**From:** Gehle, Sean <sean.gehle@ascension.org>
**Sent:** Friday, October 20, 2017 2:28 PM
**To:** MDHHS-ConWebTeam
**Subject:** Public Comment on behalf of Ascension Michigan - 2017 CON Standards eligible for reivew



To whom it may concern:
On behalf of Ascension Michigan please find comments on 2017 CON Standards eligible for review: Bone Marrow Transplant services, MRI Services, Psych Beds and Services and Heart, Lung, Liver Transplantation Services.

**BMT Services – no comments**

**Heart, Lung, Liver Transplantation Services- no comments**

**MRI Services** – Ascension Michigan supports continued regulation and has no recommendations for modifications

**Psych Beds and Services** – Add Nurse Practitioners and Physician Assistants to definition section individually and include as part of "Mental Health Professional" and in Project Delivery Requirements; Determine if "developmentally disabled", "geriatric Psych", and "medical Psych" need to be called out separately in the definitions section (2) (j) "Department inventory of beds"

**MRT** – Ascension Michigan recognizes that MRT Standards are not on the list of standards eligible for review in 2017 however we recommend these standards be opened out of order (before next scheduled review in 2020). The justification we would utilize for this is that the state's compliance review highlighted that changes in practice patterns and changes in how Radiation Therapy is being delivered, warrants reviewing these standards "out of turn" specifically to revisit the procedure weighting factors and the minimum volume requirements in light of the changing practice patterns across the state. All of the following are specific practice/treatment changes that technology and protocols have brought about that have affected volume in the recent past and will continue in the future: SRS brain treatment is 1-3 fractions for a course of treatment compared to 10 treatments with conventional RT, SBRT lung and other body site treatments are 3-5 fractions for a treatment course compared to 30-35 treatments with conventional RT, some breast protocols consist of 3-4 weeks of external beam treatment (15-20 treatments) compared to the traditional 30 treatments, Mammosite breast treatments are generally 10 treatments (2 treatments daily for 5 days) compared to 30 external beam treatments. These are also done on the HDR unit and because they area considered 'brachytherapy" they are not counted by the State on their annual CON report, higher daily dose for some palliative sites like bone mets are done in fewer treatments so instead of 10 treatments, the patient may get 1-5 treatments, for patients that are receiving combined external beam and brachytherapy instead of 40-43 external beam treatments, they are getting an implant with 10-25 external beam treatments, brachytherapy treatment is not counted by the state.

Thank you for the opportunity to provide these comments. Please do not hesitate to contact me if you have questions and/or concerns.

Sean Gehle
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**THE ECONOMIC ALLIANCE FOR MICHIGAN**
**Public Comment on 2018 Work Plan**
**Dennis McCafferty, EAM Vice President Health Policy**

Following a review of the Public Comments related to the 2018 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:

**Bone Marrow Transplantation (BMT) Services:**

Again, the question before the Commission is, the needs of the citizens of Michigan for additional access to BMT services vs. the CON Standard's CAP of three adult BMT programs in Southeast Michigan. On the one hand, it can be said that the CON Standard's CAP of three programs is arbitrary, on the other hand, the justification for additional BMT programs in Michigan, given the following, does not seem to be supportable:

- Annual volumes for Autologous procedures over the last 4 years, has been decreasing slightly and the volume for the Allogenic procedures has, except for 2015, been consistent. (see attached 6-year volume summary)
- There is a national shortage of trained BMT professionals and dedicated BMT support staff. Allowing additional BMT programs in Michigan will likely result in greater competition for this limited resource, which would further inflate the cost of providing there services.
- There is a need to maintain minimum annual volumes at the existing BMT programs to ensure staff competencies and to maintain high quality outcomes.

EAM member organizations are not convinced that allowing additional BMT programs in the near suburbs of Detroit would result in improved access and increased utilizations of this service. Our members are also concerned that additional BMT programs that focus primarily on Autologous procedures, would drain the support staff and financial resources of existing BMT programs, resulting in jeopardizing the existing high levels of staff competencies and the high quality and we currently enjoy.

**Heart/Lung & Liver Transplantation Services:**

The issue limiting the number of Heart/Lund and Liver transplants performed at Michigan hospitals is the number of compatible organs that are available for transplanting. The number of these transplants performed annually is not likely to increase if additional Michigan hospitals were granted a CON for these services. While this CON Standard also has a CAP of three Heart/Lung and three Liver programs in Southeast Michigan and a CAP of one Heart/Lung transplant program in west Michigan, we are unaware of any hospitals seeking to change this Standard. The justification for any additional Heart/Lung and Liver Transplantation Services does not seem supportable, given the following:

- While the annual volume of Health/Lung transplants performed is limited by the number of compatible organs available, the newest program in west Michigan, Spectrum, was able to capture additional patients who would have otherwise had this procedure performed out-of-state. Any additional Heart/Lung or Liver transplant programs would pull most of their volume from the existing Michigan Heart/Lung and Liver transplant programs. (see attached 6-year volume summary)
- The high cost of establishing a new Heart/Lung or Liver Transplant program and the national shortage to trained professionals and staff to perform these services, would seem to make any programs cost prohibitive.
- There is a need to maintain minimum annual volumes at the existing organ transplant programs to ensure staff competencies and to maintain high quality outcomes.

EAM member organizations are not convinced that allowing additional Heart/Lung or Liver Transplant programs in Michigan would result in improved access, increased utilization, lowering the cost or improving the quality of these services for the citizens of Michigan.

**MRI 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.

**Psychiatric Bed and Services:**

The issues that negatively impact the patient access to Psychiatric Bed and Services in Michigan would seem to beyond the scope of the Michigan CON Standards. Patient's timely access to inpatient psychiatric services is a problem but would seem to be more related to:

- The state-wide shortage of psychiatrists needed to admit a patient
- The ability to find a hospital that has psychiatric beds available to meet the needs of a patient that has both a medical and psychiatric diagnosis.
- The ability to find a hospital that has psychiatric bed available that can accept a patient that is potentially abusive or a threat to themselves.
- The ability to find a hospital that has psychiatric bed available to accept a patient based upon the patient's gender.
- The ability to find a hospital that has psychiatric bed available to accept a patient based upon the patient being a minor.

In recent years, the CON Standard for Psychiatric Bed and Service were revised to allow greater flexibility for hospitals to switch between licensed Adult and Pediatric Beds. However, the above issue are currently beyond the scope of the CON regulations.

The Commission has also endorsed the need for legislation to establish a state-wide, on-line directory of available psychiatric beds in an effort to help emergency departments find suitable available beds. The Commission has also encouraged legislation to provide greater incentives for keeping psychiatrist in Michigan. Other than these proposals, EAM member organizations would be interested in identifying other potential solutions to this problem of Michigan's patient's ability to access psychiatric beds and services.

| BMT Autogous | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|
| | | | | | | |
| University of Michigan | 159 | 127 | 157 | 149 | 115 | 124 |
| Children's | 3 | 10 | 4 | 5 | 4 | 10 |
| Henry Ford | 27 | 27 | 47 | 50 | 50 | 44 |
| Karmanos | 167 | 173 | 176 | 162 | 165 | 169 |
| Spectrum | 5 | 11 | 30 | 44 | 67 | 52 |
| | | | | | | |
| Total | 361 | 348 | 414 | 410 | 401 | 399 |
| | | | | | | |
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| **BMT Allogenic** | | | | | | |
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| University of Michigan | 101 | 119 | 116 | 104 | 122 | 87 |
| Children's | 3 | 9 | 6 | 17 | 9 | 9 |
| Henry Ford | 21 | 26 | 22 | 27 | 39 | 34 |
| Karmanos | 123 | 119 | 94 | 115 | 109 | 115 |
| Spectrum | 10 | 8 | 16 | 33 | 44 | 47 |
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| Total | 258 | 281 | 254 | 296 | 323 | 292 |
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| Sumarized by EAM | | | | | | |
| From CON Survey Report 120 | | | | | | |
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| Heart Transplants | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 |
|---|---|---|---|---|---|---|
| University of Michigan | 33 | 43 | 39 | 35 | 34 | 32 |
| Children's | 3 | 0 | 0 | 1 | 4 | 7 |
| Henry Ford | 9 | 7 | 14 | 16 | 18 | 23 |
| Spectrum | 13 | 9 | 9 | 12 | 13 | 20 |
| | | | | | | |
| Total | **58** | **59** | **62** | **64** | **69** | **82** |
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| **Lung Transplants** | | | | | | |
| University of Michigan | 22 | 23 | 44 | 28 | 36 | 36 |
| Children's | 0 | 0 | 0 | 0 | 0 | 0 |
| Henry Ford | 8 | 14 | 13 | 16 | 26 | 19 |
| Spectrum | 0 | 0 | 13 | 11 | 15 | 22 |
| | | | | | | |
| Total | **30** | **37** | **70** | **55** | **77** | **77** |
| | | | | | | |
| | | | | | | |
| **Liver Transplants** | | | | | | |
| Beaumont-Royal Oak | 16 | 16 | 16 | 16 | 13 | 14 |
| University of Michigan | 78 | 69 | 71 | 77 | 66 | 63 |
| Children's | 0 | 0 | 0 | 2 | 2 | 3 |
| Henry Ford | 91 | 94 | 88 | 82 | 95 | 112 |
| | | | | | | |
| Total | **185** | **179** | **175** | **177** | **176** | **192** |
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| | | | | | | |
| **Pancreas Tranplants** | | | | | | |
| University of Michigan | 13 | 18 | 15 | 12 | 11 | 2 |
| Henry Ford | 5 | 7 | 9 | 6 | 5 | 8 |
| St. John | 1 | 1 | 0 | 0 | 0 | 0 |
| | | | | | | |
| Total | **19** | **26** | **24** | **18** | **16** | **10** |
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| From CON Survey, Report 120 | | | | | | |

# Beaumont

Beaumont Hospital, Royal Oak
3601 West 13 Mile Road
Royal Oak, MI 48073

October 20, 2017

Certificate of Need Commission
c/o 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 Commission:

Thank you for the opportunity to provide comment on the C.O.N. Review Standards for Bone Marrow Transplantation (BMT) Services that are scheduled for their 3-year review in 2018.

On behalf of Beaumont Health and the 1.4 million patients we serve through our eight hospitals, 35,000 employees and 5,000 physicians, we recommend that BMT services be de-regulated for the following reasons:

- The current standards place a cap on the number of BMT services allowed in the State, without a need methodology or any data to support a cap

- The Division of Policy, Planning and Legislative Services of the Michigan Department of Health and Human Services has repeatedly recommended de-regulation for many years; the rationale being that sufficient regulations are already in place to assure quality and access- and that further regulation under C.O.N. is unnecessary given the experience in other states.

- Also at the Commission's request, the Department developed revised BMT Review Standards that removed the cap and established additional quality related requirements that would have limited the number of new programs that could be approved. After opposition from existing BMT providers, the Commission took no action and left the cap in place.

Given that only seven states regulate BMT at all, and none of them have a cap, we recommend de-regulation of BMT services in Michigan as there is no demonstrated benefit in doing so from a cost, quality or access standpoint. De-regulation will not result in a significant number of new programs in Michigan, but will increase access for patients in need of BMT. Patients will benefit from increased access because studies show that BMT as a cancer treatment is significantly underutilized.

Sincerely,

Carolyn Wilson

Carolyn Wilson, RN, MBA
Executive Vice President & Chief Operating Officer
Beaumont Health

Henry Ford Health System
One Ford Place
Detroit, MI 48202

October 17, 2017

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

Dear Commissioner Mukherji:

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

Henry Ford Health System (HFHS) supports the continued regulation of Bone Marrow Transplant (BMT). In light of the very recent (March 2017) CON Commission vote to retain the existing methodology within the BMT standards, we do not believe there is cause to revisit these standards again in 2018. The actions leading up to the March 2017 vote were thorough involving an external expert and a Standard Advisory Committee that all pointed to the complexity of revising the BMT standards and that in the end the existing standards are effectively working to control costs, quality and access throughout the state.

**Cost**: Adding a new BMT program is expensive and puts existing programs at risk.

**Quality**: Each program offers high quality care based on all current programs meeting or exceeding the CIMBTR expected outcomes. Spreading a low volume service over more programs could compromise quality.

**Access**: The existing BMT programs throughout Michigan all have capacity to see more patients and there are programs on both the east and west sides of the state providing geographical access. Studies have proven that Michigan has as good or better access than most states.
While other health systems have expressed a desire to have a BMT program, there is no evidence that there is an unmet need in Michigan. This demonstrates the standards, as written, are effectively achieving CON's intention of a balance of cost, quality and access and ensuring only needed services and facilities are developed throughout Michigan.

Respectfully,

Robert G. Riney
President, Healthcare Operations
Chief Operating Officer

Steven N. Kalkanis, M.D.
Professor and Chairman, Depart. Of Neurosurgery
Mark L. Rosenblum Endowed chair in Neurosurgery
Medical Director – Henry Ford Cancer Institute

BARBARA ANN
Karmanos
CANCER INSTITUTE
Wayne State University

October 20, 2017

Suresh Mukherji, MD, MBA
Certificate of Need Commission Chair
Department of Health and Human Services
Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

**RE: Bone Marrow Transplantation Services - Certificate of Need Standards Review**

Dear Dr. Mukherji:

Karmanos Cancer Institute (Karmanos) is an integrated center of research, patient care and education, dedicated to the prevention, early detection, treatment and eventual eradication of cancer. An integral component of cancer research and treatment is Bone Marrow Transplantation (BMT) Services. As one of two nationally designated cancer institutes in the State of Michigan Karmanos has long advocated for the highest quality BMT Standards through the Certificate of Need (CON) process.
Karmanos supports the continued regulation of BMT to ensure these high quality and patient safety standards, and further recommends a workgroup be formed to specifically address an emerging therapy approved by the Food and Drug Administration (FDA) on August 30, 2017.
Kymriah® (tisagenleuleucel) is now approved for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults. The commercialization of Kymriah® in childhood ALL is the first of multiple cell therapy trials the FDA will be reviewing in the upcoming decade, for both pediatric and adult disorders. Kymriah® represents a new classification of blood products, termed "chimeric antigen receptor T-cells (CAR-T). As a result, Karmanos is asking the CON Commission to amend the regulations defining BMT services to incorporate infusion of cell therapy products, including CAR-T cells.

**Existing BMT CON standards (Section 2) state:** *"BMT service means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source."*

**We propose amending the BMT CON standards to read: "***BMT service means the transplantation of proliferating hematopoietic cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source." (Modification: Deletion of the term "stem", while maintaining the terms "proliferating hematopoietic cells").*

**Background:** Our proposal takes into account recent changes in the practice of bone marrow transplantation, including:

1. The focus of BMT is changing from delivery of proliferating hematopoietic stem cells to a platform for cellular immunotherapy, tumor vaccine strategies, and tissue engineering. BMT CON standards will require modification to account for this change in clinical practice. Each of these cell therapy products are derived from blood cells and have proliferative potential.

2. Administration of cell therapy products have historically been managed by transplant programs, both locally and nationally.

3. In November 2016, the Center for Medicare and Medicaid Services (CMS) established a common billing code for both Hematopoietic Cell Transplant and Cellular Therapy (HCTCT) services (*CMS MLN Matters MM957).*

**What constitutes hematopoietic cellular therapy:** The Foundation for Accreditation of Cellular Therapy (FACT), the oversight body for BMT services, defines cellular therapy as: *"any protocol that modulates an immune response for therapeutic intent, such as dendritic cells, natural killer cells, T cells, or B cells. This includes, but is not limited to, genetically engineered chimeric antigen receptor T cells (CAR-T cells) and therapeutic vaccines."*

- ***Specifically, what are CAR-T cells?*** CAR-T cells are proliferating hematopoietic cells that are derived from T-cells in the blood and/or bone marrow. T-cells are critical for our immune system, serving as the primary cell that recognizes "self from non-self". T-cells spend much of their life-span seeking out viruses or bacteria that have entered our body, in order to 'jump start" our immune system to attack that pathogen. CAR-T cells are a sub-group of T-cells that have been genetically modified for one purpose, to target a patient's own tumor. In essence, CAR-T cells are trained assassins, trained to target a protein on the outer surface of a patient's tumor. CAR-T represents a major advance from chemotherapy, as chemotherapy attacks any cell (good or bad) that is actively growing at the time of administration (i.e. why your hair falls out with chemotherapy).

- ***How are CAR-T cells made:*** To create CAR-T cells, a patient must initially undergo a process called apheresis, in which an aliquot (~1%) of a patient's own T-cells are removed from the body through a special intravenous (IV) catheter. A one-month manufacturing process to insert a specified gene into the T-cells is performed in a specialized laboratory, coupled with the expansion / proliferation of the T-cells to increase their numbers. The final CAR-T product is administered as an IV infusion to patients.

- ***Are CAR-T cells specific for childhood leukemia?*** No, they can be created to attack any tumor in which a specified protein (termed antigen) is located on the outer surface of that tumor. Over the next 5 years, the FDA will be reviewing CAR-T protocols for the treatment of multiple myeloma, lymphomas, and a variety of other malignancies in children and adults.

- ***Does CAR-T have proliferative potential, thus meeting the CON's definition?*** CAR-T cells are blood (hematopoietic) derived cells with the potential to proliferate. Like hematopoietic stem cells, CAR-T cells can be expanded (proliferate) to increase their numbers. CAR-T cells are expanded in culture before they are infused into the patient. In addition, they expand and proliferate after infusion into the patient. They may be found in the patient's blood for at least 6 months after the initial infusion.

- ***What are the risks could potentially be associated with CAR-T therapy?*** There are several theoretical risks.

Theoretical risk #1: For CAR-T therapy to work effectively, every tumor cell in a particular patient should possess that target protein. For example, if only 90% of a patient's tumor cells had the protein, the CAR-T will only attack that 90%. The remaining 10% tumor cells would escape detection by CAR-T therapy. Patients would ultimately relapse, from growth of tumor cells missing that protein.

Theoretical risk #2: What if the protein being targeted (by CAR-T cells) were also located on healthy, normal cells? This could have disastrous (even lethal) consequences for a patient, with the CAR-T cells potentially destroying normal cells.

Theoretical risk #3: The gene insertion process must be exact, with the CAR-T genes required to be inserted into the correct place in the T-cell genome. If not, there could be a multitude of negative effects, including the potential development of secondary cancers.

- ***What clinical risks do patients with CAR-T therapy have?*** Over 60 patients with CAR-T therapy were treated on the FDA licensing study in childhood ALL. Eighty-one percent developed a serious complication termed cytokine release syndrome (CRS), associated with high spiking fevers, shakes, chills, rigors, fluid leakage, blood pressure changes and often severe organ failure, the CRS developing within 3 days (median) of CAR-T infusion and lasting up to 4-8 weeks. Neurologic events, including seizures were common, noted in 31% of patients on this trial. Some patients require mechanical ventilation as well as renal dialysis.

- **Collectively, both the theoretical and clinical risks of CAR-T therapy point out the specialty nature of the process, and the required need for oversight by a dedicated team (physicians, nursing, pharmacy) with expertise and credentialing in cell therapy administration**. Similar expertise is required for administration of other "specialized cell therapy products", including Natural Killer (NK) cells, Mesenchymal cells (MSC), Tumor-pulsed dendritic cells, Gene therapy products, and other cellular therapy products derived from hematopoietic stem cells.

- For further definition of CAR-T, see NIH's website: www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=771302

**Which "cell therapy" products would specifically meet our proposed definition?**

- **Bone marrow, Umbilical Cord Blood, Peripheral Stem Cells:** Yes. They are stem cell products and have proliferative capabilities. Existing CON standards currently cover infusion of these cell therapy products.
- **CAR-T cells:** Yes. CAR-T cells are ultimately derived from bone marrow stem cells and have proliferative capabilities.
- **NK cells, dendritic cells, or mesenchymal cells:** Yes. Each of these blood cells are derived from bone marrow stem cells. They can proliferative capabilities, as their numbers can be "expanded" either in vivo (inside the body) or ex vivo (outside the body).
- **Gene-therapy:** All gene therapy products derived from hematopoietic stem cells should require CON regulation.
- **Red Blood Cell transfusions:** No. Red Blood Cells do not have proliferative capabilities. They do not require CON regulation.
- **Platelet transfusions**: No. Platelets do not have proliferative capabilities. They do not require CON regulation.
- **Plasma product infusions**: No. Plasma is not a cell product. It does not require CON regulation.

To maintain quality, dedicated oversight from individuals knowledgeable in cellular therapy is required. Administration of cell therapy products (marrow, peripheral stem cell, cord blood and CAR-T) have historically been under the purview of BMT programs. The administration of cell therapy products, including CAR-T, should be recognized as a BMT service, requiring specialty training and expertise at all levels, 24/7/365.

In summary, we ask the CON Commission to consider amending the existing BMT CON standards, to include administration of cell therapy products with a proliferative capacity. To meet this definition, BMT services (CON-229, section 2) should be redefined from "administration of proliferating hematopoietic stem cells" to "administration of hematopoietic cells."

Thank you for allowing Karmanos Cancer Institute to provide these comments for consideration.

Respectfully submitted,

Justin F. Klamerus, MD, MMM
President
Karmanos Cancer Hospital &
Karmanos Cancer Network

Joseph Uberti, MD, PhD
Lambert Webber Endowed Chair, Stem Cell
ResearchDivision Head - BMT, Leukemia &
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SPECTRUM HEALTH

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October 20, 2017

**Suresh Mukherji, M.D., Chairperson**
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Re: CON Standards for Bone Marrow Transplantation (BMT) Services.

Dear Chairperson Mukherji,

Thank you for this opportunity to provide written comment regarding the CON Standards for Bone Marrow Transplantation (BMT) Services.

Just seven months ago, in March 2017, the CON Commission voted to keep the current standards in place. At that time, Commissioners felt that there was no need for additional BMT programs in the state. We do not believe anything has changed within the last seven months that would require reopening the standards at this time. We believe the current methodology and standards are balancing cost, access, and quality of this service.

Spectrum Health believes the current methodology works well and according to a study by Dr. Paul Delamater and Dr. Joseph Uberti, the geographical distribution of transplant centers in Michigan is at or above national averages in terms of driving times.[1] This is further proof that there is no need to reopen the standards.

Again, thank you for the opportunity to provide feedback on the CON Standards for Bone Marrow Transplantation (BMT) Services. Spectrum Health appreciates the Commission's consideration of our comments.

Respectfully,

Stephanie Williams, MD

[1] Delamater, PL, and Uberti, JP. "Geographic access to hematopoietic cell transplantation services in the United States." Bone Marrow Transplantation (2015).

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

**David A. Spahlinger, MD**
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October 20, 2017

Suresh Mukherji, MD - 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: Bone Marrow Transplantation Services - Certificate of Need Standards Review**

Dear Commissioner Mukherji:

This letter is written as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Bone Marrow Transplantation (BMT) Services. The University of Michigan Health System (UMHS) supports the continued regulation of this covered service and would like to recommend that a special workgroup be formed to evaluate and address a new cell therapy modality that must be incorporated into the BMT CoN Standards.

On August 30th, 2017 the Food and Drug Administration (FDA) approved the use of Kymriah® (tisagenleuleucel) for the treatment of acute lymphoblastic leukemia (ALL) in children and young adults. The commercialization of Kymriah® in childhood ALL is the first of multiple cell therapy trials the FDA will be reviewing in the upcoming decade, for both pediatric and adult disorders. Kymriah® represents a new classification of blood products, termed "chimeric antigen receptor T-cells (CAR-T). We are asking the CoN Commission to amend the regulations defining BMT services to incorporate infusion of cell therapy products, including CAR-T cells.

**Existing CoN standards (CoN-229, section 2) state:** *"BMT service means the transplantation of proliferating hematopoietic stem cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source."*

**We propose amending CoN standards to read: "***BMT service means the transplantation of proliferating hematopoietic cells essential to the survival of a patient derived from the bone marrow, the peripheral circulation, cord blood, or any other source." (Modification: Deletion of the term "stem", while maintaining the terms "proliferating hematopoietic cells").*

**Background:** Our proposal takes into account recent changes in the practice of bone marrow transplantation, including:

1. The focus of BMT is changing from delivery of proliferating hematopoietic stem cells to a platform for cellular immunotherapy, tumor vaccine strategies, and tissue engineering. CoN BMT standards will require modification to account for this change in clinical practice. Each of these cell therapy products are derived from blood cells and have proliferative potential.

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3. In November 2016, the Center for Medicare and Medicaid Services (CMS) established a common billing code for both Hematopoietic Cell Transplant and Cellular Therapy (HCTCT) services (*CMS MLN Matters MM957).*

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- ***Does CAR-T have proliferative potential, thus meeting the CoN's definition?*** CAR-T cells are blood (hematopoietic) derived cells with the potential to proliferate. Like hematopoietic stem cells, CAR-T cells can be expanded (proliferate) to increase their numbers.

- ***What are the theoretical risks of CAR-T therapy?*** There are several theoretical risks.

Theoretical risk #1: For CAR-T therapy to work effectively, every tumor cell in a particular patient should possess that target protein. For example, if only 90% of a patient's tumor cells had the protein, the CAR-T will only attack that 90%. The remaining 10% tumor cells would escape

detection by CAR-T therapy. Patients would ultimately relapse, from growth of tumor cells missing that protein.
Theoretical risk #2: What if the protein being targeted (by CAR-T cells) was also located on healthy, normal cells? This could have disastrous (even lethal) consequences for a patient, with the CAR-T cells potentially destroying normal cells.
Theoretical risk #3: The gene insertion process must be exact, with the CAR-T genes required to be inserted into the correct place in the T-cell genome. If not, there could be a multitude of negative effects, including the potential development of secondary cancers.

- ***What clinical risks do patients with CAR-T therapy have?*** Over 60 patients with CAR-T therapy were treated on the FDA licensing study in childhood ALL. Eighty-one percent developed a serious complication termed cytokine release syndrome (CRS), associated with high spiking fevers, shakes, chills, rigors, fluid leakage, blood pressure changes and often severe organ failure, the CRS developing within 3 days (median) of CAR-T infusion and lasting up to 4-8 weeks. Neurologic events, including seizures were common, noted in 31% of patients on this trial. At our own center, over 50% of patients treated with CAR-T therapy for childhood ALL required management in our intensive care unit, with many of the patients requiring mechanical ventilation for respiratory failure or hemodialysis for renal failure.

- **Collectively, both the theoretical and clinical risks of CAR-T therapy point out the specialty nature of the process, and the required need for oversight by a dedicated team (physicians, nursing, pharmacy) with expertise and credentialing in cell therapy administration**. Similar expertise is required for administration of other "specialized cell therapy products", including Natural Killer (NK) cells, Mesenchymal cells (MSC), Tumor-pulsed dendritic cells, Gene therapy products, and other cellular therapy products derived from hematopoietic stem cells.

- For further definition of CAR-T, see NIH's website: www.cancer.gov/publications/dictionaries/cancer-terms?cdrid=771302

**Which "cell therapy" products would specifically meet our proposed definition?**

- **Bone marrow, Umbilical Cord Blood, Peripheral Stem Cells:** Yes. They are stem cell products and have proliferative capabilities. Existing CON standards currently cover infusion of these cell therapy products.

- **CAR-T cells:** Yes. CAR-T cells are ultimately derived from bone marrow stem cells and have proliferative capabilities.

- **NK cells, dendritic cells, or mesenchymal cells:** Yes. Each of these blood cells are derived from bone marrow stem cells. They can proliferative capabilities, as their numbers can be "expanded" either in vivo (inside the body) or ex vivo (outside the body).

- **Gene-therapy:** All gene therapy products derived from hematopoietic stem cells should require CoN regulation.

- **Red Blood Cell transfusions:** No. Red Blood Cells do not have proliferative capabilities. They do not require CoN regulation.

- **Platelet transfusions**: No. Platelets do not have proliferative capabilities. They do not require CoN regulation.
- **Plasma product infusions**: No. Plasma is not a cell product. It does not require CoN regulation.

To maintain quality, dedicated oversight from individuals knowledgeable in cellular therapy is required. Administration of cell therapy products (marrow, peripheral stem cell, cord blood and CAR-T) have historically been under the purview of BMT programs. The administration of cell therapy products, including CAR-T, should be recognized as a BMT service, requiring specialty training and expertise at all levels, 24/7/365.

In summary, we ask the CoN Commission to consider amending the existing CoN standards for BMT services, to include administration of cell therapy products with a proliferative capacity. To meet this definition, BMT services (CoN-229, section 2) should be redefined from "administration of proliferating hematopoietic stem cells" to "administration of hematopoietic cells."

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

Respectfully submitted,

David A. Spahlinger, MD
President, University of Michigan Health System and
Executive Vice Dean for Clinical Affairs
University of Michigan Medical School

Gregory Yanik, MD
Leland and Elaine Blatt Family Professor of Pediatric Hematology/Oncology

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

October 19, 2017

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

Dear Commissioner Mukherji,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Heart/Lung and Liver Transplant Services:

Henry Ford Health System (HFHS) supports the continued regulation of Heart/Lung and Liver Transplant Services and we do not believe there are any necessary changes to the standards as they are currently written. The existing standards are effectively working to control costs, quality and access throughout the state.

- Cost: Adding a new Transplant program is expensive and puts existing programs at risk.
- Quality: Each program offers high quality care based on all current programs meeting or exceeding the OPTN expected outcomes and operational measures. Spreading a low volume service over more programs could compromise quality.
- Access: The existing Transplant programs throughout Michigan all have capacity to see more patients and there are programs on both the east and west sides of the state providing geographical access. Michigan has as good or better access than most states.

Thank you for the opportunity to share our comments.

Respectfully,

Marwan Abouljoud, MD, FACS, CPE, MMM
Director, Transplant Institute and Hepatobiliary Surgery
Benson Ford Chair in Transplantation
Henry Ford Health System
Professor, Clinician-Educator; Wayne State University School of Medicine
One Ford Place, 4A
Detroit, MI 48202

HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

**T. Anthony Denton, MHA, JD**
Senior Vice President & Chief Operating Officer

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October 20, 2017

Suresh Mukherji, MD - 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: Heart/Lung & Liver Transplantation Services - Certificate of Need Standards Review**

Dear Commissioner Mukherji:

This letter is written as formal testimony pertaining to the Certificate of Need Review Standards for Heart/Lung & Liver Transplantation Services. The University of Michigan Health System supports the continued regulation of this covered service and does not believe specific revisions to these standards are necessary at this time.

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

Beaumont

October 19, 2017

Certificate of Need Commission
c/o Policy, Planning and Legislative Services
Michigan Department of Health and Human Services
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

This letter is written as formal testimony on behalf of Beaumont Health related to the C.O.N. review standards for Heart/Lung and Liver Transplantation Services, Magnetic Resonance Imaging (MRI) Services, and Psychiatric Beds and Services which are scheduled for review in 2018.

**Heart/Lung and Liver Transplantation Services:**

Beaumont Health supports the continued regulation of Heart/Lung and Liver Transplantation Services. No specific changes to these standards are recommended at this time.

**Magnetic Resonance Imaging (MRI) Services:**

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

**Psychiatric Beds and Services:**

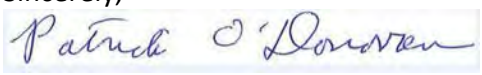
Beaumont Health proposes the following changes to the Psychiatric Beds and Services standards:

1. **Section 6 – Requirements for approval to initiate service**

   **Comment**: Currently, a provider of adult inpatient psychiatric services cannot also provide child/adolescent psychiatric services unless they also have a C.O.N. to do so, or if the planning area is underbedded. There is also no opportunity to "transfer" beds from one child/adolescent psychiatric unit to another hospital that does not currently have a child/adolescent unit (unless the entire child/adolescent unit is transferred). As the Commission is aware behavioral health is an enormous challenge across the country and in Michigan- and most of the issues do not relate directly to C.O.N. However, as providers look for solutions and approaches to better serve behavioral health patients, there should be flexibility to serve both adult and child/adolescent patients. Beaumont Health requests that the Commission support this flexibility and explore ways to accomplish this. One option could be to allow adult psychiatric units with a certain number (TBD) of beds to be allowed to establish a child/adolescent unit with a smaller number (TBD) of child/adolescent beds. An alternative option would be to allow a some (but not necessarily all) child/adolescent beds to be transferred from one child/adolescent psychiatric unit to a facility that currently has an adult psychiatric unit (thus creating a new child/adolescent psychiatric unit but no increase in child/adolescent beds).

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

Sincerely,



Patrick O'Donovan
Director, Strategy & Business Development

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

October 19, 2017

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

Dear Commissioner Mukherji,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Magnetic Resonance Imaging (MRI) Services:

Henry Ford Health System (HFHS) supports the continued regulation of MRI Services. Additionally, based on evolving clinical practice, we see opportunity in revising the following sections of the standards to best support the operations of our hospitals and delivery of high quality care to our patients. Recommendations include:

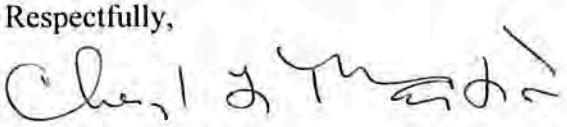
- Section 4(1) financial cap for equipment changes: HFHS recommends that the definition of "Replace an existing MRI unit" be modified and updated to remove the capital expenditure threshold for an equipment change that does not require CON approval. The current threshold is outdated and we believe it would be simpler and more clear to allow for any equipment changes and/or upgrade to a MRI machine that does not lead to a change in the machine's serial number without CON approval. This is consistent with similar provisions in the CT standards.
- Section 5(b) volumes for expansion: HFHS recommends the minimum volume requirement of 11,000 adjusted procedures per unit be reduced. HFHS MRI services are operational 16 hours a day, 7 days a week at some of our facilities, and patient services are being delayed due to lack of availability of machines. Even with this extended service times, we struggle to meet the 11,000 requirement for expansion at these sites. HFHS recommends the minimum adjusted procedure requirement be reduced to 10,000.
- Section 15(1) (a) weighting: HFHS recommends that procedures requiring general Anesthesia be considered for an increase in weighting. The current weighting does not take into consideration the extended period of time the patient is in the MRI during pre and post procedure care due to the Anesthesia

requirements. HFHS recommends adding procedures under general anesthesia to (a) with a base value weight of 2.0.

- Section 18- Physician Pledge forms: HFHS recommends there be a formal Q&A document included with physician pledge forms, clearly outlining what pledging volumes means for a physician when signing a pledge form. We have seen slightly misleading Q&A documents distributed to HFHS physicians in the past. A standard Q&A would help physicians understand what commitment of volumes means to them and their patients, and protect both the physician and institutions involved in the process.

Thank you for the opportunity to share our comments.

Respectfully,



Cheryl Martin
Henry Ford Health System
Vice President-Product Line, Radiology
2799 W. Brand Blvd
Detroit, MI 48202

MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

October 30, 2017

Suresh Mukherji, MD - 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: Magnetic Resonance Imaging - Certificate of Need Standards Review**

Dear Commissioner Mukherji:

This letter is written as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Magnetic Resonance Imaging (MRI) Services. The University of Michigan Health System (UMHS) supports the continued regulation of this covered service; however, UMHS strongly believes a definitional revision is necessary to more accurately classify pediatric patients.

Under the current CoN Standards a Dedicated Pediatric MRI is defined as an MRI unit on which at least 80% of the MRI procedures are performed on patients under 18 years of age. Sections 8 (Dedicated Pediatric MRI) and 9 (Hospital Based IMRI) also utilize this same pediatric age cohort as a requirement for approval.

UMHS recommends increasing the age limit for pediatric MRI studies through 21 years of age (< 22 years of age). This change is necessary to reflect the practice of pediatric medicine in the current era. This change is critical to assure proper health care for the entire "pediatric" patient population.

In 1988 (***Pediatrics*** 1988;81:736), the American Academy of Pediatrics (AAP), the leading professional society in pediatric medicine, redefined the upper limit of age for pediatrics as through age 21 years (up to a patient's 22nd birthday). In 2017, the AAP (Policy Statement: Age Limit of Pediatrics: ***Pediatrics***, September, 2017) has broadened this further by stating that "The establishment of arbitrary age limits on pediatric care by health care providers should be discouraged. Health care insurers and other payers should not place limits that affect a patient's choice of care provider solely on the basis of age." This reflects the common practice of patients with pediatric diseases to be cared for in a pediatric setting often beyond 21 years of age. The United States Food and Drug Administration considers patients to be "pediatric" through age 21 years, defining patients from 18 years to 21 years of age in the "late adolescence" band of pediatrics for classification of study of new drugs and devices (Guidance for Industry and FDA Staff: Pediatric Expertise for Advisory Panels – U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, 2003).

On September 1, 2017 UMHS redefined "pediatric" as including patients up to their 21st birthday. Patients who are 18 to 20 years of age who are new to the system are now preferentially directed to, seen in and cared for within the pediatric hospital and within pediatric clinics. This includes a majority of 18 to 20-year-old emergency room patients. To provide the highest quality, safest and

most efficient imaging of these patients, patients 18 to 20 years of age undergo imaging studies in the pediatric environment - this is where the patients are; this is where their doctors are.

This evolution of the definition of the pediatric age range is not unique to UMHS and is occurring at many medical centers throughout the country.

As stated above, the current MRI CoN Standards define pediatric as less than 18 years of age. This definition does not align with today's practice of pediatric medicine. Left unchanged this will cause access impediments to MRI in a pediatric environment resulting in less than optimal outcomes.

To redefine pediatric as including through age 21 (younger than 22 years of age), this will modernize the guidelines to reflect the current practice of pediatric and young adult medicine and ensure that pediatric patients can obtain imaging with MRI proximate within their health care environment, facilitating timely, efficient and high quality health care in patients 18-21 years old.

UMHS urges the CoN Commission to form a Workgroup or Standards Advisory Committee to further evaluate the redefinition of pediatric age limits and develop CoN Standards that appropriately align with this change in care.

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

Respectfully submitted,

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine

Paul King, CMPE
Executive Director, C.S. Mott Children's Hospital
and Von Voigtlander Women's Hospital
Michigan Medicine

Peter J. Strouse, MD, FACR
John F. Holt Collegiate Professor of Radiology
Director, Section of Pediatric Radiology
C. S. Mott Children's Hospital
Department of Radiology
Michigan Medicine

Chris J. Dickinson, MD
Chief Clinical Officer, C.S. Mott Children's Hospital
and Von Voightlander Women's Hospital
Professor Pediatric Gastroenterolgy,
Pediatrics and Communicable Diseases
Michigan Medicine

October 20, 2017

Suresh Mukherji, 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: Public Comment for Certificate of Need Standards**

Dear Chairman Mukherji:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Magnetic Resonance Imaging (MRI) services and Psychiatric Beds and Services. Trinity Health Michigan supports continued CON regulation of MRI and Psychiatric services.

Trinity Health Michigan believes the changes made in 2016 to the Certificate of Need Review Standards for both MRI services and Psychiatric Beds appropriately assure Michigan residents have access to safe, low cost, high quality care resources. As such, Trinity Health Michigan does not believe further revisions to the Certificate of Need Review Standards are necessary at this time.

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

Respectfully,

Robert Casalou
President and CEO, Saint Joseph Mercy Health System

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

October 19, 2017

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

Dear Commissioner Mukherji,

The Department has been conducting a statewide compliance review of all MRT services. The compliance review has prompted our radiation therapy team to take a closer look at the formula used to determine equivalent treatment visits. Despite being very busy with high-quality patient care, the use of more abbreviated (i.e., hypofractionated radiation courses for breast cancer and lung cancer) and cost-effective radiation regimens (e.g., 3D techniques instead IMRT techniques), the result is a decrease in the calculated MRT equivalent treatment visit volumes based on the current calculation algorithm. Our team has heard that up to about 50% of MRT facilities in Michigan are facing issues related to the calculated MRT volumes based on the historic calculation algorithm.

Given the fundamental changes in the way radiation therapy is being delivered to several of the most common types of patients treated with radiation therapy, we have great concern that without considered revision of the current MRT standards, future compliance actions may ultimately result in limitations regarding MRT services and a significant reduction in access to radiation services for patients across the State. Moreover, such compliance actions against institutions diligently working to maintain practice consistent with current high-quality, evidenced-based standards, such as hypofractionated radiations courses, may discourage such institutions from adopting such high-quality standards and result in the practice of longer treatment courses and utilizing less cost-effective treatment regimens. Based on these concerns, we believe there should be a review of the ETV weightings and minimum volume requirements in the standards to ensure that we are accurately measuring how fully utilized an MRT unit is.

The Department's proposed compliance settlement agreements require the MRT services to meet minimum volumes by December 31, 2019. Although the MRT standards are not scheduled for review again until 2020 we respectfully request a Standards Advisory Committee or Workgroup be formed in 2018 to review these standards early in order to ensure that any necessary updates are made to the standards before the Department's next review of volumes expected in 2020 for the 2019 calendar year.

We appreciate the schedule you have followed for reviewing CON standards but we ask you to please consider reviewing these standards early given the circumstances.

Respectfully,

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

DMC
DETROIT MEDICAL CENTER

**Eric D. Fischer**
Director, Strategic Planning

The Detroit Medical Center
Orchestra Place
3663 Woodward Avenue
Suite 200
Office 2-709
Detroit, MI 48201-2403
Phone 313-578-2221

October 13, 2017

Mr. Suresh Mukherji
Certificate of Need 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

Dear Chairman Mukherji,

The Detroit Medical Center (DMC) appreciates the opportunity to provide testimony regarding the Psychiatric Beds and Services scheduled for review in 2018.

The Detroit Medical Center (DMC) supports the overall regulations for this service; however, DMC would like the CON Commission to review the methodology for determining the inpatient psychiatric bed need in the state, including the proper percentage of psychiatric beds that should be allocated to the special pool for psychiatric beds.

We believe the psychiatric bed need methodology is the only bed need methodology that has not yet been reviewed by the MSU Department of Geography and/or Mr. Paul Delamater, PHD. With the difficulties placing patients in psychiatric inpatient beds, it seems appropriate to have the methodology itself reviewed to ensure it is adequately predicting need for beds. We appreciate the work completed during the last review to create the "Special Pool for Psychiatric Beds" to add 5% more adult, child and adolescent psychiatric beds to help ease the acute inpatient psychiatric access problem in the State of Michigan for the care of developmental disabilities, geriatric care and patients with medical needs. These changes were well received but many of the special pools were so popular that all of the beds were awarded in the very first application window and 2 of the pools actually had more beds requested than what were available. More specifically, the applications for adult geriatric psychiatric beds totaled 198 beds, but only 110 were available. Similarly, the applications for child/adolescent developmental disability beds totaled 25, but only 20 beds were available.

Approval of additional Special Pool Psychiatric Beds would again help alleviate access issues and stop psychiatric patients from being turned away at hospital facilities for not having available psychiatric beds to treat these special populations of patients. We also want to assure that all psychiatric patients have access to appropriate beds, and we believe review of the overall bed need methodology is important to ensure this.

Thank you for your time in considering these suggestions. We look forward to working with the Commission and Department during the upcoming review.

Sincerely,

Eric D. Fischer,
Director, Strategic Planning

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

October 19, 2017

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

Dear Commissioner Mukherji,

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

Henry Ford Health System (HFHS) supports the continued regulation of Psychiatric Beds and Services. Currently, psychiatric care is receiving significant attention at a state and federal level, with focus on care access, payment and support. HFHS has also experienced growing demand, increased acuity levels and volatility of patients and a shortage of qualified workers. Given these factors, we are asking for the following changes to the current standards:

- Section 14(3) access to care: HFHS recommends slight revisions to the language in (3)(b)(i). We believe the intent of sections (2)(b) and (3)(b)(i) is to guarantee access to an inpatient environment that allow for safe, high quality care. However, the current language in (3)(b)(i) does not call out that access may be denied if the admission creates an unsafe environment for the patient and/or staff. Specifically, given the organization of patient pods in a facility (male vs. female, adult vs. child/adolescent) access may be denied based on gender or age if that admission creates an unsafe environment. We are requesting language be added to this section to clarify when denial of access is permissible.

Thank you for the opportunity to share our comments.

Respectfully,

Dr. Cathy Frank
Henry Ford Health System
Chair of Psychiatry and Behavioral Services
One Ford Place, 1F
Detroit, MI 48202

**From:** Nykamp, Bob <Bob.Nykamp@PineRest.org>
**Sent:** Friday, October 06, 2017 4:02 PM
**To:** MDHHS-ConWebTeam
**Subject:** MRI Public Hearing Comment 2-4-16 through 2-11-16

Public Comment on Psychiatric Beds and Services:

1. The absence of clear qualitative review criteria for the specialty bed pools is a disservice to our citizens. An organization making application for beds should be required to demonstrate the ability to provide the clinically specific hiring, training and competencies of their staff related to these special populations. The CON review teams at the department could not describe or provide the competency measures they would use to review an application in a comparative review process. I would assume that our citizens would expect the department to insure they are approving beds to providers that are clinically competent and financial solvent, however neither was required for application review. I would ask the Commission to ask themselves this question: Do we have clear clinical componence review for open heart surgery programs? Why then would we potentially discriminate against the citizens who may have an acute psychiatric issue by not having similar clinical quality comparative standards?
2. Some of the total bed inventory numbers for the specialty population pools have not received applications for the full allotment of beds, while other special population pool applications have been asked to reduce their request to stay within the arbitrary special bed inventory allocation. I would ask the commission to allow the staff to move un allocated beds from the different special population bed categories as they deem appropriate.

Thank you for the opportunity to comment. I am more than willing to provide further detail as requested.

Bob Nykamp
Vice President & Chief Operating Officer
Pine Rest Christian Mental Health Services

SPECTRUM HEALTH

Spectrum Health Hospital Group
Executive Administration | MC005
100 Michigan Street NE
Grand Rapids, MI 49503
www.spectrumhealth.org

October 20, 2017

**Suresh Mukherji, M.D., Chairperson**
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Re: CON Review Standards for Psychiatric Beds and Services

Dear Chairperson Mukherji:

Thank you for this opportunity to provide written comment regarding the CON Review Standards for Psychiatric Beds and Services.

When the standards were last reviewed, the CON Commission approved special pool inpatient psychiatric beds in the following categories:

- Developmentally Disabled
- Geriatric Psych
- Medical Psych

These special pools were well received by the provider community and based on the amount of applications filed, popular. As such, it seems appropriate for the Commission to consider allocating additional beds to these special pools, specifically the Geriatric & Medical Psych pools.

Additionally, Spectrum Health has repeatedly heard about the need for additional psych beds in our community. It appears that the current bed need methodology does not accurately reflect the true need of the psychiatric patient population. The methodology seems designed to perpetuate the status quo. This is unacceptable as many go without the treatment they need. Therefore, Spectrum Health recommends the Commission ask the Department to contract with Dr. Paul Delamater to review the bed need methodology and recommend replacement or modification.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Psychiatric Beds and Services. Spectrum Health appreciates the Commission's consideration of our comments.

Respectfully,

Gwen G. Sandefur
President, Spectrum Health Hospital Group

HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

**T. Anthony Denton, MHA, JD**
Senior Vice-President and Chief Operating Officer

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October 20, 2017

Suresh Mukherji, MD - 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: Psychiatric Beds and Services - Certificate of Need Standards Review**

Dear Commissioner Mukherji:

This letter is written as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Psychiatric Beds and Services. The University of Michigan Health System supports the continued regulation of this covered service and does not believe specific revisions to these standards are necessary at this time.

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