From: Gehle, Sean <sean.gehle@ascension.org>

Sent: Friday, October 21, 2016 9:19 AM

To: MDHHS-ConWebTeam

Cc: Kelley, Rachel; Ciokajlo, Michele; Tesner, Kirstin; Skowronski, Carol; Brady, Mark **Subject:** Ascension Michigan comments for CON standards eligible for Review in 2017

This message was sent securely using ZixCorp.

To Whom it May Concern/Tania Rodriguez:

On behalf of Ascension Michigan, I would like to record our comments for <u>all</u> CON Standards eligible for review in 2017 (Cardiac Catheterization Services, Open Heart Surgery Services, Hospital Beds, PET Scanner Services, MRT Services, Surgical Services) as noted below:

Support for continued CON regulation / No changes suggested at this time.

Thank you and please do not hesitate to contact me if you have any questions or concerns, regarding Ascension Michigan's position on any of these standards.

Sean Gehle

VP, Advocacy

Ascension | Michigan

328 W. Ottawa Street

Lansing, MI 48933

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T: 517-482-1422 F: 517-374-1326

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This are the 71 Comp(R)

This message was secured by **ZixCorp**(R).

From: Harrison, Monica J < Monica. Harrison@beaumont.org>

Sent: Friday, October 21, 2016 3:58 PM

To: MDHHS-ConWebTeam Cc: O'Donovan, Patrick

Subject: 2017 Public Comment Period

Attachments: Testimony for 2017 CON Standards Up for Review10-20-16.dotx

Please see attached testimony.

Thank you, Monica

Monica Harrison Beaumont Health Planning Department Sr. Planning Specialist

Phone: 313-586-5478 Fax: 313-792-7156

Beaumont

October 20, 2016

Certificate of Need Commission c/o Michigan Department of Community Health Certificate of Need Policy Section South Grand Building 333 S. Grand Avenue Lansing, MI 48933

Dear Certificate of Need Commission:

This letter is written as formal testimony pertaining to the CON Review Standards for Cardiac Catheterization Services, Hospital Beds, MRT Services/Units, OHS Services, PET Scanner Services, and Surgical Standards which are scheduled for review in 2017.

Cardiac Catheterization Services:

Beaumont Health proposes the following changes to the cardiac cath standards:

1. Section 2 (n) – Definition of "Primary Percutaneous Coronary Intervention (PCI)"

Comment: The definition is too restrictive in that some patients without ST-segment elevation are appropriate candidates for emergency intervention. For example, patients with true posterior wall MI secondary to occlusion of the circumflex artery typically do not manifest ST-segment elevation; rather there is a typical ECG pattern with ST-segment depression in leads V1-V2 associated with a prominent r-wave. Additionally, cardiogenic shock needs to be included (many of these cases do not have ST-segment elevation).

Proposed language: "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."

2. <u>Section 10 (5)(c) – Door-to-Balloon Time</u>

Comment: This requirement should exclude patients with cardiogenic shock who often require intensive resuscitation and medical stabilization before revascularization.

3. Section 10 (5)(f) – Facility Requirements

Comment: This language requires that an applicant seeking to replace a cath lab must obtain Corazon or ACE certification. This includes applicants who are replacing a lab but who also operate open heart programs. Beaumont Health recommends that open heart facilities not be required to obtain this certification as these facilities are already required to meet stringent quality standards and protocols.

4. Section 11 – Cardiac Cath Equivalents

Comment: 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)

Hospital Beds:

Beaumont Health supports the continued regulation of hospital beds. No specific changes to these standards are recommended at this time.

MRT Services/Units:

Beaumont Health supports the continued regulation of MRT services. No specific changes to these standards are recommended at this time.

Open Heart Surgery Services:

Beaumont Health supports the continued regulation of open heart surgery services. No specific changes to these standards are recommended at this time.

PET Scanner Services:

Beaumont Health supports the continued regulation of PET scanner services. No specific changes to these standards are recommended at this time.

Surgical Services:

<u>Section 6 – Requirements for Expansion</u>

Comment: Beaumont Health recommends this section 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. However our understanding is 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.

Thank you for the opportunity to provide comment on these CON Review Standards.

Sincerely,

Patrick O'Donovan
Director, Strategy & Business Development

From: Abu-Omarah, Maysoon <MAbu-oma@dmc.org>

Sent: Wednesday, October 19, 2016 4:46 PM

To: MDHHS-ConWebTeam

Cc:Sheiko, KyleSubject:CON Letter

Attachments: CON Letter revised.docx

This message was sent securely using ZixCorp.

This email is being sent on behalf of Dr. Theodore Schreiber President of The DMC Heart Hospital and Cardiovascular Institute, and Kyle Sheiko Regional Director of Cardiology Service Line.

Best Regards,

Maysoon Abu-Omarah Sr Executive Secretary Office 313-832-0300 Fax 313-745-9222

mabu-oma@dmc.org

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October 18, 2016

Re: Certificate of Need Review Standards for Cardiac Catheterization Services and Open Heart Surgical Services.

Dear Sirs:

On behalf of Detroit Medical Center's Cardiovascular Departments, we appreciate the opportunity to comment on Michigan's Certificate of Need (CON) review standards for Cardiac Catheterization Services (CCS) and Open Heart Surgical Services (OHS).

After reviewing the state of Michigan's 2013 CON standards for both CCS and OHS Services; we recommend the CON committee consider revising and adding the following components to each document.

- 1. Volume
- 2. Quality
- 3. Cost
- 4. Patient Experience

Listed below is a brief rationale of each component for your consideration.

VOLUME

Over the past decade there has been continuous erosion of PCI procedures and OHS procedures. This steady decline has been associated with a decrease in the prevalence of coronary artery disease (CAD) due to the following:

- Improved primary prevention.
- Improved and increase use of pharmacological therapy and secondary prevention (i.e. community screenings/early detection, Cardiac Rehabilitation).
- Reduction of restenosis related to the widespread use of drug-eluting stents (DES), more recently Absorbable stents.
- Outcome results of the COURAGE trial.
- Appropriate scrutiny of low risk elective procedures.
- Greater regulatory oversight from Recovery Audit Contractors (RAC), Medicare Administrative Contractors (MAC), Department of Justice (DOJ), Two-midnight rule.
- Pressure to reduce hospital readmissions.
- Market saturation of cardiac catheterization labs with and without on-site surgery and open heart programs.

According to the advisory board, expect a continued downward trend nationally as well as in the state of Michigan for Cardiovascular Services, for many of the reasons listed above.

See national volume forecasts (tables 1a & 1b) listed below

Cardiovascular Roundtable National Forecasts (Table 1a):

Service Line	2015 Volume	2020 Volume	2025 Volume	5 Yr Growth	10 Yr Growth
Cardiac Services	3,902,162	3,504,781	3,611,146	-10.2%	-7.5%

Cardiovascular Roundtable National Inpatient & Outpatient Volume Forecasts (Table 1b)

Service Line and Subservice Line	Predicted Change 2015-2020			
	Inpatient	Outpatient		
Cardiac Services	-10.2%	11.6%		
Vascular Services	-6.8%	17.7%		
Cardiac Surgery	-3.6%	NA		
Cardiac Cath	-7.6%	-10.5%		
Cardiac EP	-6.1%	19.3%		
Medical Cardiology	-11.7%	11.4%		

Not only has this decline been noticeable nationally, but also in the state of Michigan.

State of Michigan (Table 2)

Service Line	Subservice Line	2015 Volume	2020 Volume	2025 Volume	5 Yr Growth	10 Yr Growth
Cardiac Services	Cardiac Cath	17,858	16,006	16,320	-10.4%	-8.6%
Cardiac Services	Cardiac EP	6,503	5,936	6,023	-8.7%	-7.4%
Cardiac Services	Cardiac Surgery	9,972	9,362	9,327	-6.1%	-6.5%
	Medical					
Cardiac Services	Cardiology	93,393	79,995	79,500	-14.3%	-14.9%

Given the information provided above; cardiac catheterization services and open heart surgical services CON 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. By utilizing SCAI/ACC/AHA Expert Consensus Document: for Cardiac catheterization Laboratories and the American College of Surgeons (ACS) guidelines for standards in cardiac surgery; the CON committee can incorporate the most current recommendations for institutional and operator performance for both programs.

QUALITY

As health care shifts from volume to value it is imperative to incorporate specific quality indicators for both CCS and OHS programs. We believe 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.

- 1. Procedural Appropriateness
- 2. Door to Balloon (DTB)
- 3. Risk Adjusted 30 day Readmissions
- 4. Risk Adjusted 30 day Mortality
- 5. Discharge medication compliance

Open Heart Surgery programs annual quality reporting should include the following quality/performance indicators:

- 1. Internal Mammary Artery (IMA) Usage
- 2. Risk Adjusted 30 day readmissions
- 3. Risk adjusted 30 day mortality
- 4. Risk Adjusted complications
- 5. JCAHO's Surgical Care Improvement Project (SCIP's)
- 6. Overall STS STAR Rating

COST

Hospitals have always been concerned about quality, but with today's pressures, it makes it financially imperative to develop collaborative approaches that combine strong clinical outcomes with effective cost containment. Thus tracking wage severity adjusted cost and severity adjusted length of stay (LOS) is paramount.

PATIENT EXPERIENCE

Finally, patient experience, the last recommended component for consideration has been at the forefront of many governmental program roll-outs. Since the Affordable Care Act (ACA) became law in 2010, many healthcare leaders began to address the delivery of healthcare quality. As a result, "Triple Aim" was developed by the Institute of Healthcare improvement (IHI). The aim is to improve patient experience, improve patient outcomes while reducing cost. All three are interdependent. Not only was this concept birthed from the ACA, but it is now tied to reimbursement for both hospital and practitioner.

We appreciate this opportunity to comment and we hope that the CON committee will not only take into consideration the four components; volume, quality, cost and patient experience but additionally assign relative weights for each.

Sincerely,

Theodore Schreiber MD, FACC
President, DMC Heart Hospital
Specialist-in-Chief Cardiovascular Medicine
Professor of Medicine Wayne State University, SOM

From: Dennis Mccafferty <dmccafferty-eam@sbcglobal.net>

Sent: Wednesday, October 19, 2016 10:51 AM

To: MDHHS-ConWebTeam
Cc: bretjackson@eamonline.org

Subject:Public Comment for 2017 Work PlanAttachments:Public Comment 2017 Work Plan.doc

Attached are the Public Comments related to all six of the CON Standards up for review on the 2017 Work Plan from the business and labor members of the Economic Alliance for Michigan. If the Department wishes us to submit separate comments for each of the six standards up for review in 2017, please let us know.

Dennis McCafferty

Vice President Health Policy
The Economic Alliance for Michigan
41650 Gardenbrook Road, Suite 175
Novi, MI 48375
248.596.1006
Dennismccafferty@eamonline.org
www.eamonline.org



THE ECONOMIC ALLIANCE FOR MICHIGAN Public Comment on 2017 Work Plan Dennis McCafferty, EAM Vice President Health Policy

Following a review of the Public Comments related to the 2017 Annual Work Plan and the posted agenda, on behalf of our business and labor member, the Economic Alliance for Michigan wishes to make the following comments:

Cardiac Catheterization Services:

The last revision of these standards has enabled many more hospitals to perform elective angioplasties. Since this change, some facilities that were performing only emergency angioplasty have already begun to perform elective while others will be beginning soon. Our members would like to see publicly available reports on both the volume of elective and emergency angioplasty being performed at each facility and some objective, third-party assessment of quality of services being provided.

We ask that the Commission review how the CON Standards address both the community need for Cardiac Catheterization services and the quality of the services being provided.

Hospital Beds:

In the recently published (October 2016) Hospital Bed Inventory of the 33 Hospital Groups, there are over 9,000 excess licensed beds in the state of Michigan. This inventory of excess licensed beds should preclude the need for any additional CON approved in-patient beds for existing or new hospitals.

Our members are concerned that these CON Hospital Bed Standards are being circumvented by the growing trend of hospitals to add Out-patient Observational Beds, which are neither licensed nor regulated under CON. Our members tell us that hospitals are now regularly keeping their employees and dependents in these out-patient "observational beds" for 2 or more days. Because these out-patient Observational Beds are not licensed or covered under CON, there is no means to knowing how many there are at each hospital, in each of the 33 Hospital Groups or in the State. We have no way of knowing their occupancy rate, length of stay and how they impact the hospital's occupancy rate for the CON approved in-patient beds. Since the services provided in an out-patient Observation Bed would appear to the layman as identical to the services provided by a CON approved in-patient bed, the cost to build and operate an Observational Bed would seem to be identical to that of a CON approved in-patient bed. If the CON Hospital Bed Standards are intended to limit capacity to what is actually needed by a community, this growing number of unlicensed and unregulated Observation Beds have voided this CON safe-guard.

We suggest that the Commission consider the question of should these out-patient Observation Beds to be regulated in a fashion similar to the in-patient hospital beds.

We would further suggest that the Bed Standards could be improved by 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.

MRT Services/Units:

Our members are not aware of any changes in technology since the last time this CON standard was reviewed, that would warrant a revision of this Standard.

We would be most interested in hearing from the experts what may have change that could justify a revision in this Standard.

Open Heart Surgical Services

The last revision of these standards implemented both lower minimum volumes and quality standards. Our members have the following question:

- 1. 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?
- 2. 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?
- 3. 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?
- 4. 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?
- 5. 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?

We would suggest that the CON Commission direct the Department to report their respond to these questions prior to the January Planning meeting. Our members' recommendation to the Commission on these standards would depend upon the result of this report.

PET Scanner Services:

Our members are not aware of any changes in technology since the last time this CON standard was reviewed, that would warrant a revision of this Standard.

We would be most interested in hearing from the experts what may have change that could justify a revision in this Standard.

Surgical Services:

Our members are not aware of any changes in technology since the last time this CON standard was reviewed, that would warrant a revision of this Standard.

We would suggest that the Surgical 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 hospital.

From: Arlene Elliott <arlene@arbor-advisors.com>
Sent: Thursday, October 20, 2016 5:25 PM

To: MDHHS-ConWebTeam

Subject: Public Comment for Certificate of Need Review Standards

Attachments: CON Public Comment Letters October 2016 - Trinity Health Michigan.pdf

Good afternoon -

On behalf of Trinity Health Michigan, please accept the attached comment letters regarding the Certificate of Need Review Standards scheduled for review in 2017.

Thank you, Arlene

Arlene Elliott
Arbor Advisors, LLC

734-426-3196 (office) 734-277-3878 (cell) arlene@arbor-advisors.com Marc D. Keshishian, M.D., Chairperson Certificate of Need Commission Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building, 333 S. Grand Ave. Lansing, MI 48933

RE: Cardiac Catheterization Services

Dear Chairman Keshishian:

Trinity Health Michigan would like to thank the Certificate of Need ("CON") Commission for the opportunity to comment on what, if any, changes need to be made to existing Certificate of Need Standards.

Trinity Health Michigan supports the continued regulation of Cardiac Catheterization Services to assure Michigan's residents have adequate access to low cost, high quality Cardiac Catheterization. Trinity Health Michigan would like to encourage the CON Commission to establish a workgroup to review 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.

Trinity Health Michigan believes the revisions made to the Certificate of Need Standards for Cardiac Catheterization Services during its comprehensive review in 2014 and 2015 are responsive to other changes in professional guidelines and medical practice. As such, we believe only this one matter requires attention and we would be happy to support a workgroup to identify an appropriate requirement.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou

President and CEO, Saint Joseph Mercy Health System

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Roger Spoelman

Marc D. Keshishian, M.D., Chairperson Certificate of Need Commission Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building, 333 S. Grand Ave. Lansing, MI 48933

RE: Surgical Services

Dear Chairman Keshishian:

Trinity Health Michigan would like to thank the Certificate of Need ("CON") Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards.

Trinity Health Michigan believes the existing Certificate of Need Standards for Surgical Services assure Michigan's residents have access to low cost, high quality surgical resources. As such, Trinity Health Michigan supports the continued regulation of Surgical Services without any further modification to the existing Certificate of Need Standards.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou

President and CEO, Saint Joseph Mercy Health System

r (worker)

Roger Spoelman

Marc D. Keshishian, M.D., Chairperson Certificate of Need Commission Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building, 333 S. Grand Ave. Lansing, MI 48933

RE: Hospital Beds

Dear Chairman Keshishian:

Trinity Health Michigan would like to thank the Certificate of Need ("CON") Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards.

Trinity Health Michigan supports the continued regulation of Hospital Beds to assure Michigan's residents have adequate access to low cost, high quality acute inpatient care. Trinity Health Michigan believes the current bed need calculation methodology, revised under a comprehensive review in 2011, effectively ensures the Certificate of Need Standards for Hospital Beds are responsive to the changing Michigan environment as related to hospital beds. Trinity Health Michigan also believes the existing Certificate of Need Standards for Hospital Beds are effective in addressing issues of high occupancy, acquisition, relocation and replacement. As such, Trinity Health Michigan supports the continued regulation of Hospital Beds without any further modification to the existing Certificate of Need Standard.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou

President and CEO, Saint Joseph Mercy Health System

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Roger Spoelman

Marc D. Keshishian, M.D., Chairperson Certificate of Need Commission Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building, 333 S. Grand Ave. Lansing, MI 48933

RE: Megavoltage Radiation Therapy ("MRT") Services/Units

Dear Chairman Keshishian:

Trinity Health Michigan would like to thank the Certificate of Need ("CON") Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards.

Trinity Health Michigan believes the existing Certificate of Need Standards for Megavoltage Radiation Therapy (MRT) assure Michigan's residents have access to low cost, high quality Megavoltage Radiation Therapy. As such, Trinity Health Michigan supports the continued regulation of MRT without any further modifications to the existing Certificate of Need Standards.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou

President and CEO, Saint Joseph Mercy Health System

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Roger Spoelman

Marc D. Keshishian, M.D., Chairperson Certificate of Need Commission Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building, 333 S. Grand Ave. Lansing, MI 48933

RE: Open Heart Surgery ("OHS") Services

Dear Chairman Keshishian:

Trinity Health Michigan would like to thank the Certificate of Need ("CON") Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards.

Trinity Health Michigan supports the continued regulation of Open Heart Surgery Services. Trinity Health Michigan believes the existing Certificate of Need Standards for Open Heart Surgery, which underwent a thoughtful review and update in 2012 and 2013, effectively assure Michigan's residents have access to low cost, high quality providers of open heart surgical care. Trinity Health Michigan supports the continued regulation of Open Heart Surgery Services without any further modification to the existing Certificate of Need Standards.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou

President and CEO, Saint Joseph Mercy Health System

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Roger Spoelman

Marc D. Keshishian, M.D., Chairperson Certificate of Need Commission Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building, 333 S. Grand Ave. Lansing, MI 48933

RE: Positron Emission Tomography ("PET") Services

Dear Chairman Keshishian:

Trinity Health Michigan would like to thank the Certificate of Need ("CON") Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards.

Trinity Health Michigan believes the existing Certificate of Need Standards for Positron Emission Tomography (PET) Services assure Michigan's residents have access to low cost, high quality surgical resources. As such, Trinity Health Michigan supports the continued regulation of PET without any modification to the existing Certificate of Need Standards.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

Robert Casalou

President and CEO, Saint Joseph Mercy Health System

(worker 2

Roger Spoelman

From: Bressack, Barbara <BBRESSA1@hfhs.org>

Sent: Friday, October 21, 2016 3:05 PM

To: MDHHS-ConWebTeam

Subject: 2017 CON Review Public Comment Period 10/7 to 10/21

Attachments: Cardiac Cath CON Public Comments Oct 2016.pdf; Hospital Beds Public Comments Oct

2016.pdf; MRT Public Comments Oct 2016.pdf; OHS Public Comments Oct 2016.pdf

Please see the attached public comments from Henry Ford Health System.

Thanks, Barbara

Barbara Bressack
Director, Planning & CON Strategy
One Ford Place, 4A
Detroit, MI 48202
(313) 874-6665
Bbressa1@hfhs.org

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Henry Ford Health System One Ford Place - Suite 4A Detroit, MI 48202

October 20, 2016

Marc D. Keshishian, M.D. CON Commission Chairperson South Grand Building, 4th Floor 333 S. Grand Avenue Lansing MI 48933

Dear Commissioner Keshishian,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Cardiac Catheterization services:

In 2014 the last Cardiac Catheterization Standards Advisory Committee (SAC) recommended a number of changes to the Certificate of Need Standards for Cardiac Catheterization Services to allow for the performance of elective PCI at facilities that do not have Open Heart Surgery Services. As part of those recommendations the SAC added a requirement that, "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." (Sec. 10(5)(f)) It was our understanding that this provision was intended to apply to those facilities performing PCI without onsite open heart surgery. However, the way it was written into the Standards, the Department is applying this to all facilities with cardiac catheterization services with the exception of diagnostic-only cath labs. From a practical perspective this means that every time a facility replaces or adds a cardiac cath lab, they must demonstrate that they meet this requirement. The Department has offered the following options for demonstrating compliance:

- Accreditation through ACE or Corazon (\$25,000 \$45,000 initial investment plus additional fees to continue accreditation).
- Hire an expert or work with a cath lab director from an unrelated facility to evaluate your program and attest to the fact that it meets all requirements (must be done every 2 years, every time you replace/add a cath lab, or every time the guidelines change, whichever is longer)

Although we appreciate the need for the additional oversite on programs that do not offer open heart surgery on-site, we feel that this added burden on existing programs with open heart surgery is unnecessary and unintended by the SAC. We would request that the language be clarified to have this requirement only apply to facilities that do not have on-site open heart surgery.

Respectfully,

Barbara Bressack Henry Ford Health System Director, Planning & CON Strategy One Ford Place, 4A

Detroit, MI 48202

From: David.WalkerII@spectrumhealth.org
Sent: Wednesday, October 19, 2016 1:28 PM

To: MDHHS-ConWebTeam

Subject: Cardiac Catheterization Services Public Comment

Attachments: Spectrum Health Cardiac Catheterization Services Comment Letter.pdf

Please see attached letter.

David A. Walker Strategic Regulatory Senior Analyst Spectrum Health System Government Affairs | MC 065 100 Michigan Street NE Grand Rapids, MI 49503 phone 616.391.2043 cell 202.821.8217 fax 616.391.2092





October 19, 2016

Certificate of Need Commission
Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need (CON) Commission Chairman and Members,

Thank you for the opportunity to provide written comments on the need for continued CON regulation of Cardiac Catheterization Services.

Spectrum Health believes that maintaining CON regulation of Cardiac Catheterization Services will continue to serve the citizens of Michigan well. Spectrum Health would like to provide comment on two areas within the Standards.

First, the Centers for Medicare & Medicaid Services recently approved pacemakers and implantable cardioverter defibrillator (ICD) implants to be performed in Ambulatory Surgical Centers (ASC). Although Michigan CON Standards do allow for these procedures to be performed in an operating room, we do not believe it was ever the intention that they would be performed outside of an inpatient hospital setting. Therefore we would recommend the standards be updated to make it clear that these procedures must be performed within a licensed hospital. Moving them to ASCs will likely decrease quality and increase harm, from our perspective.

Second, the Standards have historically limited Cardiac Catheterization Services to hospitals only. However, it was recently discovered that the word "hospital" was inadvertently removed. Spectrum Health believes, for clarity purposes, that the word "hospital" should be included in the Standards.

We appreciate the Commission's consideration of our comments.

Sincerely,

Dr. Penny Wilton, MBA, MBBS, FANZCA, FRCA, FFICM

Department Chief, Cardiovascular Services

From: Szelag, Steven <sszelag@med.umich.edu>

Sent: Friday, October 21, 2016 3:59 PM

To: MDHHS-ConWebTeam

Subject: CON Public Comments for Covered Services up for Review in 2017

Attachments: UMHS_CC_CON_Commission_Letter_21Oct2016.pdf

Good afternoon,

Attached are the public comments for the following CON Covered Service up for review in 2017:

Cardiac Catheterization

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

Steven E. Szelag, MHA
Strategic Planner
Office of the Senior Vice-President and Chief Operating Officer
University of Michigan Health System
300 N. Ingalls, 4A 11-3
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October 21, 2016

Marc Keshishian, M.D. - CON Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Cardiac Catheterization - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Cardiac Catheterization. The University of Michigan Health System (UMHS) supports the overall regulations for this service; however, UMHS would like the CON Commission to provide clarification and consider a technical revision(s), if recommended, to Section 10: Project delivery requirements and terms of approval for all applicants.

Section 10(5) requires: "Compliance with the following primary and elective PCI requirements for hospitals providing therapeutic cardiac catheterization services, primary PCI services <u>without</u> on-site OHS service, or elective PCI services without on-site OHS service, if applicable:"

Section 10(5)(f) requires: "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."

UMHS recently received CON approval to replace one of its Electro-physiology (EP) laboratories. The final decision letter included the following condition:

The applicant shall provide to the Department within six (6) months of implementation of this CON (i.e., performance of the first procedure) documentation that the applicant complies with Section 10(5)(f) of the CON Review Standards for Cardiac Catheterization Services, effective September 14, 2015. Specifically, the applicant's 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. Credible documentation includes:

- a. Accreditation by Accreditation for Cardiovascular Excellence (ACE) or Corazon, Inc.; or
- b. A signed and certified itemized report from a hospital-selected independent professional consultant attesting to the hospital's compliance with Section 10(5)(f).

Is it the intent of this section to require all applicants, including those with on-site OHS service, to meet this condition for replacing an EP Lab under the CON Standards for Cardiac Catheterization?

Our perspective is that the replacement of an EP Lab would not be applicable to the condition listed above. The SCAI/ACC/AHA Expert Consensus Document does not relate to EP Labs and is specifically focused on Cardiac Catheterization Labs providing coronary angiography and interventional procedures. UMHS recommends that the CON Commission form a Workgroup to further study this matter and revise the condition for approval.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

I Son Tank

T. Anthony Denton

Senior Vice President and Chief Operating Officer

Chief, Division of Cardiovascular Medicine

From: Bressack, Barbara <BBRESSA1@hfhs.org>

Sent: Friday, October 21, 2016 3:05 PM

To: MDHHS-ConWebTeam

Subject: 2017 CON Review Public Comment Period 10/7 to 10/21

Attachments: Cardiac Cath CON Public Comments Oct 2016.pdf; Hospital Beds Public Comments Oct

2016.pdf; MRT Public Comments Oct 2016.pdf; OHS Public Comments Oct 2016.pdf

Please see the attached public comments from Henry Ford Health System.

Thanks, Barbara

Barbara Bressack
Director, Planning & CON Strategy
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Henry Ford Health System One Ford Place – Suite 4A Detroit, MI 48202

October 20, 2016

Marc D. Keshishian, M.D. CON Commission Chairperson South Grand Building, 4th Floor 333 S. Grand Avenue Lansing MI 48933

Dear Commissioner Keshishian,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Hospital Beds:

Henry Ford Health System (HFHS) supports the continued regulation of Hospital Beds. HFHS does not have any proposed changes to the standards as written, at this time.

Respectfully,

Barbara Bressack

Henry Ford Health System

Director, Planning & CON Strategy

One Ford Place, 4A

Detroit, MI 48202

From: Szelag, Steven <sszelag@med.umich.edu>

Sent: Friday, October 21, 2016 2:09 PM

To: MDHHS-ConWebTeam

Subject: CON Public Comments for Covered Services up for Review in 2017

Attachments: UMHS_MRT_CON_Commission_Letter_21Oct2016.pdf;

UMHS_HB_CON_Commission_Letter_21Oct2016.pdf; UMHS_PET_CON_Commission_Letter_21Oct2016.pdf

Good afternoon,

Attached are the public comments for the following CON Covered Services up for review in 2017:

Megavoltage Radiation Therapy

Hospital Beds

Positron Emission Tomography

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

Steven E. Szelag, MHA
Strategic Planner
Office of the Senior Vice-President and Chief Operating Officer
University of Michigan Health System
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October 21, 2016

Marc Keshishian, M.D. - CON Commission Chairperson Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building 333 S. Grand Ave. Lansing, MI 48933

RE: Hospital Beds- Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Hospital Beds. The University of Michigan Health System (UMHS) supports the overall regulations for this service; however, UMHS would like the CON Commission to consider a technical change to Section 6: Requirements for approval – new beds in a hospital.

Section 6(4) (f) requires: "Applicants proposing to add new beds under this section [High Occupancy] shall demonstrate to the Department that they have pursued a good faith effort to relocate unused inpatient bed licenses from other acute care hospitals within the Health Service Area (HSA). At the time an application is submitted to the Department, the applicant shall demonstrate that contact was made by (providing) one certified mail return receipt for each organization contacted."

Our perspective is that "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. UMHS recommends that this subsection (f) of Section 6 (4) be removed from the CON Standards.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton

Senior Vice President and Chief Operating Officer

From: Bressack, Barbara <BBRESSA1@hfhs.org>

Sent: Friday, October 21, 2016 3:05 PM

To: MDHHS-ConWebTeam

Subject: 2017 CON Review Public Comment Period 10/7 to 10/21

Attachments: Cardiac Cath CON Public Comments Oct 2016.pdf; Hospital Beds Public Comments Oct

2016.pdf; MRT Public Comments Oct 2016.pdf; OHS Public Comments Oct 2016.pdf

Please see the attached public comments from Henry Ford Health System.

Thanks, Barbara

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Henry Ford Health System One Ford Place – Suite 4A Detroit, MI 48202

October 21, 2016

Marc D. Keshishian, M.D. CON Commission Chairperson South Grand Building, 4th Floor 333 S. Grand Avenue Lansing MI 48933

Dear Commissioner Keshishian,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need standards for MRT services:

Henry Ford Health System (HFHS) strongly supports the continued regulation of MRT services and proposes the following change:

• Requiring that any MRT service have at least one Board Certified dosimetrist. The current standards, Section 11(2)iii, requires a dosimetrist, but does not specify board certification for this member of the radiation oncology team.

Respectfully,

Spencer Hoover

Spencer Hoover

Henry Ford Health System

VP, Planning & Business Development

One Ford Place, 4A

Detroit, MI 48202

Rogers, Brenda (DHHS)

From: David.WalkerII@spectrumhealth.org
Sent: Wednesday, October 19, 2016 1:28 PM

To: MDHHS-ConWebTeam

Subject:Megavoltage Radiation Therapy (MRT) Services/Units Public CommentAttachments:Spectrum Health Megavoltage Radiation Therapy Comment Letter.pdf

Please see attached letter.

David A. Walker Strategic Regulatory Senior Analyst Spectrum Health System Government Affairs | MC 065 100 Michigan Street NE Grand Rapids, MI 49503 phone 616.391.2043 cell 202.821.8217 fax 616.391.2092



SPECTRUM HEALTH
Cancer Center | MC 120
145 Michigan St. NE Suite 5120
Grand Rapids, MI 49503

October 18, 2016

Certificate of Need Commission Michigan Department of Health and Human Services Certificate of Need Policy Section South Grand Building 333 S. Grand Avenue Lansing, MI 48933

Dear Certificate of Need (CON) Commission Chairman and Members,

Thank you for the opportunity to provide comments on the need for continued CON regulation of Megavoltage Radiation Therapy (MRT) Services/Units.

Spectrum Health believes that maintaining CON regulation of MRT Services/Units will continue to serve the citizens of Michigan well. We do not believe there is any need to make changes to the standards that are currently in effect.

We appreciate your consideration of our comments.

Sincerely,

Judy L. Smith MD MS CPE FACS

Chief of Oncology

Spectrum Health Cancer Center

Angela Ditmar, MBA, BSA, RN Vice President Operations

angele Dehn

Spectrum Health Cancer Center

From: Szelag, Steven <sszelag@med.umich.edu>

Sent: Friday, October 21, 2016 2:09 PM

To: MDHHS-ConWebTeam

Subject: CON Public Comments for Covered Services up for Review in 2017

Attachments: UMHS_MRT_CON_Commission_Letter_21Oct2016.pdf;

UMHS_HB_CON_Commission_Letter_21Oct2016.pdf; UMHS_PET_CON_Commission_Letter_21Oct2016.pdf

Good afternoon,

Attached are the public comments for the following CON Covered Services up for review in 2017:

Megavoltage Radiation Therapy

Hospital Beds

Positron Emission Tomography

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

Steven E. Szelag, MHA
Strategic Planner
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October 21, 2016

Marc Keshishian, M.D. - CON Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Megavoltage Radiation Therapy - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Megavoltage Radiation Therapy (MRT). The University of Michigan Health System (UMHS) supports the overall regulations for this service; however, our suggestion is that Section 3(4) needs to 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.

Section 3(4): "Initiate an MRT Service with a High MRT (HMRT) Unit", requires "the applicant to file a CON as a *collaborative*, consisting of at least 40% of all Michigan-based hospital MRT services with more than 30,000 Equivalent Treatment Visits (ETV) as reflected in the most current data available to the Department". Based on the 2014 Michigan CON Annual Survey data, five services in Michigan meet this definition: Genesys Hurley Cancer Institute, Karmanos Cancer Center, Lemmen Holton Cancer Pavilion, UMHS and William Beaumont Hospital – Royal Oak.

William Beaumont Hospital – Royal Oak¹ and Karmanos Cancer Center's parent company McLaren Health Care² received HMRT CON approval in July and August 2008, respectively, for single-provider proton therapy services prior to these specific "collaborative" CON Standards going into effect in November, 2008. As of the date of this letter, both of these providers are still working to activate their HMRT units.

Given concerns regarding cost, quality and access when Section 3 (4) was first initiated, requiring qualified providers to form a collaborative and work together in singular fashion was an important

and innovative approach to balance the provision of proton therapy with population size, need and cost.

The Particle Therapy Institute of Michigan (PTIM), was officially formed as a collaborative in September, 2008, consisting of Ascension, Henry Ford Health System, Karmanos Cancer Center, McLaren Health Care, St. Joseph Mercy and UMHS. McLaren Health Care and St. Joseph Mercy dropped out of the collaborative soon after the formation of PTIM. After numerous due diligence meetings over the course of several years a CON application was never filed under the CON Standards contained within Section 3(4). PTIM was officially dissolved in September, 2016.

The "collaborative" methodology to attain CON approval for HMRT was progressive and well thought out; however, it appears that the original intentions have not led to the practical aims as first envisioned, including creating this technological capacity to serve cancer patients who could benefit directly by having greater access to the technology in a State where there is significant provider consolidation and systems of care. We suggest that if the CON approval path to entry were more flexible, particle therapy services might become more readily available through individual organizational investment as costs have come down over time.

Cost containment was one of the primary drivers for the development of CON Standards, an important basis for requiring a collaborative for HMRT. Proton Therapy, a heavy particle accelerator covered under the definition of HMRT, requires a substantial capital investment. However, the costs for proton therapy facilities have been reduced over time, as more cost-effective alternatives have been introduced into the marketplace. In a 2009 article published in *The National Association for Proton Therapy*, the author talks about the \$144 million radiation therapy center being constructed at the University of Pennsylvania and describes it as the most complex and expensive medical machinery every built³. In dramatic contrast, there was a 2015 article published in *The Wall Street Journal*, and that author talks about compact proton systems costing between \$25 million and \$30 million⁴, a clear shift to make the technology more cost-effective. To further reinforce this point, the project costs contained in both Beaumont's and McLaren's CON applications were amended down suggesting that the investment associated with this type of therapy modality has been reduced with the introduction of lower cost alternatives. Based on the amended project budgets of both CON applications, the cost of the Proton Therapy facilities in each was reduced by over \$100 million.

Quality and Safety goals are quite important as well. The National Association for Proton Therapy states that this therapy modality is the highest precision therapy for radiation treatment in use today. It delivers a higher effective radiation dose to the tumor site while sparing healthy tissues and organs when compared to other types of radiation therapy. This type of therapy also reduces the side effects of radiation treatment, particularly secondary cancers in pediatric populations ⁵. Occurrence of treatment-related tissue damage and other side effects is reduced because of the precision of dose

delivery and the resulting limited amount of radiation delivered to healthy tissues adjacent to the tumor site⁶. M.D. Anderson Cancer Center indicates Proton Therapy appears to be a promising treatment for certain types of tumors where precision is of utmost importance⁷. Such tumors may include, but are not limited to: Brain, Head & Neck, Liver, Lung, Ocular and Pediatric.

Access to proton therapy is a challenge for the citizens of Michigan. Currently there is no access to proton therapy in the State of Michigan, requiring patients who need this treatment to travel out-of-state. Today, due to market consolidation, provider realignment and lower ETV numbers; the number of MRT services qualified to form a collaborative is half of what it was nine years ago. As previously stated there was an unsuccessful attempt to form a HMRT collaborative and it is unlikely a second attempt would yield any different results. Access to this life-changing therapy is being impeded by CON Standards that are not applicable to today's health care environment.

Speaking as the statewide leader in adult and pediatric cancer treatment⁸, UMHS urges the CON Commission to form a Workgroup or Standards Advisory Committee to develop new CON Standards for the Initiation of an MRT Service with a HMRT Unit.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

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T. Anthony Denton

Senior Vice President and Chief Operating Officer

Theodore S. Lawrence

Produce of Livery

Isadore Lampe Professor of Radiation Oncology

Chair, Department of Radiation Oncology

References

- 1. CON 08-0072, Add 1 MRT Unit for Proton Beam Therapy: Effective Date: 07/10/2008
- 2. CON 08-0089, Add 1 MRT Unit for Proton Beam Therapy: Effective Date: 08/11/2008
- 3. The National Association for Proton Therapy: The \$150 Million Zapper, David Whelan and Robert Lagerth: originally published in Forbes Magazine: March 16, 2009
- 4. The Wall Street Journal: Big Bets on Proton Therapy Face Uncertain Future, Melinda Beck: May 26, 2015
- 5. The National Association for Proton Therapy: Proton Therapy Fact Sheet, 2007 www.proton-therapy.org/facts.htm
- 6. The University of Texas M.D. Anderson Cancer Center: Clinical Benefits, 2008 www.mdanderson.org/care_centers/radiationonco/ptc/
- 7. The University of Texas M.D. Anderson Cancer Center: Clinical Benefits, 2008 www.mdanderson.org/care_centers/radiationonco/ptc/
- 8. US News & World Report 2016 Best Hospitals Rankings: http://health.usnews.com/best-hospitals/rankings/cancer

From: Bressack, Barbara <BBRESSA1@hfhs.org>

Sent: Friday, October 21, 2016 3:05 PM

To: MDHHS-ConWebTeam

Subject: 2017 CON Review Public Comment Period 10/7 to 10/21

Attachments: Cardiac Cath CON Public Comments Oct 2016.pdf; Hospital Beds Public Comments Oct

2016.pdf; MRT Public Comments Oct 2016.pdf; OHS Public Comments Oct 2016.pdf

Please see the attached public comments from Henry Ford Health System.

Thanks, Barbara

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Henry Ford Health System One Ford Place – Suite 4A Detroit, MI 48202

October 20, 2016

Marc D. Keshishian, M.D. CON Commission Chairperson South Grand Building, 4th Floor 333 S. Grand Avenue Lansing MI 48933

Dear Commissioner Keshishian,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Open Heart Surgery services:

Henry Ford Health System (HFHS) supports the continued regulation of Open Heart Surgery (OHS) and we do not believe there are any necessary changes to the standards as they are currently written.

Respectfully,

Barbara Bressack

Henry Ford Health System

Director, Planning & CON Strategy

One Ford Place, 4A

Detroit, MI 48202

From: Szelag, Steven <sszelag@med.umich.edu>

Sent: Friday, October 21, 2016 2:09 PM

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Subject: CON Public Comments for Covered Services up for Review in 2017

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Good afternoon,

Attached are the public comments for the following CON Covered Services up for review in 2017:

Megavoltage Radiation Therapy

Hospital Beds

Positron Emission Tomography

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

Steven E. Szelag, MHA
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October 21, 2016

Marc Keshishian, M.D. - CON Commission Chairperson Department of Health and Human Services - Certificate of Need Policy Section 5th Floor South Grand Building 333 S. Grand Ave. Lansing, MI 48933

RE: Positron Emission Tomography - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Positron Emission Tomography. The University of Michigan Health System (UMHS) supports the overall regulations for this service. At this time UMHS has not identified any potential issues with the current CON Standards and recommends that they not be opened during this review cycle.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

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T. Anthony Denton

Senior Vice President and Chief Operating Officer