 25, 2008	2014
Computed Tomography (CT) Scanner Services	June 20, 2008	2013
Heart/Lung and Liver Transplantation Services	May 28, 2010	2012
Hospital Beds and Addendum for HIV Infected Individuals	March 2, 2009	2014
Magnetic Resonance Imaging (MRI) Services	November 21, 2011	2012
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	2012
Positron Emission Tomography (PET) Scanner Services	November 21, 2011	2014
Psychiatric Beds and Services	November 5, 2009	2012
Surgical Services	June 20, 2008	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 Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.