

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

Tuesday January 28, 2014

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

APPROVED MINUTES

I. Call to Order & Introductions

Chairperson Falahee called the meeting to order @ 9:36 a.m., and introduced newly appointed Commissioner Jessica Kochin.

A. Members Present:

Gail J. Clarkson, RN
Kathleen Cowling, DO
James B. Falahee, Jr., JD, Chairperson
Marc Keshishian, MD, Vice-Chairperson
Denise Brooks-Williams (arrived at 9:38 a.m.)
Charles Gayney
Robert Hughes (arrived at 9:43 a.m.)
Jessica Kochin
Gay L. Landstrom, RN, (arrived at 10:17 a.m.)
Suresh Mukherji, MD

B. Members Absent

Luis Tomatis, MD

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Community Health Staff Present:

Scott Blakeney
Tulika Bhattacharya
Natalie Kellogg
Beth Nagel
Tania Rodriguez

II. Review of Agenda

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

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of December 12, 2013

Motion by Commissioner Gayney, seconded by Commissioner Cowling, to approve the minutes of December 12, 2013 as presented. Motion Carried.

V. Cardiac Catheterization (CC) Services – October 9, 2013 Public Comment Period Summary & Report

Ms. Nagel gave a brief overview of the public hearing summary and the department's recommendations (see Attachment A).

A. Public comment

Karen Kippen, Henry Ford Health Systems (HFHS)
Steve LeMoine, Oakwood Healthcare System (see Attachment B)
Steve Szelag, UMHS (see Attachment C)
Sean Gehle, Ascension Health (see Attachment D)
Patrick O'Donovan, Beaumont Health System
Arlene Elliott, Mercy Health St. Mary's
Eric Fischer, Detroit Medical Center (DMC)
Dr. Michael Sandler, HFHS
Meg Tipton, Spectrum Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Vice-Chairperson Keshishian, seconded by Commissioner Brooks-Williams, to seat a Standard Advisory Committee (SAC) and to delegate developing a charge to the Chairperson of the Commission. Motion Carried in a vote of 8 - Yes, 0 - No, and 1 - Abstained.

VI. Hospital Beds – October 9, 2013 Public Comment Period Summary & Report

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

A. Public Comment

Karen Kippen, HFHS

After Commission discussion, Chairperson Falahee requested HFHS to submit to the department what it believes needs to be changed and an explanation of why. The department will then review and bring back a summary/recommendation of its findings at a future meeting.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Hughes, to accept the department's recommendations and to take no action on the Hospital Bed standards. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

**VII. Megavoltage Radiation Therapy (MRT) Services/Units – October 9, 2013
Public Comment Period Summary & Report**

Ms. Nagel gave a brief summary of the public's comments and the department's recommendations (see Attachment F).

A. Public Comment

Mark Montross, Oaklawn Hospital
Dr. Michael Sandler, HFHS

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Vice-Chairperson Keshishian, seconded by Commissioner Cowling, to seat a SAC and delegate the formation of a charge to the Commission Chairperson. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

**VIII. Open Heart Surgery (OHS) Services – October 9, 2013 Comment Period
Summary & Report**

Ms. Nagel gave a brief summary of the public's comments and the department's recommendations (see Attachment G).

A. Public Comment

None.

B. Commission Discussion

None.

C. Commission Action

Motion by Commissioner Gayney, seconded by Commissioner Hughes, to accept the department's recommendations and to take no action on the OHS standards. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

IX. Positron Emission Tomography (PET) Scanner Services – October 9, 2013 Comment Period Summary & Report

Ms. Nagel gave a brief summary of the public's comments and the department's recommendations (see Attachment H).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Vice-Chairperson Keshishian, seconded by Commissioner Cowling, for the formation of a workgroup. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

X. Surgical Services (SS) – October 9, 2013 Public Comment Period Summary & Report

Ms. Nagel gave a brief summary of the public's comments and the department's recommendations (see Attachment I).

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Clarkson, seconded by Commissioner Landstrom, to accept the department's recommendations and to take no action on the SS standards. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

XI. Public Comment

Melissa Cupp, Wiener Associates

After Commission discussion, Chairperson Falahee asked the department to bring a summary regarding Karmanos PPS exemption to the March Commission meeting.

XII. Review of Commission Work Plan

Ms. Nagel gave a brief review of the current work plan stating that the addition of today's actions will be added.

A. Commission Discussion

Discussion followed.

B. Commission Action

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to accept the amended workplan with the understanding that the department will prioritize seating the CC & MRT SACs first and then work on the formation of the PET workgroup. Motion carried in a vote of 9- Yes, 0- No, and 0- Abstained.

XIII. Future Meeting Dates – March 18, 2014, June 12, 2014, September 25, 2014, and December 11, 2014

XIV. Adjournment

Motion by Commissioner Mukherji, seconded by Commissioner Cowling, to adjourn the meeting @ 11:02 a.m. Motion Carried in a vote of 9 - Yes, 0 - No, and 0 - Abstained.

Certificate of Need (CON) Commission Summary of Standard Scheduled for 2014 Review

Cardiac Catheterization (CC) Services Standards			
Should Cardiac Catheterization services continue to be a CON Covered Service?			MDCH Recommendation: Yes
All Identified Issues	Does the issue require further review?	Recommended Course of Action to Review Issue	Comments
Review the requirements for Elective Therapeutic Cardiac Catheterization specifically in relation to on-site Open Heart Surgery programs	Yes	Formation of a Standards Advisory Committee (SAC)	
Insert language for a second acquisition similar to other standards	Yes	Formation of a SAC	Requested by MDCH Evaluation Section
Consider any technical changes from the Department e.g., updates or modifications	No		MDCH is not aware of any technical changes at this time
Develop specific, measurable quality metrics in the project delivery requirements	Yes	Formation of a SAC	MDCH Recommendation for all Standards that will come under review in 2014

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 CC Services Standards are scheduled for review in calendar year 2014.

Public Comment Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2013 and ending October 24, 2013. Testimony was received from 16 individuals and is summarized as follows:

1. *David Westerlund, West Branch Regional Medical Center*
 - Supports amending the standards to allow hospitals without Open Heart Surgery services to perform elective therapeutic cardiac catheterization.
2. *Brian Witte, West Branch Regional Medical Center*
 - Supports amending the standards to allow hospitals without Open Heart Surgery services to perform elective therapeutic cardiac catheterization.

Certificate of Need (CON) Commission Summary of Standard Scheduled for 2014 Review

3. *Joe Bell, RRT, West Branch Regional Medical Center*
 - Supports changing the standards to allow hospitals without on-site backup open heart surgical services to perform elective therapeutic cardiac catheterizations.

4. *Edward Napierala, West Branch Regional Medical Center*
 - Supports the review of the standards as they apply to cardiac catheterization laboratories without on-site backup open heart surgical services to allow for elective therapeutic cardiac catheterization.
 - States that more than 65% of patient base is Medicare patients (65 and older) and as people age their need for cardiac services increases. Current CC standards force many elderly patients to drive out of service area to have cardiac procedures performed.

5. *Tom Oesch, West Branch Regional Medical Center*
 - Supports Cardiac Stenting procedures at a facility without Open Heart Surgery.

6. *Annette Reeves, West Branch Regional Medical Center*
 - Supports changing the CON standards to allow hospitals without on-site backup Open Heart Surgery services to perform elective therapeutic cardiac catheterizations.

7. *Laura N Vaughn, West Branch Regional Medical Center*
 - Supports changing the CON standards to allow hospitals without on-site backup Open Heart Surgery services to perform elective therapeutic cardiac catheterizations.
 - Many states that allow elective therapeutic cardiac catheterizations without on-site backup Open Heart Surgical services and studies have shown that outcomes are virtually the same.

8. *Dennis McCafferty, Economic Alliance for Michigan*
 - Recommends no review at this time, because elective angioplasty is currently provided at the existing 33 OHS program hospitals that are well distributed across the state and emergency Angioplasty is available at 12 additional hospitals.
 - If formation of a SAC is decided, then EAM feels there are three concerns about elective angioplasty that need to be considered; 1- the risk to patients, 2- the recent clinical studies suggesting that elective angioplasty does not offer long term benefits and demonstrates potential for excess, and 3- inappropriate elective Angioplasty procedures being performed on patients.

9. *Meg Tipton, Spectrum Health*
 - Supports the standards, but offers concerns regarding residents' proximity to cardiac catheterization services.

Certificate of Need (CON) Commission Summary of Standard Scheduled for 2014 Review

- Maintains that access is not an issue for the vast majority of residents and that 33 sites performing elective PCI and 12 performing emergency angioplasty are well distributed throughout the state.
- If elective PCI is available in places where there are no OHS programs, there will be an unmanaged proliferation of PCI programs, diluting volume and expertise, and worsening quality.
- Cardiac catheterization cases are in decline nationally and Michigan needs fewer, not more, hospitals offering the service.
- Proposes that measurement using quality standards should be included in the CC standards.

10. *Garry C. Faja & Roger W. Spoelman, Catholic Health East – Trinity Health Michigan*

- Supports continued regulation of Cardiac Catheterization services and recommends that a SAC or Workgroup should be established to review the allowance of elective angioplasty without onsite open heart surgery.
- The American College of Cardiology Foundation issued a consensus that supports elective angioplasty at sites without OHS services. Other national studies have demonstrated that onsite OHS is not needed for elective PCI.
- Recommends specific criteria listed below for requirements to perform elective PCI in Michigan:
 - Performed PCI for at least 24 months
 - Meets all project delivery requirements
 - Projects a minimum of 300 procedure equivalents
 - Participates in the NCDR CathPCI registry
 - Agrees not to perform transcatheter aortic valve replacements

11. *Veronica Marisch, Metro Health - Michigan*

- The requirement to initiate cardiac catheterization services that requires onsite OHS should be eliminated for the reason that the medical scientific evidence no longer supports the notion that on-site OHS back-up capacity is necessary.
- Since this was last considered the American College of Cardiology has revised its own standards to make clear that it does not believe that open heart surgical back up for such procedures should be required.
- Keeping these standards in place will harm communities and patients where OHS programs do not exist or are limited to one hospital.
- Attached two articles.

12. *Sunita Vadakath, MD, FRCA, MPA & F. Michael Jaggi DO, FACP, FACEP, Hurley Medical Center*

- Consider revisions to the Cardiac Catheterization standards to allow institutions that do not have open heart programs to provide elective coronary angioplasty services.
- Clinical practice, expanded expertise and technology advances have resulted in the decline of complications and emergency surgery from elective PCI. More than 500 centers in 39 states allow elective PCI without surgery with varying requirements.

Certificate of Need (CON) Commission Summary of Standard Scheduled for 2014 Review

- Since the Commission last reviewed Cardiac Catheterization standards in June of 2011 the following has occurred:
 - ACCF/AHA/SCAI guidelines for PCI placed this intervention at Class IIb.
 - The 2012 multistate clinical trial on Angioplasty conducted at 60 hospitals without onsite cardiac surgery found that elective PCI could be performed safely without onsite OHS.
 - MASS COMM results demonstrated non-inferiority of elective PCI at centers without surgical backup compared to those with on-site surgery.
- The current restriction impacts patients' access to care and a reversal of this regulation will particularly benefit underinsured and poor patients who are often the least likely to undergo PCI due to barriers accessing specialized cardiac services such as geography, distance, culture, race, language, poverty, and lack of education.

13. *Karen Kippen, Henry Ford Health System*

- Supports continued regulation and recommends a SAC or workgroup to review the requirements for performing elective PCI without on-site open heart surgery.
- The American College of Cardiology and American Heart Association published updated guidelines which recognize the appropriateness of offering these services in facilities without open heart surgery on-site.
- Four major studies on the safety and efficacy of elective PCI without onsite heart surgery all show this procedure to be safe and effective with no difference in quality or outcome.
- Suggests the standards be updated to add quality measures to include specific outcomes, complications, process and appropriateness of utilization.

14. *Eric D. Fisher, Detroit Medical Center*

- Supports allowing elective PCI without on-site open heart surgery based on new research and newly published guidelines by the ACC.
- The ACC and AHA changed the classification of elective PCI without onsite open heart surgery and four major studies have concluded the procedure is effective and safe, and MDCH has clarified that they do have the ability to enforce the quality and volume provisions in the CC standards.
- Recommends quality measures be added to the standards as ACC/NCDR tracks outcomes, complications, process measures and appropriate utilization. BMC2 reviews all elective PCI data and uses this data.

15. *Patrick O'Donovan – Beaumont Health System*

- States the previous SAC recommendations were entirely adopted except for the elective PCI recommendations. Encourages the Commission to adopt the SAC recommendation to allow elective PCI without on-site cardiac surgery.

Certificate of Need (CON) Commission Summary of Standard Scheduled for 2014 Review

- It is contrary to quality patient care to transfer a patient in need of PCI to another institution if the referring institution already has the capability to treat the patient safely, effectively and efficiently.
 - Allowing PCI w/o on-site surgical back-up will not result in excess utilization.
 - Provided documentation.
16. *Sean Gehle, Ascension Health - Michigan*
- Supports continued regulation of Cardiac Catheterization services and recommends no changes to the standard.

Summary of the Covered Service

Michigan is one of 26 states to regulate Cardiac Catheterization in 2012.

The last SAC on this standard met from November 2010 to May 2011.

The last date of final action by the CON Commission on the Cardiac Catheterization standards was December 15, 2011.

The current standards have an effective date of February 27, 2012.

In fiscal year 2012, MDCH approved 0 new Cardiac Catheterization/Primary PCI facilities and 7 new labs.

In fiscal year 2013, MDCH approved 0 new Cardiac Catheterization/Primary PCI facilities and 2 new labs.

Certificate of Need (CON) Commission Summary of Standard Scheduled for 2014 Review

Summary of 2012 Annual Survey Data

Facilities	Number of Labs	Hybrid OR/ CC Labs	Left Heart Cardiac Cath*	Number of Sessions			
				Diagnostic CC & Peripherals	Therapeutic CC & Peripherals	Complex Percutaneous Valvular	CC/EP Pediatric Age
Statewide							
63	192	6	7,082	90,690	67,331	996	346
HSA 1 - Southeast Michigan							
33	100	4	5,748	41,400	31,890	188	338
HSA 2 - Mid-Southern							
4	13	0	45	4,983	4,612	3	4
HSA 3 - Southwest							
4	14	0	269	14,047	6,987	11	4
HSA 4 - West Michigan							
6	16	0	373	6,990	7,072	152	0
HSA 5 - Genesee, Lapeer, Shiawassee							
4	11	1	51	5,324	4,085	0	0
HSA 6 - East Central							
8	24	0	512	13,408	7,607	635	0
HSA 7 - Northern Lower							
3	10	1	84	3,556	4,162	7	0
HSA 8 - Upper Peninsula							
1	4	0	0	982	916	0	0

* Diagnostic programs only

** Pediatric age patients (<18 years for CC and <14 years for EP) at adult programs

Pediatric Cardiac Catheterization Services

Facilities	Number of Labs	Number of Sessions		
		Diagnostic CC & Peripherals	Therapeutic CC & Peripherals	Complex Percutaneous Valvular
Statewide				
3	4	1,001	1,040	37
HSA 1 - Southeast Michigan				
2	3	973	649	37
HSA 4 - West Michigan				
1	1	28	391	0

The data appear as they were reported by the facility and do not necessarily reflect CON approved Services.

MDCH Staff Recommendations

MDCH recommends the formation of a SAC to review the issues identified in the public comments.

**Public Testimony
CON Special Commission Meeting
January 28, 2014**

Good Morning,

My name is Steve Le Moine, Administrator of Heart and Vascular services at Oakwood Healthcare System. The System is comprised of four acute care hospitals located in Dearborn, Wayne, Taylor, and Trenton. The Dearborn facility offers a therapeutic cardiac cath program as well as open heart services. The Wayne and Trenton sites offer diagnostic caths and emergency PCI services.

We feel that access to elective cardiac cath services is not an issue. Many high-quality programs offer elective angioplasty within a 30-60 minute drive. We are concerned that by allowing additional hospitals to perform elective angioplasty without open heart backup, there could potentially be a proliferation of PCI programs at facilities within a few miles of each other. Nationwide, the number of cardiac cath cases is on the decline. A Healthcare Advisory Board article from mid-2012 estimated a five percent decline in projected PCI volumes over the next five years.

Oakwood does not feel the formation of a SAC is necessary. However, we would support a workgroup to look at the inclusion of quality measures in the standards (similar to the language that was added in the open heart standards). We feel a workgroup could more expediently develop these quality measures – rather than a SAC which could take a year or so until such changes are finalized.

Oakwood appreciates the opportunity to provide comment on these standards. If a work group is established, we would be happy to participate as appropriate.



**Certificate of Need (CON) Review Standards for
Cardiac Catheterization Services
January 28, 2014**

On behalf of the University of Michigan and its Cardiovascular Services, we would like to offer the following comments related to the Certificate of Need activities for Cardiac Catheterization Services.

Overall, the population in Michigan has been shrinking over the past several years. Also, through prevention efforts and better medical treatments, the overall need for coronary vasculization has been going down. Access for coronary interventions is not a major issue with the vast majority of Michigan's residents. Three years ago, the SAC Committee was nearly unanimous in its recommendations that cardiac catheterization services should continue to be regulated, that the methodology for determining procedure equivalents should be simplified, that counting procedures to meet minimum volume requirements should be maintained, and that an adjustment for the minimum annual volume requirements for PCI should be consistent with the reported national and international literature. Also, the SAC three years ago added new therapeutic procedures as is consistent with current day practice.

In terms of the possibility of changing standards to allow hospitals to perform elective PCI in the absence of onsite cardiac surgery back-up, the University of Michigan continues to have the position that elective PCI without surgical back up should not be allowed. First, previous studies have shown that Michigan already has a number of low volume operators and at least some studies have suggested that these operators have an associated higher risk of complications. Second, it is believed that expansion of therapeutic cardiac catheterization services creates the potential to increase the number of inappropriate procedures which will have an effect on increasing costs and a reduction in overall quality of care. With overall PCI rates going down, it is not felt that there is a need for expansion of services in our state. Lastly, we believe that the state may lack the infrastructure and will to close underperforming programs.

In addition, it is worth noting that current cardiac catheterization lab activity in the state does allow for the treatment of ST segment elevation MI's in hospitals that have met certain volume and quality requirements and do not have on site cardiac surgery. Thus the argument that expansion of cardiac catheterization services to more hospitals for the timely reperfusion of acute myocardial infarction treatment is not justified.

Sincerely,

Kim Eagle, MD
David Pinsky, MD
Richard Prager, MD



Attachment D
Advocacy Office:
328 West Ottawa Street
Lansing, MI 48933-1587
Phone: 517.482.1422
Fax: 517.374.1326

January 27, 2014

Mr. James Falahee
Chairman, Michigan Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Via e-mail

Dear Chairman Falahee,

We are writing, on behalf of Ascension Health – Michigan, and subsequent to comments we provided in October during the Department's public comment period soliciting input on CON Cardiac Catheterization standards to again recommend no changes to the CON Cardiac Catheterization standards.

We understand that a number of healthcare organizations have testified in support of modifying the Cardiac Catheterization standards to allow for elective angioplasty to be performed at hospitals without on-site Open Heart Surgery programs. We continue to oppose this change for a variety of reasons, outlined below, even though we recognize that recent data suggests that elective angioplasty may be done safely without on-site Open Heart Surgery.

First and foremost, we do not believe that there is a geographic access issue in Michigan and therefore there is not the need for additional PCI programs. This is especially true in southeast Michigan where there are 15 programs in the region with Diagnostic & Therapeutic cardiac catheterization with Open Heart Surgery on-site. Additional sites in southeast Michigan offer Primary PCI for emergent cases. As a result, residents of Southeast Michigan have more than adequate access to this service. Similarly, across the state of Michigan elective angioplasty is currently provided at the existing 33 Open Heart Surgery program hospitals and Emergency Angioplasty is available at 12 additional programs. These programs are well distributed across the state ensuring that residents statewide have adequate access to this service.

Secondly, we remain unconvinced that additional PCI sites ensure more timely access to the PCI procedure. In a recent study published in the July 9, 2013 edition of *Circulation: Cardiovascular Quality and Outcomes* the following conclusions were reached:

1. From 2004 to 2008 the # of hospitals that established new PCI programs grew by 16.5%, but population with timely access grew only 1.8%
2. 251 hospitals with new PCI programs added costs of \$2-\$4 billion to the system
3. New PCI programs were more likely to be built in markets with a good payer mix and existing programs rather than places that may have the greatest need

On a related note, we are concerned about the overutilization of this procedure if additional PCI sites are

BORGESS HEALTH

GENESYS
HEALTH SYSTEM

ST JOHN
PROVIDENCE
HEALTH SYSTEM

ST JOSEPH
HEALTH SYSTEM

ST. MARY'S
OF MICHIGAN

WE ARE CALLED TO: service of the poor reverence integrity wisdom creativity dedication



Attachment D
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established in Michigan. The attached map showing above average PCI's per 1000 Medicare enrollees in Southeast Michigan seems to suggest that such overutilization may be occurring in Southeast Michigan and the addition of PCI sites throughout the state could exacerbate this phenomenon.

Additionally, we continue to have concerns regarding patient safety if complications arise at sites without Open Heart Surgery Programs on site. This is of particular concern in northern Michigan, rural areas and the Upper Peninsula in which the closest Open Heart Surgery program can be a significant distance away, but can also be a concern in more urban areas given factors such as traffic congestion, time of day etc.

Finally, in an environment where the volume of cardiac procedures are decreasing across the board adding additional sites performing PCI serves only to diffuse volume and expertise across a greater number of sites. Subsequently, we believe this has the potential to negatively impact patient outcomes.

Ascension Health – Michigan appreciates the opportunity to comment on CON Review standards for Cardiac Catheterization Services. If the CON Commission does elect to engage in further review based on the interest of other organizations in modifying this standard it would be our recommendation that this be limited to a discussion of quality measures that might be included in the standard similar to those included in the Open Heart Surgery standard. As always Ascension Health – Michigan is interested in participating in any further discussion of changes to this standard in any future workgroup or SAC convened to discuss this issue.

Sincerely,

Patricia Maryland, Dr. PH
Ministry Market Leader, Ascension Health Michigan

Jean M. Meyer, RN
President & CEO, St. John Providence Health System

John Graham
President & CEO, St. Mary's of Michigan

Paul Spaude
President & CEO, Borgess Health

Elizabeth Aderholdt
President & CEO, Genesys Health System

BORGESS HEALTH

GENESYS
HEALTH SYSTEM



Certificate of Need (CON) Commission Summary of Standards Scheduled for 2014 Review

Hospital Beds (HB)			
Should Hospital Beds continue to be a CON covered service?			MDCH Recommendation: Yes
All Identified Issues	Does the issue require further review?	Recommended Course of Action to Review Issue	Comments
Add a definition of "Contiguous site" to mean within 750 yards of the existing licensed site	No		MDCH and Licensing and Regulatory Affairs (LARA) reviewed this issue and do not recommend this suggested change.
Revise the definition of long term acute care hospital with Prospective Payment System exemption	No		LTAC is a Center for Medicare and Medicaid Services definition and should not be altered at the state level.
Eliminate the requirement for High Occupancy applicants to demonstrate that they have pursued good faith efforts to relocate acute care beds	No		The previous SAC reviewed this issue extensively. The language is meant to demonstrate that the applicant is making an effort relocating beds instead of adding more beds. Given the excess of hospital beds, MDCH does not recommend altering this requirement.
Consider any technical changes from the Department e.g., updates or modifications	No		MDCH is not aware of any changes at this time.

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 Hospital Bed Services Standards are scheduled for review in calendar year 2014.

Public Comment Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2013 and ending October 24, 2013. Testimony was received from seven organizations and is summarized as follows:

Certificate of Need (CON) Commission Summary of Standards Scheduled for 2014 Review

1. *Patrick O'Donovan, Beaumont Health System*
 - Supports the current standard and does not recommend any substantive changes at this time.
 - Supports technical changes or formula updates as necessary.
2. *Dennis McCafferty, Economic Alliance for Michigan*
 - Supports continued regulation and how the standards determines both the need for inpatient bed capacity and how the distribution of existing inpatient bed inventory addresses the access needs of the citizens of Michigan.
 - Suggests if a SAC is seated to review alternative methodologies for projecting community need that those with alternative ideas bring those to the SAC's attention at the beginning of deliberations and not the end.
3. *Garry C. Faja & Roger W. Spoelman, Catholic Health East – Trinity Health Michigan*
 - Supports continued regulation and does not believe specific changes to these standards are necessary at this time.
 - Supports the high occupancy provisions as a mechanism to secure additional beds when hospitals demonstrate a need for additional capacity.
 - Supports the low occupancy requirements which address the issues of excess capacity.
4. *Karen Kippen, Henry Ford Health System*
 - Supports continued regulation and recommends a SAC or workgroup to clarify and standardize specific items.
 - Add a definition of "Contiguous site" to mean within 750 yards of the existing licensed site.
 - Revise the definition of long term acute care hospital with Prospective Payment System exemption.
5. *Meg Tipton, Spectrum Health*
 - Supports the standards and how the standards determine both the need for inpatient bed capacity and the distribution of existing inpatient bed inventory. Provides a more realistic projection of demand for the inpatient beds as well as volume and location of the current excess capacity.
 - Recommends no changes at this time.
6. *Sean Gehle, Ascension Health - Michigan*
 - Supports continued regulation and recommends no changes.
7. *Steven Szelag, University of Michigan Health System*
 - Supports continued regulation and supports the standards with the elimination of the requirement for High Occupancy applicants to

Certificate of Need (CON) Commission Summary of Standards Scheduled for 2014 Review

demonstrate that they have pursued good faith efforts to relocate acute care beds.

Summary of the Covered Service

Michigan is one of 28 states to regulate Hospital beds in 2012.

The last SAC on this standard met from June 2011 to December 2011.

The last date of final action by the CON Commission on the Hospital Beds standards was June 14, 2012.

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

In fiscal year 2012, MDCH approved 0 new Hospitals and 24 new beds.

In fiscal year 2013, MDCH approved 1 new Hospital and 40 new beds.

Summary of 2012 Annual Survey Data – Hospital Beds

Facilities	Acute Care Beds			Total Acute Care Beds	Psych (Adult & Minor)	Total Licen. Beds
	Med/ Surg	Pediatrics	Obstetrics			
Statewide						
185 Facilities	22,404	2,032	1,838	26,274	2,244	28,518
HSA 1 - Southeast Michigan						
65 Facilities	12,031	1,189	880	14,100	1,249	15,349
HSA 2 - Mid-Southern						
13 Facilities	1,374	140	139	1,653	145	1,798
HSA 3 - Southwest						
18 Facilities	1,660	167	178	2,005	163	2,168
HSA 4 - West Michigan						
30 Facilities	2,511	225	239	2,975	339	3,314
HSA 5 - Genesee - Lapeer - Shiawassee						
6 Facilities	1,207	121	123	1,451	135	1,586
HSA 6 - East Central						
25 Facilities	2,032	133	152	2,317	121	2,438
HSA 7 - Northern Lower						
12 Facilities	947	24	83	1,054	29	1,083
HSA 8 - Upper Peninsula						
16 Facilities	642	33	44	719	63	782

Licensed bed counts are listed as of December 31, 2012 from the Licensing and Certification Division, BHS, LARA.

MDCH Staff Recommendations

MDCH does not recommend any changes at this time.

Megavoltage Radiation Therapy (MRT) Services/Units Standards			
Should MRT Services/Units continue to be a CON covered service?			MDCH Recommendation: Yes
All Identified Issues	Does the issue require further review?	Recommended Course of Action to Review Issue	Comments
Update the definition of a "special purpose MRT unit" to reflect new technologies	Yes	Formation of a Standard Advisory Committee (SAC)	
Clarify accreditation requirements; All MRT programs ACOS accredited	No		It would not be appropriate to have all programs accredited by ACOS when there are multiple accrediting bodies that are acceptable.
Review and Revise definition, use of a "Cyber Knife"	Yes	Formation of a SAC	Requested by MDCH Evaluation Section
Revise the methodology for determining need to utilize patient residence data	No		This issue was discussed at the previous workgroup and the workgroup chose not to revise the methodology.
Revise the planning areas to be mileage radius and not the current Health Service Areas	No		This issue was discussed at the previous workgroup and they chose not to revise the Planning Areas.
Consider any technical changes from the Department e.g., updates or modifications	Yes		MDCH is aware of technical changes and will make those changes.
Add language that addresses the expansion of more than one special purpose MRT unit(s)	Yes	Formation of a SAC	Requested by MDCH Evaluation Section
Develop specific, measurable quality metrics in the project delivery requirements	Yes	Formation of a SAC	MDCH Recommendation for all Standards that will come under review in 2014

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 MRT Services/Units Standards are scheduled for review in calendar year 2014.

Public Comment Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2013 and ending October 24, 2013. Testimony was received from seven organizations and is summarized as follows:

1. *Dennis McCafferty, Economic Alliance for Michigan*
 - Supports the current standards, specifically the prevention of physician owned MRT services and how cancers should be counted and other issues related to changes in this technology.

2. *Garry C. Faja & Roger W. Spoelman, Catholic Health East – Trinity Health Michigan*
 - Supports continued regulation and suggests improvements be made to the definition of a “special purpose MRT unit” to address new technologies.
 - States radiation therapy vendors have expanded their platform capabilities to create hybridized machines capable of a range of treatment options. This technological shift has caused confusion between the current CON definitions of non-special and special-purpose MRT units.
 - Recommends revising the existing definition of “special-purpose MRT unit” to read: “A special-purpose MRT unit is any MRT that is not used for standard radiotherapy, but is dedicated to providing radiosurgery (1-5 fractions), total body irradiation, or IORT.”

3. *Karen Kippen, Henry Ford Health System*
 - Strongly supports continued regulation and does not recommend reviewing the standards in 2014.
 - Specifically supports the inclusion of the utilization based need methodology and the accreditation requirement from ACR/ASTRO or ACRO.

4. *Meg Tipton, Spectrum Health*
 - Supports the standards and recommends no changes.

5. *Steven Szelag, University of Michigan Health System*
 - Supports continued regulation and supports the standards as currently written.

6. *Paul Chuba, MD, PhD, Michigan Radiological Society*
 - Recommends clarifying the accreditation language to ensure all MRT programs be accredited by the American College of Surgeons Commission on Cancer, to insure they are true cancer programs.
 - Supports the requirement for supervision of a board-certified or board eligible Radiation Oncologist.

- Recommends reporting only radiation treatments that are medically necessary for CON volume purposes.
- Strongly supports the new methodology for projecting ETVs based on physician MRT volume.
- Recommends strict enforcement of CON relocation requirements, specifically volume thresholds and requirements.

7. *Ginger Williams, MD, FACEP, FACHE, Oaklawn Hospital*

- Recommends revising the planning areas and methodology to support patients receiving care in their community, as it is commonly held that patients who are able to continue to work and maintain routines have improved outcomes.
- A new methodology should be based on location of the patient rather than facility location. The recent revisions only allow initiations in areas where existing services have excess cases available to be committed, making it extremely difficult to initiate services in geographic areas that did not already have it.
- Recommends looking at the residence location of the patient being treated rather than the facility location where they receive their treatment.
- Utilize mileage radius planning area instead of the Health Service Areas (groupings of counties). A mileage radius is much more true to a provider's market area and is used in most other covered clinical services. The larger the radius, the less restrictive as it relates to collecting data for initiating new service, allowing for greater flexibility in initiating new services in geographic areas that are not yet served.

Summary of the Covered Service

Michigan is one of 23 states to regulate MRT in 2012.

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

The last date of final action by the CON Commission on the MRT standards was March 28, 2013.

The current standards have an effective date of May 24, 2013.

In fiscal year 2012, MDCH approved 1 new site and 2 new units.

In fiscal year 2013, MDCH approved 1 new site and 3 new units.

Summary of 2012 Annual Survey Data - MRT

Facilities	Type of Unit							
	Cobalt	Linear Accelerator	Gamma Knife	Stereotactic Radio-Surgery	OR Based Linear Accelerator	Total Body Irradiators	Cyber Knife	High MRT
Statewide								
68 Facilities	0	114	3	0	0	1	3	1
HSA 1 - Southeast Michigan								
37 Facilities	0	61	2	0	0	1	2	1
HSA 2 - Mid-Southern								
4 Facilities	0	8	0	0	0	0	0	0
HSA 3 - Southwest								
3 Facilities	0	7	0	0	0	0	0	0
HSA 4 - West Michigan								
7 Facilities	0	13	0	0	0	0	0	0
HSA 5 - Genesee - Lapeer - Shiawassee								
4 Facilities	0	7	0	0	0	0	0	0
HSA 6 - East Central								
8 Facilities	0	10	1	0	0	0	1	0
HSA 7 - Northern Lower								
3 Facilities	0	6	0	0	0	0	0	0
HSA 8 - Upper Peninsula								
2 Facilities	0	2	0	0	0	0	0	0

Facilities	Patients Treated	Courses of Treatment	IORT Visits	HMRT Visits	HMRT < 5 Years Old	Equivalents
Statewide						
68 Facilities	24,292	69,510	11	0	0	22
HSA 1 - Southeast Michigan						
37 Facilities	13,308	46,442	11	0	0	22
HSA 2 - Mid-Southern						
4 Facilities	1,301	1,818	0	0	0	0
HSA 3 - Southwest						
3 Facilities	1,555	1,665	0	0	0	0
HSA 4 - West Michigan						
7 Facilities	3,068	13,785	0	0	0	0
HSA 5 - Genesee - Lapeer - Shiawassee						
4 Facilities	1,617	1,796	0	0	0	0
HSA 6 - East Central						
8 Facilities	1,759	2,020	0	0	0	0
HSA 7 - Northern Lower						
3 Facilities	1,229	1,496	0	0	0	0
HSA 8 - Upper Peninsula						
2 Facilities	455	488	0	0	0	0

IORT = Interoperative Radiation Therapy; HMRT = High Megavoltage Radiation Therapy

MDCH Staff Recommendations

MDCH recommends the formation of a SAC to address the issues identified in the public comments.

Open Heart Surgery (OHS) Services

Should OHS Services continue to be a CON covered service?			MDCH Recommendation: Yes
All Identified Issues	Does the issue require further review?	Recommended Course of Action to Review Issue	Comments
Standards have been updated in 2013 and should not be reviewed again in 2014	No.		

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 OHS Services Standards are scheduled for review in calendar year 2014.

Public Comment Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2013 and ending October 24, 2013. Testimony was received from five organizations and is summarized as follows:

1. *Dennis McCafferty, Economic Alliance for Michigan*
 - Recommends no review of this standard as there has been no opportunity to see how they are working.

2. *Garry C. Faja & Roger W. Spoelman, Catholic Health East – Trinity Health Michigan*
 - Supports the standards that were approved by the CON Commission on September 17, 2013 and does not believe that further changes are needed at this time.

3. *Karen Kippen, Henry Ford Health System*
 - Strongly supports continued regulation and the pending changes to the Standards; specifically:
 - The proposed volume changes with regard to lowering the attending surgeon annual volume requirement to 50 adult cases and the annual maintenance volume to 150 adult cases.
 - The use of the STS Composite Star Rating System as a means to measure quality and risk-adjusted outcomes, as well as an additional method for assuring compliance with the Standards.
 - Recommends no review of the OHS standards at this time.

4. *Meg Tipton, Spectrum Health*
 - Supports the standards that were approved by the CON Commission on September 17, 2013 and does not believe that further changes are needed at this time.

5. *Steven Szlag, University of Michigan Health System*
 - Supports continued regulation and recommends that these standards are not reviewed until 2017.

Summary of the Covered Service

Michigan is one of 25 states to regulate Open Heart Surgery 2012.

The last SAC on this standard met from April 2012 to October 2012.

The last date of final action by the CON Commission on the Open Heart Surgery standards was September 17, 2013.

The current standards have an effective date of November 15, 2013.

In fiscal year 2012, MDCH approved 0 new Open Heart Surgery programs.

In fiscal year 2013, MDCH approved 0 new Open Heart Surgery programs.

Summary of 2012 Annual Survey Data - OHS

Facilities	Adult Cases	Pediatric		Congenital Cases	Total Cases	Total Hours	Avg Hours Per Case
		Program	Other				
Statewide							
34 Facilities	10,296	722	6	413	11,437	63,048	5.50
HSA 1 - Southeast Michigan							
17 Facilities	5,165	657	5	221	6,048	35,178	5.80
HSA 2 - Mid-Southern							
3 Facilities	590	0	1	15	606	3,087	5.10
HSA 3 - Southwest							
3 Facilities	726	0	0	17	743	4,655	6.30
HSA 4 - West Michigan							
2 Facilities	1,202	65	0	110	1,377	7,463	5.40
HSA 5 - Genesee - Lapeer - Shiawassee							
2 Facilities	516	0	0	0	516	2,879	5.60
HSA 6 - East Central							
4 Facilities	1,216	0	0	3	1,219	6,044	5.00
HSA 7 - Northern Lower							
2 Facilities	691	0	0	47	738	3,063	4.20
HSA 8 - Upper Peninsula							

1 Facility	190	0	0	0	190	679	3.60
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The data appear as they were reported by the facility and do not necessarily reflect CON approved services.

MDCH Staff Recommendations

MDCH recommends no further review until the next review period in 2017.

Certificate of Need (CON) Commission Summary of Standards Scheduled for 2014 Review

Positron Emission Tomography (PET) Scanner Services			
Should PET Scanner Service continue to be a CON covered service?			MDCH Recommendation: Yes
All Identified Issues	Does the issue require further review?	Recommended Course of Action to Review Issue	Comments
Review initiation requirements in section 3 for relevance	Yes	The formation of a workgroup	Requested by MDCH Evaluation Section
Review Section 3(4) methodology for projecting PET data units	Yes	The formation of a workgroup	Requested by MDCH Evaluation Section
Insert language for second acquisition similar to other standards	Yes	The formation of a workgroup	Requested by MDCH Evaluation Section
Consider any technical changes from the Department e.g., updates or modifications	Yes	MDCH will make any necessary changes.	MDCH is aware of technical changes that need to be made.
Develop specific, measurable quality metrics in the project delivery requirements	Yes	The formation of a workgroup	MDCH Recommendation for all Standards that will come under review in 2014.

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 Workplan, the PET Scanner Services Standards are scheduled for review in calendar year 2014.

Public Comment Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2013 and ending October 24, 2013. Testimony was received from five organizations and is summarized as follows:

1. *Garry C. Faja & Roger W. Spoelman, Catholic Health East – Trinity Health Michigan*

- Supports continued regulation and does not believe specific changes to these standards are necessary at this time.
2. *Dennis McCafferty, Economic Alliance for Michigan*
 - Supports the standards as currently written.
 3. *Karen Kippen, Henry Ford Health System*
 - Supports continued regulation and supports the standards as currently written.
 4. *Meg Tipton, Spectrum Health*
 - Supports the standards and recommends no changes.
 5. *Steven Szelag, University of Michigan Health System*
 - Supports continued regulation and supports the standards as currently written.
 - Recommends opening the standards within the next review period in 2017.

Summary of the Covered Service

Michigan is one of 20 states to regulate PET Scanners in 2012.

The last workgroup on this standard met from February 2012 to March 2012.

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

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

In fiscal year 2012, MDCH approved 7 new PET sites.

In fiscal year 2013, MDCH approved 2 new sites.

Summary of 2012 Annual Survey Data

Not available.

MDCH Staff Recommendations

MDCH recommends that a workgroup is formed to review the issues identified by the MDCH Evaluation Section.

Surgical Services (SS)			
Should Surgical Services continue to be a CON covered service?			MDCH Recommendation: Yes
All Identified Issues	Does the issue require further review?	Recommended Course of Action to Review Issue	Comments
Remove references to endoscopy and cystoscopy in Standards	No		These rooms are within the definition of operating room and are still relevant to many facilities.
Discontinue annual survey activities related to endoscopy and cystoscopy	No		These rooms are within the definition of operating room and are still relevant to many facilities.
Consider any technical changes from the Department e.g., updates or modifications	No		MDCH is not aware of any technical changes to be made at this time.

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 SS Standards are scheduled for review in calendar year 2014.

Public Comment Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards starting on October 9, 2013 and ending October 24, 2013. Testimony was received from six organizations and is summarized as follows:

1. *Garry C. Faja & Roger W. Spoelman, Catholic Health East – Trinity Health Michigan*
 - Supports continued regulation and does not recommend any changes to the standards at this time.

2. *Karen Kippen, Henry Ford Health System*
 - Supports continued regulation and recommends that all references to Endoscopy and Cystoscopy be removed and discontinue tracking dedicated Endoscopy and Cystoscopy rooms and volumes in the Annual CON Survey.

3. *Sean Gehle, Ascension Health - Michigan*
 - Supports continued regulation and recommends no changes.
4. *Dennis McCafferty, Economic Alliance for Michigan*
 - Not aware of any issues with current standard and recommends a workgroup to discuss any issues raised during public comment.
5. *Meg Tipton, Spectrum Health*
 - Supports the standards and recommends no changes.
6. *Steven Szelag, University of Michigan Health System*
 - Supports continued regulation and supports the standards as currently written.

Summary of the Covered Service

Michigan is one of 27 states to regulate Surgical Services in 2012.

The last workgroup on this standard met from July 2011 to August 2011.

The last date of final action by the CON Commission on the Surgical Services standards was December 15, 2011.

The current standards have an effective date of February 27, 2012.

In fiscal year 2012, MDCH approved 1 new Surgical Services site and 12 new operating rooms.

In fiscal year 2013, MDCH approved 6 new Surgical Services sites and 26 new operating rooms.

Summary of 2012 Annual Survey Data – Surgical Services

Facilities	Total OR Rooms	Total Cases	Total Hours	Cases Per Room	Hours Per Room
Statewide					
235 Facilities	1,322	1,172,571	1,706,053	887	1,291
HSA 1 - Southeast Michigan					
99 Facilities	666	576,546	988,214	866	1,484
HSA 2 - Mid-Southern					
16 Facilities	91	90,112	101,324	990	1,113
HSA 3 - Southwest					
20 Facilities	97	80,824	104,757	833	1,080
HSA 4 - West Michigan					
32 Facilities	173	172,679	208,941	998	1,208
HSA 5 - Genesee - Lapeer - Shiawassee					
12 Facilities	81	77,073	98,586	952	1,217
HSA 6 - East Central					
26 Facilities	113	87,882	91,023	778	806
HSA 7 - Northern Lower					
14 Facilities	60	56,981	76,165	950	1,269
HSA 8 - Upper Peninsula					
16 Facilities	41	30,474	37,043	743	903

MDCH Staff Recommendations

MDCH does not recommend any changes to the standard at this time.