

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

Wednesday January 28, 2015

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

**APPROVED MINUTES**

**I. Call to Order & Introductions**

Chairperson Keshishian called the meeting to order at 9:32 a.m.

A. Members Present:

Denise Brooks-Williams  
Kathleen Cowling, DO  
James B. Falahee, Jr., JD,  
Charles Gayney  
Robert Hughes  
Marc Keshishian, MD, Chairperson  
Jessica Kochin

B. Members Absent

Gail J. Clarkson, RN  
Gay L. Landstrom, RN  
Suresh Mukherji, MD, Vice- Chairperson  
Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Tulika Bhattacharya  
Elizabeth Hertel  
Natalie Kellogg  
Beth Nagel  
Tania Rodriguez  
Brenda Rogers

**II. Review of Agenda**

Motion by Commissioner Cowling, seconded by Commissioner Falahee, to approve the agenda as presented. Motion Carried.

**III. Declaration of Conflicts of Interests**

None.

**IV. Review of Minutes of December 11, 2014**

Motion by Commissioner Kochin, seconded by Commissioner Brooks-Williams, to approve the minutes of December 11, 2014 as presented. Motion Carried.

**V. Bone Marrow Transplantation (BMT) Services – October 9, 2014 Public Comment Period Summary & Report**

Ms. Rogers gave a brief overview of the public hearing summary and the Department's recommendations (see Attachments A).

A. Public comment

Adil Akhtar, MD, Beaumont Health Systems  
Barbara Bressack, Henry Ford Health System (HFHS)  
Sean Gehle, Ascension Health (see Attachment B)  
Joseph Uberti, MD, Karmanos Cancer Center  
Gregory Yanik, MD, University of Michigan Health Systems (UMHS)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Kochin, to seat a Standard Advisory Committee (SAC), delegate developing a charge to the Chairperson of the Commission, and to bring the draft charge back to the Commission at the March meeting. Motion Failed in a vote of 5 - Yes, 2 - No, and 0 - Abstained.

The Commission asked that BMT be placed on the March meeting agenda for further discussion.

**VI. Heart/Lung and Liver (HLL) Transplantation Services – October 9, 2014 Public Comment Period Summary & Report**

Ms. Rogers gave a brief summary of the public's comments and the Department's recommendations (see Attachments C).

A. Public Comment

Barbara Bressack, HFHS  
John Magee, MD, UMHS  
Richard Pietroski, Gift of Life of Michigan (see Attachment D)

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Falahee, to maintain the current standards and continue regulation of the HLL transplantation services. Motion Carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

**VII. Magnetic Resonance Imaging (MRI) Services – October 9, 2014 Public Comment Period Summary & Report**

Ms. Rogers gave a brief summary of the public's comments and the Department's recommendations (see Attachment E).

A. Public Comment

Allison Martin, Karmanos Cancer Institute (see Attachment F)  
Carla Wilson, Pennock Hospital

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams, to form a workgroup and have the Department develop the charge based on the Department's recommendation presented at today's meeting. The workgroup will bring its recommendation to the Commission at a future meeting. Motion Carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

**VIII. Psychiatric Beds and Services – October 9, 2014 Comment Period Summary & Report**

Ms. Rogers gave a brief summary of the public's comments and the Department's recommendations (see Attachments G).

A. Public Comment

Michael Sandler, MD, MAS Strategic Consulting

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Gayney, to form a workgroup and have the Department develop the charge based on the Department's recommendation presented at today's meeting. The workgroup will bring its recommendation to the Commission at a future meeting. Motion Carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

**IX. Review of Commission Work Plan**

Ms. Rogers gave an overview of the Commissions future work plan to include the decisions made at today's meeting (see Attachment H).

A. Commission Discussion

Discussion followed. Chairperson Keshishian will appoint a chairperson for both the MRI Services and Psychiatric Beds and Services workgroups.

B. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Hughes, to accept the work plan as presented. Motion Carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

**X. Compliance**

Ms. Bhattacharya gave a verbal summary of the Open Heart Surgery (OHS) Services and Psychiatric Beds and Services compliance investigations.

**XI. Public Comment**

Brett Jackson, Economic Alliance for Michigan (EAM)

**XII. Future Meeting Dates – March 18, 2015, June 11, 2015, September 24, 2015, and December 10, 2015**

**XIII. Adjournment**

Motion by Commissioner Falahee, seconded by Commissioner Cowling, to adjourn the meeting at 11:58 a.m. Motion Carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

## Certificate of Need (CON) Commission Summary of Standards Scheduled for 2015 Review

<b>Bone Marrow Transplantation (BMT) Services</b>		
Should services continue to be regulated?	<b>MDCH Recommendation:</b> A Standard Advisory Committee (SAC) should be formed to determine if there is sufficient evidence for deregulation. If there is not sufficient evidence for deregulation, then a need-based methodology should be developed by the SAC.	
<b>All Identified Issues</b>	<b>Recommendation for Review</b>	<b>Comments</b>
Deregulate BMT Services	Formation of a Standards Advisory Committee to make recommendations to the Commission	
Develop a need based methodology	Formation of a Standards Advisory Committee to make recommendations to the Commission	

Pursuant to MCL 333.22215 (1)(m), the 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 2015.

### **Public Comment Testimony**

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2014 and ending October 23, 2014. Testimony was received from four 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.
- States that in 2006, 2009, and 2012 existing providers used the CON process to block patient access to BMT services even though need was shown through data.
- Notes that MDCH has recommended multiple times that BMT services be deregulated.

**Certificate of Need (CON) Commission Summary of Standards Scheduled for 2015 Review***2.) Dennis McCafferty, Economic Alliance for Michigan (EAM)*

- States that they are not aware of any changes in technology that would warrant a revision in the standards at this time.
- Further states there has not been a material increase in the number of patients being serviced so therefore there would be no need to increase the number of facilities providing service.

*3.) Steven Szelag, University of Michigan Health System*

- Supports continued regulation of this covered service, and the CON standards for allogeneic and autologous stem cell transplants do not require modification.

*4.) Joseph Uberti, MD, Karmanos Cancer Institute*

- States that the existing BMT standards continue to serve the needs of cancer patients in Michigan and recommends no changes at this time.
- States that none of the programs are at capacity and all are capable of increasing the number of transplants.
- States that adding more programs will increase costs with the need to purchase expensive equipment required to meet Foundation for the Accreditation of Cellular Therapy (FACT) guidelines, such as controlled rate cryopreservation systems, liquid nitrogen freezers and HEPA filtered inpatient care areas.
- Suggests that there is a well-documented shortage of physicians trained in the area of stem cell transplantation and opening new programs will require recruitment of physicians from existing programs.
- In Fiscal year 2013, over sixty percent of Karmanos patient volume had Medicaid, Medicare, or no insurance, suggesting that the newer programs will focus on insured patients, while leaving those under and uninsured patients to existing programs.
- Research indicates that the spike in transplants within the last 15 year period is from transplantation being promoted as a treatment modality for breast cancer.
- The FDA has approved a number of new therapies for many of the hematologic malignancies which include: multiple myeloma, CLL, NHL, and Hodgkins Lymphoma; and these often delay or lessen the need for transplantation in these patients.

**Summary of the Covered Service**

Michigan is one of 7 states to regulate BMT Services in 2013.

The last SAC on this standard met from June 2009 to November 2009.

## Certificate of Need (CON) Commission Summary of Standards Scheduled for 2015 Review

The last date of final action by the CON Commission on the Bone Marrow Transplantation Services standards was June 12, 2014.

The current standards have an effective date of September 29, 2014.

In fiscal year 2013, MDCH approved 0 new BMT Services.

In fiscal year 2014, MDCH approved 0 new BMT Services.

### **Summary of 2013 Annual Survey Data – BMT Services**

Bone Marrow						
Facility	Autologous			Allogenic		
	0-17	18-20	>21	0-17	18-20	>21
William Beaumont Royal Oak	0	0	0	0	0	0
University of Michigan	12	1	144	22	4	90
Children's Hospital of Michigan	4	0	0	6	0	0
Henry Ford Hospital	0	0	47	0	0	22
St. John Hospital & Medical Center	0	0	0	0	0	0
Karmanos Cancer Center	4	2	170	6	1	87
Lemmen Holton Cancer Pavilion	4	0	26	5	0	11
<b>Total</b>	<b>24</b>	<b>3</b>	<b>387</b>	<b>39</b>	<b>5</b>	<b>210</b>



28000 Dequindre  
Warren MI 48092

January 27, 2015

Dr. Marc keshishian  
Chairman, Michigan Certificate of Need Commission  
c/o Michigan Department of Community Health  
Certificate of Need Policy Section  
Capital View Building, 201 Townsend Street, Lansing, MI 48913

Via-Email

Dear Commissioner:

I am writing to urge you, as part of the Special CON meeting tomorrow, Wednesday, January 28<sup>th</sup>, to de-regulate Bone Marrow Transplantation (BMT) or to, at a minimum, develop a facility-based methodology for Bone Marrow Transplantation services. St. John Providence, as a member of Ascension Health – Michigan has advocated in the previous two cycles in which BMT services were eligible for review, for changes to the standard that would eliminate the artificial cap on the number of programs in Michigan either through de-regulation or the development of the aforementioned methodology. We continue to support either of these two options for several important reasons.

First, Bone Marrow Transplantation, once an experimental treatment, is now a standard treatment option for various cancers. Limiting this procedure to a handful of sites throughout the state results in patients being referred away from their primary oncologist and contributes to the underutilization of this technology in favor of potentially less effective and more costly alternative treatments. We believe that allowing patients to remain in their community to be treated by a team of professionals with whom they have already established a relationship will result in additional patients utilizing this life saving procedure. We do not believe that "Capacity" necessarily equals "Access" and therefore the assertion that existing programs have additional capacity to accept patients is not a true reflection of whether or not patients have access to this service.

Secondly, St. John Providence is well qualified to offer BMT services. We diagnose over 4,000 new cancer cases annually, more than some current BMT providers. We provide 44,000 radiation therapy treatments for about 2,000 patients annually and are already a tertiary organ transplant center. Additionally, much of the infrastructure necessary to operate a program in terms of facilities and/or staff already exists within our health system. Subsequently, initiating a program would require only minimal cost for our health system.

With regard to the larger issue of cost, BMT is no more expensive than alternative treatments. Unregulated chemotherapy can be more expensive than BMT. Many chemotherapeutic drugs must be given for the duration of the





patient's life increasing the cost of this alternative. Finally, we do not believe that the state would experience a significant cost due to a proliferation of programs should either BMT be de-regulated or a facility based methodology be implemented. Beaumont Health and St. John Providence have been the only two health systems that have argued for the modification of this standard. It is unlikely that there would be many more systems that would choose to initiate this service for a variety of reasons.

Third, we believe that there should be no concern regarding adequate quality oversight of BMT programs should this service be de-regulated. Two national organizations provide quality measures for BMT programs; the Foundation for Accreditation of Cellular Therapy (FACT) and the Center for International Blood and Marrow Transplant research. These Accreditations have rigorous requirements that hold programs to high standards.

Additionally, Michigan is one of only seven states that regulate BMT under CON and the only state with an artificial cap on the number of programs. Similarly, the BMT standard is one of only two CON standards that have such a cap; the majority of CON standards have some form of a volume based methodology to initiate/replace or expand a covered service.

Finally, as a result of more recent studies that show BMT is more appropriate for older patients than in the past and the opportunity for new applications of BMT outside of oncology, St. John Providence urges the CON Commission to either de-regulate this service or, at a minimum, establish a facility-specific methodology for this service in the standard. Thank you for the opportunity to comment on this issue.

Sincerely,



Jean Meyer  
President & CEO, St. John Providence

<b>Heart/Lung and Liver (HLL) Transplantation Services</b>		
<b>Identified Issues</b>	<b>Recommendation for Review</b>	<b>Comments</b>
Should services continue to be regulated?	<b>MDCH Recommendation:</b> This service should be deregulated from CON. This service has a very low number of cases and has external state and national bodies that monitor quality and costs. For example, programs must already comply with the federal Center for Medicare and Medicaid Services (CMS) quality and volume requirements and adhere to United Network for Organ Sharing (UNOS) and Organ Procurement and Transplantation Network (OPTN) certification.	
Develop institution specific methodology		Department recommends de-regulation.

**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 2015.

**Public Hearing Testimony**

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2014 and ending October 23, 2014. Testimony was received from three organizations and is summarized as follows:

*1.) T. Anthony Denton, University of Michigan Health Systems*

- Supports the continued regulation of this covered service and does not believe specific revisions to these standards are necessary at this time.

*2.) Patrick O'Donovan, Beaumont Health Systems*

- Supports the continued regulation of heart/lung and liver transplantation services.
- Recommends that the Commission consider an institution specific methodology for initiation of transplantation services in lieu of comparative review.

*3.) Dennis McCafferty, Economic Alliance for Michigan (EAM)*

- States that they are not aware of any changes in technology that would warrant a revision in the standards at this time.

- Further states there has not been a material increase in the number of organs available so therefore there would be no need to increase the number of facilities providing service.

**Summary of the Covered Service**

Michigan is one of 21 states which regulate Organ Transplants of any type within CON. An unspecified subset of the 21 states include regulation of heart, lung, heart/lung and/or liver transplants.

The last SAC on this standard met from April 2009 to September 2009.

The last date of final action by the CON Commission on the HLL Transplantation Services standards was June 14, 2012.

The current standards have an effective date as of September 28, 2012.

In fiscal year 2013, MDCH approved 0 new HLL Services.

In fiscal year 2014, MDCH approved 0 new HLL Services.

**Summary of 2013 Annual Survey Data- HLL Services**

Facility No	Type	Facility Name	Heart Trans Cases	Heart/Lung Trans Cases	Lung Trans Cases	Liver Trans Cases
410040	H	SPECTRUM BUTTERWORTH	9	1	13	0
630030	H	WILLIAM BEAUMONT, ROYAL OAK	0	0	0	16
810060	H	U OF M HOSPITALS	39	0	44	71
830080	H	CHILDREN'S HOSPITAL OF MICHIGAN	0	0	0	0
830190	H	HENRY FORD HOSPITAL	14	0	13	88
830420	H	ST. JOHN HOSPITAL & MEDICAL CENTER	0	0	0	0
830520	H	KARMANOS CANCER CENTER	0	0	0	0
41C039	F	LEMMEN HOLTON CANCER PAVILION	0	0	0	0
<b>Total</b>		<b>8</b>	<b>62</b>	<b>1</b>	<b>60</b>	<b>175</b>

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## ORAL TESTIMONY – CERTIFICATE OF NEED

JANUARY 28, 2015

### HEART/LUNG AND LIVER TRANPLANTATION SERVICES STANDARDS

Good morning. Thank you for the opportunity to speak today regarding the Heart/Lung and Liver Transplantation Services. My name is Richard Pietroski and I am the Chief Executive Officer of Gift of Life Michigan, the federally designated organ procurement organization for the state of Michigan. We are charged by the federal Organ Procurement Transplantation Network (OPTN), under the authority of the U.S. Department of Health and Human Services to coordinate all aspects of the recovery and allocation of organs and tissues from deceased donors. As such, we work closely with Michigan's nine transplant centers and affiliated Histocompatibility laboratories, and oversee the medical committees and federally required advisory board regarding the placement of hearts, lungs and livers recovered from Michigan residents. We also are responsible for registering every waiting transplant recipient in our region on the OPTN (national) waiting list. Our mission is simple: to improve and extend lives through organ transplantation.

Transplantation is a complex and ever-changing medical field. OPTN Committees of experts meet at the national level to address arising issues and to keep national regulations current with best practices. As was outlined in my written comments submitted in October, we have cited a specific example that occurred within the last year when OPTN regulations changed and were no longer in sync with CON standards. In Gift of Life's opinion, a conflict between state and national transplant policy will continue to occur as long as two sets of regulation exist on two different time tables.

There is a stringent quality inspection component on the part of the OPTN, and through the federal Scientific Registry of Transplant Recipients (SRTR) outcomes are made public every 6 months for each transplant center and organ procurement organization. These measures are also monitored by the Centers for Medicare and Medicaid Services to ensure compliance with all Medicare Conditions of Participation. The outcome report includes how many recipients are at the center, how long they have been waiting for a transplant, and, most importantly, expected versus observed outcome ratios for both graft and patient survival. Centers and procurement organizations that do not meet the outcome measures require a CAPA and monthly updates.

If the Heart/Lung and Liver Transplantation Services Standards continue in any form, a workgroup needs to be formed to look at the issues that have arisen with regards to the potential impact on Michigan's federally designated organ procurement organization and local placement of organs. With a Michigan resident dying every other day on our waiting list, conflicting regulations cannot be allowed to limit the number of organs that can be placed in our state. Three years ago, the Commission voted to renew the standards, but noted that the standards would need to be discussed extensively in 2015. It is my recommendation that, given increasingly more stringent and updated federal regulation, greater quality oversight of transplant activities, and the need to permit Michigan to continue as a leader in transplant services, if the state-level regulations remain active, Gift of Life Michigan respectfully requests that we be included in any work group or SAC discussions which may modify the state CON for heart, lung and/or liver transplant.



## MDCH Recommendations for CON Standards Scheduled for 2015 Review

Magnetic Resonance Imaging (MRI) Services		
Should the covered service continue to be regulated?	<b>MDCH Recommendation:</b> This service should continue to be regulated, and the Commission should form a workgroup to address the issues identified.	
All Identified Issues	Recommendation for Review	Comments
Consider modifying the MRI Adjusted Procedure volume threshold for expansion at a freestanding site or consider adding an additional scan weight for fixed MRI scanners located at a freestanding site.	Form a workgroup to make recommendations to the Commission.	
Consider updating the standards to allow facilities to update equipment when it has surpassed its useful life/Remove volume requirements for replacement with other CON review standards.	Form a workgroup to make recommendations to the Commission.	
Consider redefining rural counties in Michigan by utilizing population instead of the current federal designations.	Form a workgroup to make recommendations to the Commission.	This type of change goes beyond MRI and would impact all CON review standards that currently utilize the Federal designations for rural, micropolitan, and metropolitan statistical area counties.
Consider any technical changes from the Department e.g., updates or modifications.		MDCH has identified technical edits and can draft language for the Commission's review.

### MDCH Staff Analysis of the 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 Work Plan, the MRI Services Standards are scheduled for review in calendar year 2015.

#### Public Hearing Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting October 9, 2014 and ending October 23, 2014. Testimony was received from six (6) organizations and is summarized as follows:

CON 2015 Review Summary: MRI Services

1. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
  - Supports continued regulation of MRI services.
  
2. *Steve Szelag, University of Michigan Health Systems*
  - Supports continued regulation of MRI services.
  - Recommends modifying the MRI Adjusted Procedure volume threshold for expansion at a freestanding site or consider adding an additional scan weight for fixed MRI scanners located at a freestanding site.
  - Currently applicants are required to demonstrate an average of 11,000 MRI Adjusted Procedures per fixed unit for expansion at both hospital and freestanding sites. This presents a challenge for most freestanding sites to achieve as most are not 24 x 7 operations.
  - Recommends the Commission investigate a “system view” of imaging asset deployment. This would create flexibility to improve “point-of-service” care based on changing demographics and demand. The existing standards for replacement and relocation are somewhat restrictive and may not adequately meet the specific needs of the applicant.
  
3. *George Yoo, MD, Karmanos Cancer Center*
  - Supports continued regulation of MRI services.
  - Requests the Commission to consider updating the rules to allow facilities to update equipment when it has surpassed its useful life. Currently, the standards allow these facilities to upgrade and repair these machines up to an expenditure of \$750,000 but not replace them entirely.
  - MRI is becoming a standard diagnostic tool in healthcare and it is important that these facilities be allowed to replace those aged units, rather than be forced to pay for temporary fixes and potentially compromise quality or access.
  - Suggests that the replacement of an MRI unit without regard to volume could apply to MRI services that only have 1 MRI unit.
  
4. *Patrick O'Donovan, Beaumont Health System*
  - Supports continued regulation of MRI services and recommends no specific changes at this time.
  
5. *Jim Wincek, Pennock Health*
  - Supports the continued regulation of MRI services.
  - Proposes redefining rural counties in Michigan by utilizing population instead of the current federal designations.
  - Recommends allowing for the replacement of MRI units without any volume requirements.

### **Summary of the Covered Service**

Michigan is one of 16 states which regulate MRI Services.

The last workgroup on this standard met from October 2012 to December 2012.

CON 2015 Review Summary: MRI Services

The last date of final action by the CON Commission on the MRI Services standards was September 25, 2014.

The current standards have an effective date as of December 22, 2014.

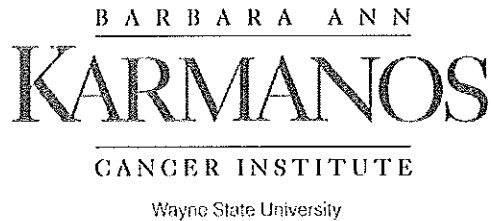
In fiscal year 2013, MDCH approved 42 MRI units, 8 units being replacements units.

In fiscal year 2014, MDCH approved 26 MRI units, 3 units being replacement units.

<b>Year</b>	<b>Mobile Units total</b>	<b>Fixed Units total</b>	<b>Statewide AAP* total-mobile</b>	<b>Statewide AAP* total-fixed</b>	<b>Average Mobile route utilization**</b>
2012	65	165	2,777	90,286	5,294
2013	60	168	2,061	110,293	4,977
2014	63	169	3,283	75,725	4,664

\*Available Adjusted Procedures

\*\* Adjusted Procedures



## **MRI Certificate of Need Standards Testimony**

January 28, 2015

We believe that Magnetic Resonance Imaging (MRI) services should continue to be regulated by the Certificate of Need program in Michigan, but request the Commission consider updating the rules to allow facilities better access to updated equipment and to be consistent with the other CON replacement standards. More specifically, there are 18 hospitals in the State of Michigan operating a single MRI unit that do not have enough volume to qualify to replace that unit when it has surpassed its useful life. The standards allow for these facilities to upgrade and repair these machines up to an expenditure of \$750,000, but not replace them entirely. As MRI has clearly become a standard diagnostic tool in health care, we feel it is important that these hospitals be allowed to replace those aged units, rather than be forced to pay for temporary fixes and potentially compromise quality or access.

Over the past several years the Department has consistently recommended that replacement of covered clinical equipment not require minimum volume for the service. In fact, that policy change has been implemented in PET, CT, and MRT over the past few years. We believe the same rationale behind those changes apply just as much to MRI as any of the other 3. We do, however, recognize that historically the volume requirement for replacement of equipment has functioned as a mechanism to ensure that facilities are not paying for equipment they do not need. Therefore we would like to offer that the replacement of an MRI unit without regard to volume could apply to MRI services that only have 1 MRI unit. Facilities with multiple units would still have to justify that their volume supports the required CON number for their MRI units.

Thank you for the opportunity to share Karmanos' suggestions for improving the MRI standards. We support the Departments recommendations for a work group, and would be interested in participating if permissible.



**Certificate of Need (CON) Commission Summary of Standards Scheduled for 2015 Review**

<b>Psychiatric Beds and Services Standards</b>		
Should the covered service continue to be regulated?	<p><b>MDCH Recommendation:</b> Yes, this service should continue to be regulated. The Commission can deregulate covered services, but Psychiatric Beds are not a defined covered clinical service. Therefore, deregulation is not an option pursuant to MCL 333.22215(1) (a).</p> <p>A workgroup should be formed to address the issues identified.</p>	
<b>All Identified Issues</b>	<b>Recommendation for Review</b>	<b>Other/Comments</b>
Consider deregulation or grandfather all psych beds regardless of occupancy rate	Form a workgroup to make recommendations on the occupancy rate issue identified	Deregulation of Psychiatric Beds is not an option per MCL 333.22215(1)(a).
Consider how the standards can promote the accommodation of special populations like geriatric, developmentally disabled, and high acuity patients	Form a workgroup to make recommendations to the Commission	This recommendation comes from MDCH as a result of findings from recent compliance action.
Consider any technical changes from the Department e.g., updates or modifications		MDCH will draft language for the Commission's review if applicable.

**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 2015.

**Public Hearing Testimony**

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2014 and ending October 23, 2014. Testimony was received from four organizations and is summarized as follows:

## Certificate of Need (CON) Commission Summary of Standards Scheduled for 2015 Review

### 1.) *Ginger Williams, Oaklawn Hospital*

- Urges the Commission to either deregulate inpatient psychiatric beds, or at a minimum, to grandfather all existing licensed inpatient psychiatric beds regardless of occupancy rate.
- Cites current CON occupancy requirements are threatening to reduce access even further.
- States that the presence of semi-private rooms, or even 3-4 bed wards, often creates a situation where >60% occupancy isn't possible due to patient diagnosis and gender mix, even if demand exists.

### 2.) *Steve Szelag, University of Michigan Health Systems*

- Supports the continued regulation of this covered clinical service and does not believe specific revisions are necessary at this time.

### 3.) *Dennis McCafferty, Economic Alliance for Michigan (EAM)*

- Supportive of the changes made in this Standard the last time it was reviewed and are not aware of any additional changes that would warrant a revision in this Standard.

### 4.) *Patrick O'Donovan, Beaumont Health System*

- Supports the continued regulation of psychiatric beds and services.
- Recommends no specific changes to the standards at this time.

## **Summary of the Covered Service**

Michigan is one of 26 states to regulate Psychiatric Services in 2013.

The last workgroup on this standard met from June 2012 to August 2012.

The last date of final action by the CON Commission on the Psychiatric Beds and Services standards was December 13, 2012.

The current standards have an effective date of March 22, 2013.

In fiscal year 2013, MDCH approved 31 additional beds.

In fiscal year 2014, MDCH approved 22 additional beds.

## **Summary of 2012 Annual Survey Data – Psych Beds**

## Certificate of Need (CON) Commission Summary of Standards Scheduled for 2015 Review

Facilities	Bed Need for Inpatient		Occupancy Rate
	Total Patient Days	Average Daily Census	
<b>Statewide</b>			
60 Facilities	563,874	1,540.6	69.6%
<b>HSA 1 - Southeast Michigan</b>			
29 Facilities	319,722	873.6	71.1%
<b>HSA 2 - Mid-Southern</b>			
5 Facilities	29,220	79.8	55.1%
<b>HSA 3 - Southwest</b>			
6 Facilities	36,183	98.9	60.7%
<b>HSA 4 - West Michigan</b>			
8 Facilities	92,080	251.6	76.8%
<b>HSA 5 - Genesee - Lapeer - Shiawassee</b>			
4 Facilities	28,771	78.6	58.2%
<b>HSA 6 - East Central</b>			
4 Facilities	4,243	90.7	76.5%
<b>HSA 7 - Northern Lower</b>			
2 Facilities	8,165	22.3	76.9%
<b>HSA 8 - Upper Peninsula</b>			
2 Facilities	16,522	45.1	71.7%

**CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN**

	2014												2015											
	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 (BMT) Services	•D	•	•R —	•P	•	• ▲F				PC			•R A											
Cardiac Catheterization Services**	•R P A	•S	• ▲F S	•S	•S	■	■	■	■	■	■	■	•	•	• R—	•P	•	• ▲F						
Computed Tomography (CT) Scanner Services	•P	•	• ▲F			• R—	•P	•	• ▲F															
Heart/Lung and Liver Transplantation Services									PC				•R A											
Hospital Beds	•R P A	•	• ▲F R	•	•	•R	•	•	• R—	•P	•	• ▲F												
Magnetic Resonance Imaging (MRI) Services						• R—	•P	•	• ▲F	PC			•R A											
Megavoltage Radiation Therapy (MRT) Services/Units**	•R A	•S	•S	•S	•S	•S	■	■	■	■	■	•	•	•	• R—	•P	•	• ▲F						
Neonatal Intensive Care Services/Beds (NICU) and Special Newborn Nursing Services						• R—	•P	•	• ▲F															
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	•	•	•	•	•	R—	P	•	• R—	•P	•	• F▲												
Positron Emission Tomography (PET) Scanner Services	•R P A	•	• ▲F	•	•	•	•	•	•	•	•	•	•	•	R—									
Psychiatric Beds and Services									PC				•R A											
Surgical Services						• R—	•P	•	• ▲F															
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	•P	•	• ▲F			• R—	•P	•	• ▲F															
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		

**KEY**

—	- Receipt of proposed standards/documents, proposed Commission action	A	- Commission Action
*	- Commission meeting	C	- Consider proposed action to delete service from list of covered clinical services requiring CON approval
■	- Staff work/Standard advisory committee meetings	D	- Discussion
▲	- Consider Public/Legislative comment	F	- Final Commission action, Transmittal to Governor/Legislature for 45-day review period
**	- Current in-process standard advisory committee or Informal Workgroup	M	- Monitor service or new technology for changes
•	- Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work	P	- Commission public hearing/Legislative comment period
1	- ICD-10 Translation	PC	- Public Comment Period for initial comments on review standards for review in the upcoming year
		R	- Receipt of report
		S	- Solicit nominations for standard advisory committee or standing committee membership

Approved December 11, 2014

Updated December 15, 2014

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, Office of Health Policy and Innovation, Planning and Access to Care Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, [www.michigan.gov/con](http://www.michigan.gov/con).

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

<b>Standards</b>	<b>Effective Date</b>	<b>Next Scheduled Update**</b>
Air Ambulance Services	June 2, 2014	2016
Bone Marrow Transplantation Services	March 22, 2013	2015
Cardiac Catheterization Services	June 2, 2014	2017
Computed Tomography (CT) Scanner Services	June 2, 2014	2016
Heart/Lung and Liver Transplantation Services	September 28, 2012	2015
Hospital Beds	June 2, 2014	2017
Magnetic Resonance Imaging (MRI) Services	September 18, 2013	2015
Megavoltage Radiation Therapy (MRT) Services/Units	May 24, 2013	2017
Neonatal Intensive Care Services/Beds (NICU)	March 3, 2014	2016
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 11, 2011	2016
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	June 2, 2014	2017
Psychiatric Beds and Services	March 22, 2013	2015
Surgical Services	February 27, 2012	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	June 2, 2014	2016

\*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.