MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES (MDHHS)
CERTIFICATE OF NEED (CON) COMMISSION MEETING

Thursday, January 26, 2017

South Grand Building
333 S. Grand Ave
1st Floor, Grand Conference Room
Lansing, MI 48933

APPROVED MINUTES

I. Call to Order & Introductions

Vice-Chairperson Mukherji called the meeting to order at 9:32 a.m.

A. Members Present:

Suresh Mukherji, MD, Vice-Chairperson
Denise Brooks-Williams
James B. Falahee, Jr., JD
Thomas Mittelbrun (participated via phone)
Luis Tomatis, MD
Jessica Kochin
Gail J. Clarkson, RN
Debra Guido-Allen, RN

B. Members Absent:

Marc Keshishian, MD, Chairperson
Kathleen Cowling, DO
Robert Hughes

C. Department of Attorney General Staff:

Joseph Potchen

D. Michigan Department of Health and Human Services Staff Present:

Tulika Bhattacharya
Amber Myers
Beth Nagel
Tania Rodriguez

II. Review of Agenda

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams, to approve the agenda as presented. Motion carried.

III. Declaration of Conflicts of Interests

None.

IV. Review of Minutes of December 7, 2016

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams, to approved the minutes as presented. Motion carried.

V. Positron Emission Tomography (PET) Scanner Services – October 7, 2016 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment A) and the Department's recommendations.

A. Public Comment

None.

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Brooks-Williams, seconded by Commissioner Kochin to accept the Department's recommendation as presented to continue regulation and review the standard again in 2020. Motion carried in a vote of 7- Yes, 0- No, and 0- Abstained.

VI. Surgical Services – October 7, 2016 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment B) and the Department's recommendations.

A. Public Comment

1. Steven Szelag, University of Michigan
2. David Walker, Spectrum Health

B. Commission Discussion
Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Clarkson to accept the Department's recommendation as presented to make technical edits and draft changes regarding commitment letters and bring this language back to the Commission. Motion carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

VII. Open Heart Surgery (OHS) Services – October 7, 2016 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment C) and the Department's recommendations.

A. Public Comment

1. David Walker, Spectrum Health
2. Barbara Bressack, Henry Ford Health System

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Kochin to accept the Department's recommendation to make technical edits and to present the Commission with language regarding the requirements for replacing an Open Heart Service from one existing licensed hospital to another licensed hospital. Motion failed in a vote of 6 - Yes, 1 - No, and 0 - Abstained.

VIII. Hospital Beds – October 7, 2016 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment D) and the Department's recommendations.

A. Public Comment

1. Steve Szelag, University of Michigan
2. David Walker, Spectrum Health
3. Jeff Garber, Mary Free Bed Rehabilitation Hospital

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Brooks-Williams to create a Standard Advisory Committee to review all of the issues identified by the Department in the summary report and the University of Michigan, with the exception that the charge will not include a discussion of observation beds. Motion failed in a vote of 5 - Yes, 2 - No, and 0 - Abstained.

Motion by Commissioner Falahee, seconded by Commissioner Tomatis to create a Standard Advisory Committee to review all of the issues identified by the Department in the summary report and the University of Michigan. Motion failed in a vote of 4 – Yes, 2 – No, and 1 – Abstained.

Motion by Commissioner Brooks-Williams, seconded by Commissioner Guido-Allen to table the action on the Hospital Bed Standards until the March 2017 Commission meeting and request the Department give the Commission guidance prior to that meeting on the Commission's ability to have jurisdiction over observation beds. Motion passes in a vote of 7 – Yes, 0 – No, 0 – Abstained.

[15 minute Break]

IX. Cardiac Catheterization (CC) Services – October 7, 2016 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment E) and the Department's recommendations.

A. Public Comment
1. Melissa Cupp, RWC Advocacy (Attachment F)
2. David Walker, Spectrum Health
3. Marlene Hanson, Mercy Health

B. Commission Discussion

Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Tomatis to form a Standards Advisory Committee to review the issues identified by the Department on the summary report. Motion passes in a vote of 7 - Yes, 0- No, and 0- Abstained.

X. Megavoltage Radiation Therapy (MRT) Services/Units – October 7, 2016 Public Comment Period Summary & Report

Ms. Nagel gave an overview of the public comment period summary (Attachment G) and the Department's recommendations.

A. Public Comment
   1. David Walker, Spectrum Health

B. Commission Discussion

   Discussion followed.

C. Commission Action

Motion by Commissioner Falahee, seconded by Commissioner Tomatis to accept the Department's recommendation to continue regulation and review this standard again in 2020. Motion passes in a vote of 7 - Yes, 0- No, and 0- Abstained

XI. Public Comment

None.

XII. Review of Commission Workplan

Ms. Nagel provided an overview of the changes to the workplan (Attachment H).

A. Commission Discussion

   Discussion followed.

B. Commission Action

   Motion by Commissioner Falahee, seconded by Commissioner Kochin to accept the workplan as discussed. Motion passes in a vote of 7 - Yes, 0- No, and 0- Abstained

XIII. Future Meeting Dates – March 16, 2017, June 15, 2017, September 21, 2017, & December 7, 2017

XIV. Adjournment

Motion by Commissioner Falahee, seconded by Commissioner Kochin, to adjourn the meeting at 11:47 a.m. Motion Carried in a vote of 7 - Yes, 0 - No, and 0 - Abstained.

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Positron Emission Tomography (PET) Scanner Services Standards

Department Recommendations: PET scanner services should continue to be regulated by CON. There are no recommended changes at this time. The next review will be in 2020.

Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
No identified issues.		No review necessary.	

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 Surgical Services Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from six (6) organizations and is summarized as follows:

1. *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health System*
   - Supports continued regulation of PET scanner services and recommends no changes at this time.

2. *Sean Gehle, Ascension Michigan*
   - Supports continued regulation of PET scanner services and recommends no changes at this time.

3. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
   - Supports continued regulation of PET scanner services and recommends no changes at this time.

4. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
   - EAM is not aware of any changes in technology to warrant a revision to the standard.

5. *Arlene Elliott on behalf of Trinity Health Michigan*
   - Supports continued regulation of PET scanner services and recommends no changes at this time.

Background:

The PET Scanner Services standards were reviewed by the Department in 2014/2015. The current effective date of the PET Scanner Services standards is September 14, 2015.

PET Scanner Services Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

PET Services - Fixed Scanners
http://www.michigan.gov/documents/mdhhs/Report_141-Fixed_PET_Scanners_and_Scans_by_Type_538229_7.pdf

PET Services - CSC http://www.michigan.gov/documents/mdhhs/Report_145-PET_Services_-_CSC_538240_7.pdf

PET Services - Mobile Routes
http://www.michigan.gov/documents/mdhhs/Report_147-PET_Services_-_Mobile_Routes_538242_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Surgical Services Standards

Department Recommendations: Surgical services should continue to be regulated by CON. The Commission should delegate to the Department to make a recommendation regarding the issues outlined below.

Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
Review Section 6 – Requirements for Expansion for possible modifications or clarifications. The current language states that all proposed operating rooms must meet projected volumes in the second twelve months of operation. It is believed that the Department interprets this requirement to mean that the facility needs to be at the "projected" volumes when submitting the CON application.	No.		The Department does not recommend any changes to this language.
Consider adding a requirement that ambulatory surgical centers and freestanding surgical outpatient facilities must participate in a nationally recognized nonprofit organization with extensive experience in collecting and reporting quality data on a public website.	No.		This type of public reporting has been reviewed with other CON review standards and is outside of the scope of the CON program.
Make typographical technical edits.	No.	The Department to develop draft language.	

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 Surgical Services Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from six (6) organizations and is summarized as follows:

1. *Sean Gehle, Ascension Michigan*
   - Supports continued regulation of surgical services and recommends no changes at this time.

2. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
   - Supports continued regulation of surgical services. Beaumont Health recommends that Section 6 – Requirements for Expansion be reviewed for possible modifications or clarifications. The current language states that all proposed operating rooms must meet projected volumes in the second twelve months of operation. They believe that the Department interprets this requirement to mean that the facility needs to be at the "projected" volumes when submitting the CON application. Thus, there appears to be a discrepancy in this interpretation.

3. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
   - EAM is not aware of any changes in technology to warrant a revision to the standard. They do suggest that the standards could be improved by adding "a requirement that ambulatory surgical centers and freestanding surgical outpatient facilities must participate in a nationally recognized nonprofit organization with extensive experience in collecting and reporting quality data on a public website. This public website would provide information to allow consumers to compare safe practices by hospitals."

4. *Arlene Elliott on behalf of Trinity Health Michigan*
   - Supports continued regulation of surgical services and recommends no changes at this time.

Background:

The Surgical Services standards were reviewed by a workgroup in 2011. The current effective date of the Surgical Services standards is December 22, 2014.

Surgical Services Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

Operating Room Utilization
http://www.michigan.gov/documents/mdhhs/Report_050_-_Operating_Room_Utilization_538293_7.pdf

Endo, Cysto, and C-Section Utilization
http://www.michigan.gov/documents/mdhhs/Report_051_-_Endo_Cysto_and_C-Section_Utilization_538295_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Open Heart Surgery (OHS) Services Standards

Department Recommendations: OHS services should continue to be regulated by CON. The Commission should delegate to the Department to make a recommendation regarding the issues outlined below.

Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
Review volume, quality, cost and patient experience for improvements as well as assign relative weights for each.	No.		Refer to comments from Theodore Schreiber, MD and Kyle Sheiko. This is already included in the current standards.
Consider adding requirements for replacing an existing OHS service from one existing licensed hospital to another existing licensed hospital with certain requirements (e.g., common ownership, 5-10 mile relocation zone, ability to meet the initiation requirements, etc.)	Yes.	Department draft language	This issue was identified by the MDHHS CON Evaluation section. Under current standards, a hospital can only replace an OHS service to a new site as part of a consolidated hospital replacement project.
Other technical edits by the Department if needed.			

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 OHS Services Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from six (6) organizations and is summarized as follows:

1. *Barbara Bressack, Henry Ford Health System (HFHS)*
   - HFHS supports the continued regulation of OHS services and recommends no changes at this time.

2. *Sean Gehle, Ascension Michigan*
    - Supports continued regulation of OHS services and recommends no changes at this time.

3. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
    - Supports continued regulation of OHS services and recommends no changes at this time.

4. *Maysoon Abu-Omarah on behalf of Theodore Schreiber, MD, FACC, The DMC Heart Hospital and Cardiovascular Institute, and Kyle Sheiko, Cardiology Service Line*
    - Volume: It is stated that OHS services "should not be solely regulated by specific procedural volume alone, but should include the total practitioners lab volume and all surgical volume performed by each practitioner whether it is a closed heart operation or open heart operation on the great vessels within the chest. Further, by utilizing the American college of Surgeons (ACS) guidelines for standards in cardiac surgery, CON can incorporate the most current recommendations for institutional and operator performance.
    - Quality: They believe that "the first step is to collaborate with the business intelligence designated for both OHS programs and CCS's (i.e. ACC/AHA, ACS, NCDR and STS Registry) for evidenced based practice as well as for quality data submission and tracking." Annual quality reporting should include the following quality/performance indicators:
        - ✓ Internal Mammary Artery (IMA) Us
        - ✓ Risk Adjusted 30 day readmissions
        - ✓ Risk adjusted 30 day mortality
        - ✓ Risk Adjusted complications
        - ✓ JCAHO's Surgical Care Improvement Project (SCIP's)
        - ✓ Overall STS STAR Rating
    - Cost: Suggest the development of collaborative approaches that combine strong clinical outcomes with effective cost containment, i.e., tracking wage severity adjusted cost and severity adjusted length of stay (LOS) is paramount.
    - Patient Experience: Improve patient experience, improve patient outcomes while reducing cost is a goal of "Triple Aim" developed by the Institute of Healthcare Improvement (IHI).
    - They recommend not only taking into consideration the four components of volume, quality, cost and patient experience but additionally assign relative weights for each.

5. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
    - EAM issued the following questions:
        - ✓ Have the OHS programs, that were unable to meet the minimum volume standards of the CON Standard they were approved under, re-applied for a CON under the newest CON Standard?
        - ✓ Are there any OHS programs that have not applied for a CON under the newest Standards, with the lower annual volume, that

continue to not meet the minimum volumes of their existing OHS CON?
- ✓ If there are OHS programs failing to meet the minimum volumes of their OHS CON Standard, what enforcement actions if any has the Department taken?
- ✓ Are all of the OHS programs, under the most recent updated version of the CON Standards participating the quality measurement initiative (STS) and making their results public?
- ✓ If there are OHS programs, which have a CON under the most recent updated version of the CON Standards, that fail to meet the minimum quality measurements under this version of the CON Standards, will the Department be willing to take corrective action?

6. *Arlene Elliott on behalf of Trinity Health Michigan*
   - Supports continued regulation of OHS services and recommends no changes at this time.

Background:

The OHS Services standards were reviewed by a standard advisory committee (SAC) in 2012. The current effective date of the OHS Services standards is June 2, 2014.

OHS Services Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

Open Heart Surgical Utilization
http://www.michigan.gov/documents/mdhhs/Report_070_-_Open_Heart_Surgical_Utilization_538298_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Hospital Beds Standards

Department Recommendations: Hospital Beds should continue to be regulated by CON. The Commission should form a workgroup to make a recommendation regarding the issues outlined below.

Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
Remove Section 6(4)(f) from the standards which requires applicants to send certified letters to every acute care hospital within the applicant's HSA when applying for high occupancy beds.	Yes.	Form a workgroup to review the issue.	The Department believes this should be reviewed to determine if this is a needed requirement.
Should out-patient Observation Beds be regulated in a fashion similar to the in-patient hospital beds?	Yes.	Form a workgroup to review the issue.	This issue was identified by the MDHHS CON Evaluation Section.
Add a requirement that hospitals with CON approved beds must participate in a nationally recognized nonprofit organization with extensive experience in collecting and reporting hospital quality data on a public website.	No.		This type of public reporting has been reviewed with other CON review standards and is outside of the scope of the CON program.
Re-evaluate Section 12, Comparative Review Criteria to determine if any updates are needed.	Yes.	Form a workgroup to review the issue.	This issue was identified by the MDHHS CON Evaluation section.
Section 9(4)(a), Project Delivery Requirements, include a technical edit to state that the 75% occupancy to the hospital applies to all the licensed beds at the hospital at the time of this 3rd 12-month period.	No.	Department will draft language for Commission review.	This issue was identified by the MDHHS CON Evaluation section.

Review space lease and lease renewal at hospitals to determine if updates are needed.	Yes.	Form a workgroup to review the issue.	This issue was identified by the MDHHS CON Evaluation section.
Other technical edits by the Department if needed.			

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 Hospital Beds Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from six (6) organizations and is summarized as follows:

1. *Barbara Bressack, Henry Ford Health System (HFHS)*
   - HFHS supports the continued regulation of Hospital Beds and does not have any proposed changes at this time.

2. *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health Systems (UMHS)*
   - UMHS supports continued regulation of Hospital Beds. They request that Section 6(4)(f) be removed from the standards. They state "'Applicants' who have met the conditions of high occupancy guidelines satisfy the principal threshold for approval under Section 6, having demonstrated a need for incremental bed licenses under the prescribed formula of these CON Standards. Requiring applicants to send certified letters subsequently to every acute care hospital within the applicant's HSA appears to be an unnecessary administrative step in the process."

3. *Sean Gehle, Ascension Michigan*
   - Supports continued regulation of Hospital Beds and recommends no changes at this time.

4. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
   - Supports continued regulation of Hospital Beds and recommends no changes at this time.

5. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
   - Should out-patient Observation Beds be regulated in a fashion similar to the in-patient hospital beds?
   - EAM suggests "adding a requirement that hospitals with CON approved beds must participate in a nationally recognized nonprofit organization with extensive experience in collecting and reporting hospital quality data

on a public website. This public website would provide information to allow consumers to compare safe practices by hospital."

6. *Arlene Elliott on behalf of Trinity Health Michigan*
   - Supports continued regulation of Hospital Beds and recommends no changes at this time.

Background:

The Hospital Beds standards were reviewed by the Department in 2014. The current effective date of the Hospital Beds standards is March 20, 2015.

Hospital Beds Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

Hospital Beds by HSA http://www.michigan.gov/documents/mdhhs/Report_010_-_Licensed_Beds_in_Hospitals_by_HSA_538169_7.pdf

Hospital Beds by County http://www.michigan.gov/documents/mdhhs/Report_011_-_Licensed_Beds_in_Hospitals_by_County_538170_7.pdf

Acute Care by HSA http://www.michigan.gov/documents/mdhhs/Report_020_-_Acute_Care_Utilization_by_HSA_538172_7.pdf

Acute Care by County http://www.michigan.gov/documents/mdhhs/Report_021_-_Acute_Care_Utilization_by_County_538173_7.pdf

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Cardiac Catheterization (CC) Services Standards

Department Recommendations: CC should continue to be regulated by CON. The Commission should form a standard advisory committee (SAC) to make a recommendation regarding the issues outlined below.

Identified Issues	Issue Recommended for Substantive Review?	Recommended Course of Action to Review Issues	Other/Comments
Modify Sec. 10(5)(f) to apply only to facilities that do not have on-site open heart surgery (OHS). Currently states "Catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document."	No.	Form a SAC if necessary to advise on technical changes.	This change was made during the most recent Standard Advisory Committee (SAC). The Department does not support making a policy change to this requirement. Many open heart surgery programs have already successfully demonstrated compliance with this requirement. This is an important quality of care requirement.
Should pacemakers and implantable cardioverter defibrillator (ICD) implants be allowed to be performed in ambulatory surgical centers (ASCs) or only in licensed hospitals?	Yes.	Form a SAC to review the issue.	The current definition of diagnostic CC services specifies that the services must be performed in a hospital. This issue may also require a change in the Surgical Services standards.
Relax the definition of Primary Percutaneous Coronary Intervention (PCI).	Yes.	Form a SAC to review the issue.	See comments from Beaumont Health.
Review Section 10 (5)(c) – Door-to-Balloon Time requirement to exclude patients with cardiogenic shock who often require intensive resuscitation and medical stabilization before revascularization.	Yes.	Form a SAC to review the issue.	

Review Section 11 – Cardiac Cath Equivalents: including Watchman, Chronic Total Occlusion Percutaneous Coronary Intervention, IMPELLA, paravalvular leak closure and alcohol septal ablation. Possibly incorporating into the cardiac cath equivalent methodology with a weighting of 4.0 (same as Complex percutaneous valvular sessions).”	Yes.	Form a SAC to review the issue.	
Review volume, quality, cost and patient experience for improvements as well as assign relative weights for each.	No.		Refer to comments from Theodore Schreiber, MD and Kyle Sheiko. These standards already address this issue and was part of the most recent updates to the standards.
Make publicly available reports on both the volume of elective and emergency angioplasty being performed at each facility as well as some objective, third-party assessment of quality of services being provided.	No.		Department has reviewed this issue during the most recent SAC and has found this proposal outside of the scope of the CON program.
Clarification on Section 4(13)(a) (Are 36 primary PCI cases needed for approval?) and (b) (What is “acceptable performance?”)	Yes.	Form a SAC to review the issue.	This issue was identified by the MDHHS CON Evaluation section.
Review the following definitions and the procedures that are allowed: diagnostic cardiac catheterization service, primary PCI service without on-site OHS, elective PCI services without on-site OHS, therapeutic cardiac catheterization service, and electrophysiology study.	Yes.	Form a SAC to review the issue.	This issue was identified by the MDHHS CON Evaluation section.
Add requirements for replacing an existing CC service from one existing licensed hospital to another existing licensed hospital with certain requirements (e.g., common	Yes.	Form a SAC to review the issue.	This issue was identified by the MDHHS CON Evaluation section. Under current standards, a hospital can only replace a CC service to a

ownership, 5-10 mile relocation zone, ability to meet the initiation requirements, etc.).			new site as part of a consolidated hospital replacement project.
Other technical edits by the Department if needed.			

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 CC Services Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from eight (8) organizations and is summarized as follows:

1. *Barbara Bressack, Henry Ford Health System (HFHS)*
   - HFHS recommends clarification of Sec. 10(5)(f) which states "Catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document." They feel that this is an added burden on existing programs with on-site open heart surgery (OHS) that is unnecessary and unintended by the SAC. They request that the language be clarified to have this requirement only apply to CC facilities that do not have on-site OHS.

2. *David Walker on behalf of Penny Wilton, Spectrum Health*
   - The Centers for Medicare & Medicaid Services recently approved pacemakers and implantable cardioverter defibrillator (ICD) implants can be performed in ambulatory surgical centers (ASCs). Spectrum Health recommends that the standards be updated to make it clear that they must be performed in a licensed hospital. Further, they believe that the word "hospital" was inadvertently removed from the standards since historically they limited CC services to hospitals only.

3. *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health Systems (UMHS)*
   - UMHS would like the CON Commission to provide clarification and consider a technical revision(s), if recommended, regarding Section 10(5)(f) which states "Catheterization lab facility requirements and collaborative cardiologists-heart surgeon relationship requirements shall conform to all SCAI/ACC Guidelines for PCI including the SCAI/ACC/AHA Expert Consensus Document. The applicant hospital shall be liable for the cost of demonstrating compliance with these criteria." They do not believe that this should be applicable to replacement of an Electro-physiology (EP) laboratory for programs with an on-site OHS service.

4. *Sean Gehle, Ascension Michigan*
    - Supports continued regulation of CC Services and recommends no changes at this time.

5. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
    - Beaumont states that the definition of "Primary Percutaneous Coronary Intervention (PCI)" is too restrictive in that some patients without ST-segment elevation are appropriate candidates for emergency intervention. They propose the following definition: "Primary percutaneous coronary intervention (PCI) means PCI performed on an emergent basis for acute ST-segment elevation myocardial infarction (STEMI), posterior wall MI, or cardiogenic shock secondary to left ventricular or right ventricular failure from acute myocardial ischemia."
    - Section 10 (5)(c) – Door-to-Balloon Time requirement should exclude patients with cardiogenic shock who often require intensive resuscitation and medical stabilization before revascularization.
    - Section 10 (5)(f) – Beaumont Health recommends that open heart facilities not be required to meet this requirement as these facilities are already required to meet stringent quality standards and protocols.
    - Section 11 – Cardiac Cath Equivalents: Beaumont Health states that "There are additional interventional procedures that are performed in a cath lab but are not identified or weighted in the current cardiac cath equivalent methodology. These include Watchman, Chronic Total Occlusion Percutaneous Coronary Intervention, IMPELLA, paravalvular leak closure and alcohol septal ablation. Beaumont Health recommends these additional procedures be incorporated into the cardiac cath equivalent methodology with a weighting of 4.0 (same as Complex percutaneous valvular sessions)."

6. *Maysoon Abu-Omarah on behalf of Theodore Schreiber, MD, FACC, The DMC Heart Hospital and Cardiovascular Institute, and Kyle Sheiko, Cardiology Service Line*
    - Volume: It is stated that cardiac catheterization services "should not be solely regulated by specific procedural volume alone, but should include the total practitioners lab volume and all surgical volume performed by each practitioner whether it is a closed heart operation or open heart operation on the great vessels within the chest. Further, by utilizing SCAI/ACC/AHA Expert Consensus Document: for Cardiac catheterization Laboratories, CON can incorporate the most current recommendations for institutional and operator performance.
    - Quality: They believe that "the first step is to collaborate with the business intelligence designated for both OHS programs and CCS's (i.e. ACC/AHA, ACS, NCDR and STS Registry) for evidenced based practice as well as for quality data submission and tracking. Additionally we believe accreditation should be a requirement for all CCL's. Detroit Medical Centers Cardiovascular Departments recommends annual reporting of the following cardiac cath quality indicators."
        - ✓ Procedural Appropriateness

    - ✓ Door to Balloon (DTB)
    - ✓ Risk Adjusted 30 day Readmissions
    - ✓ Risk Adjusted 30 day Mortality
    - ✓ Discharge medication compliance
- Cost: Suggest the development of collaborative approaches that combine strong clinical outcomes with effective cost containment, i.e., tracking wage severity adjusted cost and severity adjusted length of stay (LOS) is paramount.
- Patient Experience: Improve patient experience, improve patient outcomes while reducing cost is a goal of "Triple Aim" developed by the Institute of Healthcare Improvement (IHI).
- They recommend not only taking into consideration the four components of volume, quality, cost and patient experience but additionally assign relative weights for each.

7. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
    - EAM would like to see publicly available reports on both the volume of elective and emergency angioplasty being performed at each facility as well as some objective, third-party assessment of quality of services being provided.

8. *Arlene Elliott on behalf of Trinity Health Michigan*
    - Suggest reviewing the applicability of the project delivery requirements as currently written under Section 10(5)(f). "The SCAI/ACC Expert Consensus Document referenced in this project delivery requirement was developed specifically for programs without on-site open heart surgery. To our knowledge and that of our interventional cardiologists, SCAI/ACC has never published a specific guideline that defines facility requirements or cardiologist-heart surgeon relationship requirements for facilities that provide open heart surgery ("OHS"). We do not believe the CON Commission intended to apply expert guidelines designed for one type of facility (without OHS) to a wholly different type of facility (with OHS). Therefore, we would suggest a workgroup be convened to address alternative metrics for quality assurance that are appropriate for cardiac catheterization services with on-site open heart surgery."

Background:

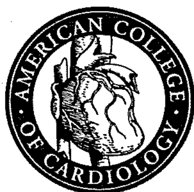
The CC standards were reviewed with a standard advisory committee (SAC) in 2014. The current effective date of the CC standards is September 14, 2015.

CC Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

Cardiac Catheterization Services – Adult http://www.michigan.gov/documents/mdhhs/Report_060_-_Cardiac_Catheterization_Services-Adult_538296_7.pdf

Cardiac Catheterization Services –
Pediatric http://www.michigan.gov/documents/mdhhs/Report_062_-_Cardiac_Catheterization_Services-Pediatric_538297_7.pdf



Michigan
CHAPTER

Attachment F

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Nancy Mesiha, MD
Arthur L. Riba, MD

January 26, 2017

Michigan Certificate of Need Commission
South Grand Building
333 S. Grand Ave
Lansing, MI 48933

Dear Commissioners:

The Michigan Chapter of the American College of Cardiology (MCACC) is committed to supporting the development and delivery of cardiovascular standards, with the ultimate goal of transforming cardiovascular care and improving heart health. We believe a robust discussion of the CON standards is a necessary step to achieve this goal.

After reviewing the public comments pertaining to the Cardiac Catheterization Standards, MCACC would like to offer a clarification on the proposal to expand the definition of primary PCI. We believe that primary PCI is defined as "emergent PCI of the infarct-related artery without prior fibrinolysis for ST-elevation MI (including posterior MI) within 12 hours of symptom onset". While performing PCI for patients with coronary ischemia in cardiogenic shock emergently at PCI centers without surgical backup merits a vigorous discussion, it should be considered separately without changing the definition of primary PCI.

MCACC members are best prepared to discuss the merits of the balance of the suggestions provided in public comment.

It is also important to note that the ACC, in partnership with the American Heart Association now offer accreditation services focused on all aspects of cardiac care, including chest pain, cardiac catheterization, atrial fibrillation, heart failure and other cardiovascular conditions. This accreditation will offer hospitals a single source of state-of-the-art process improvement tools to bridge gaps and integrate evidence-based science, quality initiatives, clinical best-practices and the latest ACC/AHA guidelines into their cardiovascular care processes. The many hospitals that have chest pain certification or Mission Lifeline accreditation are likely to be rolled in to this new accreditation. We anticipate that its accessibility will make it a preferred product over ACE and so should be considered as an option or replacement for ACE in the cath standards.

Please contact me or our Executive Director, Alice Betz (alice@accmi.org / 517-663-6622) if we can be of assistance.

Sincerely,

Akshay Khandelwal, MD, FACC, FSCAI
President
akhande1@hfhs.org

MDHHS Recommendations for CON Standards Scheduled for 2017 Review

Megavoltage Radiation Therapy (MRT) Services/Units Standards			
Department Recommendations: MRT services/units should continue to be regulated by CON. There are no recommended changes at this time. The next review will be in 2020.			
Identified Issues	**Issue Recommended for Substantive Review?**	**Recommended Course of Action to Review Issues**	**Other/Comments**
Section 11(2)(iii), add that the dosimetrist be "board-certified."	No.		The Department does not recommend any changes to this language.
Should Section 3(4) be replaced with more relevant and current standards and remove the collaborative methodology? (See public comments from Steven Szelag, University of Michigan Health System)	No. However, if the Commission decides to review Section 3(4), then the Department recommends the formation of a standard advisory committee (SAC) to review the issue.		The section cited is the High MRT (HMRT or Proton Beam Therapy) initiation criteria section. The Department does not recommend any changes to this language.
Other technical edits by the Department if needed.			

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 MRT Services/Units Standards are scheduled for review in calendar year 2017.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 7 - 21, 2016. Testimony was received from seven (7) organizations and is summarized as follows:

1. *Barbara Bressack, Henry Ford Health System (HFHS)*
    - HFHS supports the continued regulation of MRT services. Under Section 11(2)(iii), they propose adding that the dosimetrist be "board-certified."

2. *David Walker on behalf of Judy Smith, MD and Angela Ditmar, RN, Spectrum Health Cancer Center*
    - Spectrum Health Cancer Center supports the continued regulation of MRT services and recommends no changes at this time.

3. *Steven Szelag on behalf of T. Anthony Denton, University of Michigan Health Systems (UMHS)*
   - UMHS supports continued regulation of MRT services. They request that Section 3(4) be "replaced with more relevant and current standards to support delivery of health care to cancer patients who can benefit from high megavoltage radiation therapy, also referred to as particle therapy." They state that a collaborative methodology is no longer necessary as costs have come down over time. If the approval path to entry were more flexible, particle therapy services might be more readily available providing access to this highly precise therapy for radiation treatment.

4. *Sean Gehle, Ascension Michigan*
   - Supports continued regulation of MRT services and recommends no changes at this time.

5. *Monica Harrison on behalf of Patrick O'Donovan, Beaumont Health*
   - Supports continued regulation of MRT services and recommends no changes at this time.

6. *Dennis McCafferty, Economic Alliance for Michigan (EAM)*
   - Supports continued regulation of MRT services and is not aware of any technology changes at this time that would warrant a revision of the Standard.

7. *Arlene Elliott on behalf of Trinity Health Michigan*
   - Supports continued regulation of MRT services and recommends no changes at this time.

Background:

The MRT Services/Units standards were reviewed by a standard advisory committee (SAC) in 2014. The current effective date of the MRT Services/Units standards is September 14, 2015.

MRT Services Survey Data for 2015:

Annual survey data for 2015 is the latest available and can be found here:

MRT Units http://www.michigan.gov/documents/mdhhs/Report_080_-_MRT_Units_538223_7.pdf

MRT Therapy Treatments http://www.michigan.gov/documents/mdhhs/Report_086_-_MRT_Treatments_538225_7.pdf

MRT Special Purpose Radiosurgery
http://www.michigan.gov/documents/mdhhs/Report_087_-_MRT_Sp._Purpose_Radiosurgery_538226_7.pdf

MRT Special Purpose Gamma Knife (The latest available is 2014)
http://www.michigan.gov/documents/mdch/Report_088_506614_7.pdf

MRT Special Purpose Cyber Knife
http://www.michigan.gov/documents/mdch/Report_089_506615_7.pdf

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2016												2017											
	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**	▮	▮	▮	▮	▮	• R	•	•	•	•	•	• R▬												
Cardiac Catheterization Services										PC			• R A											
Computed Tomography (CT) Scanner	• R A	•	•	•	•	• R▬	•P	•	•▲ F															
Hospital Beds										PC			• R A											
Magnetic Resonance Imaging (MRI) Services	•	•P	•▲ F R▬	•	•P	•▲ F																		
Megavoltage Radiation Therapy (MRT) Services/Units										PC			• R A											
Neonatal Intensive Care Services/Beds and Special Newborn Nursing Services	• R A	•	•	•	•	• R▬	•P	•	•▲ F															
Nursing Home and Hospital Long-Term-Care Unit (NH-HLTCU) Beds**	• R A	•	• A	•	•	•	•	•	•	•	•	•												
Open Heart Surgery (OHS) Services										PC			• R A											
Positron Emission Tomography (PET) Scanner Services										PC			• R A											
Psychiatric Beds and Services	•	•	• R▬	• P	•	•▲	• P	•	•▲ F															
Surgical Services										PC			• R A											
Urinary Extracorporeal Shock Wave Lithotripsy Services	• R A	•	•	•	•	•	•	•	•	•	•	• 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			•M			•M
2-year Report to Joint Legislative Committee (JLC) – 1/1/17								•	D •	•	•	• R												
FY2016 CON Annual Report								•	•	•	•	• R												

KEY

Symbol		Meaning	Letter		Meaning
▬	-	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 appro
█	-	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
			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 on December 7, 2016

Updated November 2, 2016

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 Health and Human Services (MDHHS), Office of Health Policy and Innovation, Planning and Access to Care Section, 15th Floor Grand Tower Bldg., 235 S. Grand Ave., Lansing, MI 48933, 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	June 2, 2014	2019
Bone Marrow Transplantation Services	September 29, 2014	2018
Cardiac Catheterization Services	September 14, 2015	2017
Computed Tomography (CT) Scanner Services	December 22, 2014	2019
Heart/Lung and Liver Transplantation Services	September 28, 2012	2018
Hospital Beds	March 20, 2015	2017
Magnetic Resonance Imaging (MRI) Services	May 27, 2016	2018
Megavoltage Radiation Therapy (MRT) Services/Units	September 14, 2015	2017
Neonatal Intensive Care Services/Beds (NICU)	December 22, 2014	2019
Nursing Home and Hospital Long-Term Care Unit Beds and Addendum for Special Population Groups	March 20, 2015	2019
Open Heart Surgery Services	June 2, 2014	2017
Positron Emission Tomography (PET) Scanner Services	September 14, 2015	2017
Psychiatric Beds and Services	March 22, 2013	2018
Surgical Services	December 22, 2014	2017
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	December 22, 2014	2019

*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.