

Bone Marrow Transplants (BMT)

October 20, 2023

Chairperson James "Chip" Falahee
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

Dear Chairperson Falahee,

Corewell Health thanks the CON Commission for the opportunity to provide written comments on the CON Review Standards for Bone Marrow Transplantation (BMT) Services.

Corewell Health believes that continued regulation of BMT Services will serve the citizens of Michigan well. We do not believe that any changes are necessary to the current standards.

We appreciate the Commission's consideration of our comments. Should you have any questions regarding these comments or if you would like any additional information, please do not hesitate to contact me.

Sincerely,



Darryl Elmouchi, MD, MBA
Interim President, Corewell Health East
Chief Operating Officer, Corewell Health



October 6, 2023

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

Dear Commissioner Falahee,

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

Henry Ford Health is a Michigan-based, not-for-profit corporation and one of the nation's largest integrated healthcare systems, with over 33,000 employees. Headquartered in Detroit, we have been committed to improving the health and wellbeing of the community, including children, for over 100 years. Henry Ford Health offers healthcare services across the continuum through a diverse network of facilities in Southeast (metro Detroit) and South-Central Michigan (Jackson). Henry Ford Health operates five acute-care hospitals, including our flagship hospital, Henry Ford Hospital, which is a large academic medical center located within the city of Detroit.

The Henry Ford BMT program has been in existence since 1988 and is rooted in several critical areas to achieve high quality and engagement with our patients and their support team.

- **Comprehensive program:** Our experienced transplant team offers all types of stem cell transplant and cellular therapy, including CAR T-cell therapy. We work to find a donor match and select the best transplant method to replace damaged or destroyed stem cells with healthy ones.
 - **Team approach:** As part of the Henry Ford Cancer, our cellular therapy team partners with other experts, including medical oncologists and hematologists, to customize individual treatment plans for our patients.
 - **Advanced care:** Our Transplant Immunology Lab features state-of-the-art equipment. Our doctors perform critical tests that improve the chances of a successful transplant.
 - **Focus on quality:** We've been accredited by the Foundation for the Accreditation of Cellular Therapy (FACT) since 2006, demonstrating our commitment to quality care. And our 100-day and one-year transplant survival rates often exceed expected results.
 - **Renowned research:** Our doctors take part in clinical trials and research for stem cell transplants. We participate in cooperative groups, pharmaceutical trials and investigator-initiated studies to identify and test new therapies. Our research includes haploidentical transplant, using stem cells from family members who only partially match recipients.
 - **Full support:** Our Transplant Recovery Unit features private, spacious rooms with specially filtered air to prevent infection. We connect patients with a transplant coordinator who helps navigate the entire process as smoothly as possible. We also host monthly cancer support groups and survivorship clinics to support patients throughout their life.
-

Henry Ford Health (HFH) supports the continued regulation of Bone Marrow Transplant (BMT). We feel the BMT standards are effectively working to control costs, while ensuring 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: Hospital BMT discharge volume has declined by 17% since 2019 as CAR t-Cell therapy gains traction. The existing BMT programs throughout Michigan all have capacity to see more patients. Michigan ranks 13th nationally in the number of BMT transplants by Center in 2020 based on statistics from the Health Resources & Services Administration (HRSA). Data reflects that some centers are doing as many as 250+ BM transplants on average in some states. In Michigan, the 6 centers (6th center in data set is Helen Devos Children's Hospital currently operating within the University of Michigan Health System CON) currently offering BMT services average 122 transplants per year.

While, in the past, other health systems have expressed a desire to have a BMT program, there is not 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,



Denise Brooks-Williams
Executive Vice President & CEO
Clinical Delivery Service Operations
Henry Ford Health



Muneer Abidi, MD
Medical Director, Bone Marrow Transplant, Cellular
Therapy Program, Collection Facility & Processing Laboratory
Henry Ford Cancer



Trinity Health Michigan

October 20, 2023

James Falahee
Chair, CON 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 Bone Marrow Transplantation Services Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards for Bone Marrow Transplantation Services in 2024.

Trinity Health Michigan does not provide Bone Marrow Transplantation Services. To our knowledge, the patients and communities we serve have appropriate access to high quality, cost-effective care from the existing Michigan BMT providers. For this reason, Trinity Health Michigan supports the continued regulation of Bone Marrow Transplantation Services without any further modification to the CON Standards in 2024.

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

Sincerely,

Shannon D. Striebich
President and CEO
Trinity Health Michigan Market



UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief Environmental,
Social and Governance Officer

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October 20, 2023

James Falahee - 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 Transplant - Certificate of Need Standards Review

Dear Chairperson Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need Review Standards for Bone Marrow Transplant. University of Michigan Health supports the continued regulation of this covered service and does not believe any specific revisions to these standards are necessary at this time.

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

Respectfully submitted,

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief ESG Officer
University of Michigan Health
Michigan Medicine

Heart, Lung, Liver Transplant (HLLT)



Ascension

October 20, 2023

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairperson Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2024: Heart/Lung and Liver Transplantation Services Standards.

Ascension Michigan supports the continued regulation of Heart/Lung and Liver Transplantation Services and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards for review in 2024. We look forward to working with the Commission this, and the coming year.

Sincerely,

Douglas J. Apple, MD, MS, FHM
Chief Clinical Officer, Ascension Michigan

October 20, 2023

Chairperson James “Chip” Falahee
Certificate of Need Commission
c/o Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

Dear Chairperson Falahee,

Corewell Health appreciates the opportunity to provide written testimony on the CON Review Standards for Heart/Lung and Liver (HLL) Transplantation Services.

Corewell Health believes that continued regulation of HLL Transplantation Services will serve the citizens of Michigan well. We do not believe that any changes to the current standards are needed at this time.

Michigan residents currently have appropriate access to liver transplantation services. While the need for liver transplants in the State are increasing, the existing programs have capacity to increase the number of liver transplants, if required. Adding more programs without demonstrated need will dilute the ability of existing programs to appropriately staff their programs, which could lead to diminished quality and increased cost.

Patients with liver disease can have the vast majority of their needs managed through their local hospitals and physicians. If they require transplant, they can be referred to one of the existing liver transplant programs, and returned to their local providers for subsequent follow-up care. This model has worked successfully for other transplant services. For example, patients at Corewell Health East in need of a lung transplant have all of their pre- and post- transplant care at Corewell East facilities, but the lung transplant itself takes place at Corewell Health West (or one of the other Liver transplant programs in the State).

Additionally, liver transplants are performed on patients from across the state with no known geographic disparity in care. For example, based on data available from the United Network of Organ Sharing, in the past 12 months, 41 patients living in the western portion of the state received a liver transplant. Each of the three existing liver transplant programs participated in providing this service. Further, both Henry Ford Hospital and Beaumont Hospital – Royal Oak liver transplant programs have dedicated liver transplant outreach locations in Grand Rapids. The creation of Corewell Health expands hepatology and liver transplant care across the state of Michigan. This helps to ensure equity in care and enables patients to receive a significant portion of their care close to home.

We appreciate the Commission's consideration of our comments. Should you have any questions regarding these comments or if you would like any additional information, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to be 'D. Elmouchi', with a stylized flourish at the end.

Darryl Elmouchi, MD, MBA
Interim President, Corewell Health East
Chief Operating Officer, Corewell Health

October 16, 2023

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

Dear Commissioner Falahee:

Henry Ford Health appreciates the opportunity to offer comments on the Certificate of Need (CON) review standards for Heart/Lung and Liver Transplant Services.

Henry Ford Health is a Michigan-based, not-for-profit corporation and one of the nation's largest integrated healthcare systems, with over 33,000 employees. Headquartered in Detroit, we have been committed to improving the health and wellbeing of the community, including children, for over 100 years. Henry Ford Health offers healthcare services across the continuum through a diverse network of facilities in Southeast (metro Detroit) and South-Central Michigan (Jackson). Henry Ford Health operates five acute-care hospitals, including our flagship hospital, Henry Ford Hospital, which is a large academic medical center located within the city of Detroit – provides tertiary and quaternary care to the sickest and most complex patients.

The Henry Ford Transplant Institute (HFTI) has a rich history as a national leader in transplant care. For nearly 50 years, our transplant teams have helped forge new innovations in transplant procedures and treatments that mean better results for patients. HFTI is a well-respected, and comprehensive multi-organ transplant center that performs transplantation of the following: liver, kidney, pancreas, small bowel and multi-visceral organs, lung, heart, and stem cell. As a major research institution, HFTI offers the latest treatments and most advanced surgical options and employs strategies to increase access to transplantation, decrease the length of time patients wait for a transplant and continue to achieve superior patient outcomes.

Henry Ford Health 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, while ensuring quality and access throughout the state.

Marwan S. Abouljoud, M.D.
Director, Transplant
Benson Ford Chair

Henry Ford Hospital
2799 W. Grand Blvd.
CFP 220
Detroit, MI 48202
313.916.2941 Office
313. 916.4353 Fax

Transplant programs

Liver
313.916.8865 Phone
313.916.9147 Fax

Small Bowel and Multivisceral
313.916.8865 Phone
313.916.9147 Fax

Kidney
313.916.1269 Phone
313.916.7587 Fax

Pancreas
313.916.1590 Phone
313.916.7587 Fax

Heart
313.916.2895 Phone
313.916.8799 Fax

Lung
313.916.1258 Phone
313.916.9102 Fax

Hepatobiliary Surgery
313.916.7574 Phone
313.916.1235 Fax

- **Cost:** Adding a new transplant program is expensive and puts existing programs at risk.
- **Quality:** Each existing program offers high quality care, measured by all current programs meeting or exceeding the Organ Procurement and Transplantation Network (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. Demand decreased for heart and lung transplants, with only marginal increases in liver transplants since 2021. Even with the emerging living donor programs for liver transplants, existing programs have capacity. Compared with other states, Michigan has as good or better access to transplantation. Additionally, HFTI has created outreach clinics, bringing pre and post operation care services closer to home, implemented tele-health and remote monitoring options, making access to care even easier.

Additionally, changes to these standards may be pre-mature until the impacts of pending organ transplant system changes from recently passed state and federal legislation are understood. At the federal level, Congress recently passed, and President Biden is expected to sign, the Securing the US Organ Procurement and Transplantation Network Act of 2023. This bill would make the OPTN contract more competitive and break it up into multiple components—a major change given that the same organization has held the contract for more than 40 years. While these changes are expected to drastically change how organs are allocated and distributed in the United States, implementation has not yet begun, and the true impacts have not yet been realized. At the state level, legislation recently passed to improve and help to facilitate individuals in executing their wishes to be an organ donor by allowing individuals to sign up on the Michigan Donor Registry when obtaining their driver's license. It is unclear what impact, if any, these two items will have on organ availability in Michigan. Any changes to the CON standards should be held until the impacts of these two initiatives are better understood.

Thank you for the opportunity to share our comments.

Respectfully,



Marwan S. Abouljoud, MD, FACS, MMM, CPE
Benson Ford Endowed Chair
Director, Transplant Institute
Medical Director, Physician Partnerships, Henry Ford Health
Professor, Clinician-Educator, Wayne State University School of Medicine
Past President, American Society of Transplant Surgeons

October 20, 2023

James Falahee
Chair, CON 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 Heart/Lung and Liver Transplantation Services Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards for Heart/Lung and Liver Transplantation Services in 2024. Specifically, Trinity Health Michigan believes the Liver Transplantation requirements, which placed a cap on the number on Liver Transplant programs way back in 1988, should be reviewed and updated.

Trinity Health Michigan provided a detailed comment and presentation to the CON Commission at its January and March 2022 meetings. At that time, the CON Commission decided to defer any revisions to the normal review cycle that will occur in 2024. Trinity Health Michigan remains concerned that the current CON standard for Liver Transplant:

- Does not include initiation requirements that are based on actual need as is intended by Certificate of Need; a cap on the number of programs does not consider need, especially a cap that was established 35 years ago.
- Is potentially reducing access to appropriate liver transplants for many citizens, as evidenced by a comparison of Michigan to the national trends
- Is unfairly extending the waitlist time for patients who are more distant from a transplant center
- Is creating avoidable hardships for patients and their families by forcing them to travel farther than necessary
- Is perpetuating a continued barrier to access to care even as the underlying causes and incidence of liver transplant grows

Given these concerns, and that the Standard has not been reviewed or revised since 2012, we are asking the CON Commission to create a Standards Advisory Committee of experts to review the initiation and comparative review requirements for Liver Transplantation. We believe a robust discussion is warranted in order to consider all of the factors that ensure all Michiganders, east, west, north and south, are being provided appropriate access to adult liver transplant care. There is much data to be reviewed. We believe these data clearly show the current CON standard for Liver Transplant is perpetuating a barrier to access for patients, particularly in West Michigan.

We have attached our comment from 2021 to this letter as well.



Trinity Health Michigan

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

Sincerely,

A handwritten signature in black ink that reads "Shannon D. Striebich".

Shannon D. Striebich
President and CEO
Trinity Health Michigan Market



October 21, 2021

Amy L. McKenzie, MD
Chair, CON 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 McKenzie:

Saint Joseph Mercy Health System and Mercy Health would like to thank the Certificate of Need (CON) Commission for the opportunity to provide comment regarding the CON standards that should be reviewed in 2022. While we are aware MDHHS will not be soliciting feedback regarding Liver Transplant until Fall 2023, Saint Joseph Mercy Health System and Mercy Health are requesting that the CON Commission conduct a review in 2022. Our request to open the review standards for Liver Transplant now is based on three key considerations:

- 1. The current initiation requirements are not based on need or population distribution and have not kept up with growth.**
 - The current CON standards are not based on defined public need, but instead include an oversimplified program cap that allows just three programs statewide. All three programs are located within southeast Michigan – Henry Ford, William Beaumont and University of Michigan Hospitals. This cap has been in place since CON began regulating Liver transplantation in 1988.
 - The Grand Rapids-Kentwood-Muskegon Combined Statistical Area is the second largest CSA in Michigan, behind Metro Detroit, and has population of over 1.4 million. Residents from this area are required to travel more than 2 hours to the nearest liver transplant center. When the Kalamazoo-Battle Creek-Portage CSA is also included, nearly 2 million Michiganders reside more than 2 hours from the nearest liver transplant center.
 - Per Data Koala/MIDB, on average, 52 of the liver transplants performed each year at the three Michigan transplant centers are on residents residing in lower Michigan counties west of highway US-127 – representing approximately 26% of all liver transplants in Michigan. Additionally, on average another 6 people from the same area leave Michigan for their transplants.

- While once exceptionally rare, adult liver transplants are now performed with greater frequency. In the 30 years between 1989 (CON started 1988) and 2019, the national incidence of adult liver transplant increased 377% from 1,748 to 8,345 annually. During this same period in Michigan, the incidence of liver transplant only increased 159%. We are concerned the relatively smaller increase in adult liver transplants in Michigan points to a lack of access.

2. Future trend for liver transplant

- Unfortunately, the statistics for liver disease continue to trend in the wrong direction. Including:
 - According to state data (OPTN – [hrsa.gov](https://www.hrsa.gov)), 30-50 Michigan patients die each year while waiting for a liver transplant.
 - There are 5.5 million Americans currently living with chronic liver disease or cirrhosis.
 - Liver cancer has more than tripled since 1980, with approximately 30,000 Americans dying from liver cancer each year.
 - Approximately 4.4 million Americans are living with hepatitis B or C and most do not know they are affected.
 - Currently 773 patients in UNOS Region 10 (MI, IN, OH) are on the liver waitlist; 215 of these individuals are from Michigan.

3. Distance to a transplant center has real and immediate, negative impacts on citizens who need care.

- While the majority of patients receive treatment and care close to home prior to being placed on the transplant lists, patients are required to go through a 2-3 day evaluation at or near the transplant center before being placed on the transplant list. As part of the evaluation, patients are assigned a MELD (model for end-stage liver disease) Score and are placed in a waitlist spot based on their MELD score, blood type, and **geographic distance between** the transplant candidate and the hospital where the donor's liver is located. Once on the list, patients must live close by or have transportation on standby should they be called in for transplant. There is risk that patients far from transplant centers could be negatively disadvantaged on the wait list *simply because they are farther from a center*.
- Time away from home, family and friends does not stop after the transplant as many transplant centers require patients to stay close by the transplant center for 30-60 days post-transplant. Laboratory testing and in-person clinic visits can be as much as twice a week for the first several weeks following discharge then reduce over time. Patients are required to return to clinic at least annually for the remainder of their lifetime
- The financial and emotional toll on patients and families having to travel more than 2 hours to access liver transplant services places an undue burden on them. While difficult to quantify the toll the required travel, lodging, meals, appointments, and time away from family and support network take on patients and family, having nearer options would certainly lessen the financial, physical and emotional toll.

In summary, Trinity Health is concerned that the current CON standard for Liver Transplant:

- Does not include initiation requirements that are based on actual need (cap on number of programs does not consider need) as is intended by Certificate of Need

- Is potentially reducing access to appropriate liver transplants for many citizens, as evidenced by a comparison of Michigan to the national trends
- Is unfairly extending the waitlist time for patients who are more distant from a transplant center
- Is creating avoidable hardships for patients and their families by forcing them to travel farther than necessary
- Is perpetuating a continued barrier to access to care even as the underlying causes and incidence of liver transplant grows

Given the reasons stated above, Saint Joseph Mercy Health System and Mercy Health recommend creating a Standards Advisory Committee to review the initiation and comparative review requirements of the Liver Transplant CON standards in 2022. While we understand the Liver Transplant standards are not scheduled for review until 2023, we believe an earlier review is warranted given the number of Michiganders who die each year waiting for liver transplant and the time required to apply for, be approved, and establish a quality adult liver transplant program.

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

Sincerely,

A handwritten signature in dark ink that reads "Rob Casalou". The signature is written in a cursive, flowing style.

Rob Casalou

President and CEO

Saint Joseph Mercy and Mercy Health System



October 20, 2023

James Falahee - 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 and Liver Transplant - Certificate of Need Standards Review

Dear Chairperson Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Heart, Lung and Liver Transplant. University of Michigan Health (UMH) supports the continued regulation of this covered service; however, UMH would like the CON Commission to consider the following pertaining to liver transplantation.

Currently, the CON Standards for liver transplantation allows for 3 adult liver transplant programs, which are all currently located in Health Service Area (HSA) 1, southeast Michigan. We are concerned that this geographic arrangement restricts access to liver transplantation for Michigan residents outside HSA1. UMH recommends that the CON Commission create a Standards Advisory Committee of experts to review the liver transplant sections of the CON Standards and consider the appropriate data to make certain that access to liver transplantation matches appropriately the burden of chronic liver disease among adults in Michigan's other 7 HSAs. We believe this analysis is necessary and overdue as the current requirements for liver transplantation programs has existed since 1998.

The current era in liver transplantation is marked by excellent patient outcomes and significant growth in organ donor utilization through advancements in surgical technique and organ preservation technology. We believe the primary challenge in liver transplantation today is to expand efficient and timely access to populations who have traditionally not had access to liver transplant care related to geographic location, socioeconomic status, race/ethnicity, or medical complexity. Based on objective data, we further suggest that several metrics indicate that access to liver transplantation for residents within many of Michigan's HSAs are challenged:

- For example, the greater Grand Rapids metropolitan area (HSA 4 in West Michigan) is one of the largest population centers in the Midwest without a liver transplant program. Other smaller Midwest metropolitan areas with liver transplant programs include Madison, WI and Iowa City, IA.
- Liver transplants performed in the US has grown 52% between 2012 and 2022, while liver transplants performed in Michigan only increased 28% over the same time period.

- The age-adjusted death rate due to chronic liver disease in the state of Michigan has risen 55% between 2012 to 2021 (versus 26% nationally over the same time period), again while transplants done in the state have only increased 28%.
- Multiple studies have documented that the distance a patient lives from a transplant center is inversely proportional to their likelihood receiving a transplant.
- Disparities in access to transplantation related to distance from a transplant center are further exacerbated in traditionally marginalized populations, which poses a significant challenge to health equity.

An evaluation of population density, socioeconomic and other key factors seem warranted in light of the time since initiation of the current standards approximately 25 years ago.

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

Respectfully submitted,



T. Anthony Denton, JD, MHA
Senior Vice-President & Chief ESG Officer
University of Michigan Health
Michigan Medicine



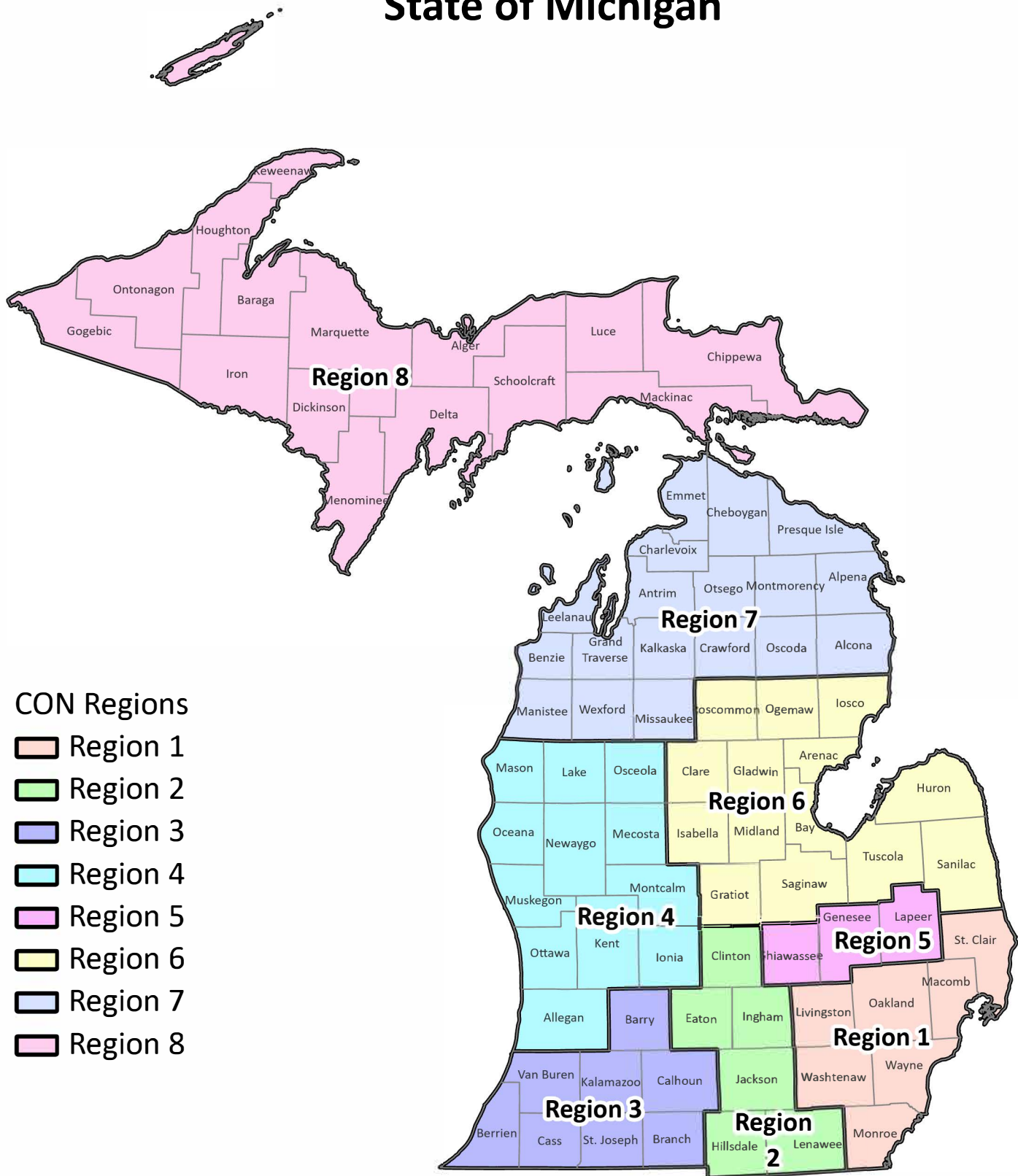
Christopher J. Sonnenday, MD, MHS
Transplant Center Director
Surgical Director of Living Donor Liver
Transplantation
Surgical Director, Multidisciplinary Liver Tumor
Program
Executive Vice-Chair, Department of Surgery
University of Michigan Health
Michigan Medicine

Attachment

Certificate of Need (CON) Review Regions

Health Service Areas (HSA)

State of Michigan



PLANNING AREAS BY COUNTY

1	Livingston Macomb Wayne	Monroe Oakland	St. Clair Washtenaw
2	Clinton Eaton	Hillsdale Ingham	Jackson Lenawee
3	Barry Berrien Branch	Calhoun Cass Kalamazoo	St. Joseph Van Buren
4	Allegan Ionia Kent Lake	Mason Mecosta Montcalm Muskegon	Newaygo Oceana Osceola Ottawa
5	Genesee	Lapeer	Shiawassee
6	Arenac Bay Clare Gladwin Gratiot	Huron Iosco Isabella Midland Ogemaw	Roscommon Saginaw Sanilac Tuscola
7	Alcona Alpena Antrim Benzie Charlevoix Cheboygan	Crawford Emmet Gd Traverse Kalkaska Leelanau Manistee	Missaukee Montmorency Oscoda Otsego Presque Isle Wexford
8	Alger Baraga Chippewa Delta Dickinson	Gogebic Houghton Iron Keweenaw Luce	Mackinac Marquette Menominee Ontonagon Schoolcraft

Magnetic Resonance Imaging (MRI)

October 20, 2023

Chairperson James “Chip” Falahee
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

Dear Chairperson Falahee,

Corewell Health thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Magnetic Resonance Imaging (MRI) Services.

Corewell Health believes that continued regulation of MRI Services will serve the citizens of Michigan well. Should the Commission form a Standard Advisory Committee (SAC) or workgroup to review the MRI standards, we would request that the charge include consideration of adding adjustments for patients with implants or other metallic foreign bodies.

We at Corewell Health are committed to high-quality healthcare access for all patient populations. One population that may be underserved in the MRI space is patients with complex implants that require in-depth research, identification, and coordination prior to MRI imaging. These are implants such as pacemakers, defibrillators, stimulators, abandoned device leads, certain programmable shunts, cochlear implants, intracranial aneurysm clips, and shrapnel or other metallic foreign bodies (BB's, shrapnel, etc). We have developed a patient screening process and protocols that allow these patients with medical implants or other metal objects to be able to receive MRI scans safely.

For MRI studies involving pacemakers or defibrillators, similar resources are used as our IV sedation cases. Specifically, an advanced cardiovascular life support (ACLS)-trained RN and a vendor rep or physician are involved with every MRI performed on a patient with one of these devices.

We have found that approximately 1,350 patients per month meet the criteria for these scans, which demonstrates a need for access. Additionally, we estimate that each month approximately \$140,000 of loss avoidance occurrence, which helps contain costs.

It takes a considerable amount of time to prep patients for this screening. Additionally, part of the process may require longer time on an MRI unit as we have to run the machine at lower energy levels. This often results in a patient needing two-time slots to complete one scan. As such, we would recommend a potential SAC or workgroup consider additional additive factors be provided for facilities that perform this type of service.

We appreciate the Commission's consideration of our comments. Should you have any questions regarding these comments or if you would like any additional information, please contact David Walker, Public Policy Advisor, Corewell Health Government Relations & Public Policy, David.Walkerii@corewellhealth.org.

Sincerely,

A handwritten signature in blue ink that reads "John C. Shull". The signature is fluid and cursive, with the first name "John" and last name "Shull" clearly legible.

John C. Shull
Vice President, Imaging
Corewell Health



Ascension

October 20, 2023

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairperson Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2024: Magnetic Resonance Imaging (MRI).

Ascension Michigan supports the continued regulation of Magnetic Resonance Imaging (MRI) Services and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards for review in 2024. We look forward to working with the Commission this, and the coming year.

Sincerely,

Douglas J. Apple, MD, MS, FHM
Chief Clinical Officer, Ascension Michigan



October 16, 2023

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

Dear Commissioner Falahee,

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

HFH appreciates the work completed by the Workgroup in 2021 and into 2022. HF Health supports the continued regulation of MRI services and does not recommend any changes to the standards currently.

Respectfully,

A handwritten signature in black ink, which appears to read "Denise Brooks-Williams".

Denise Brooks-Williams, FACHE
Executive Vice President & Chief Executive Officer
Care Delivery System Operations



Trinity Health Michigan

October 20, 2023

James Falahee
Chair, CON 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 Magnetic Resonance Imaging (MRI) Services Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on what, if any, changes need to be made to the Certificate of Need Standards for Magnetic Resonance Imaging (MRI) Services in 2024.

Trinity Health Michigan believes the current Certificate of Need Standard ensures that Michigan's citizens have appropriate access to affordable, high-quality MRI services. Further, the current MRI Standards were updated in 2022 and have been effective for less than a year. For these reasons, Trinity Health Michigan supports the continued regulation of MRI Services without any further modification to the existing CON Standards.

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

Sincerely,

Shannon D. Striebich
President and CEO
Trinity Health Michigan Market



October 20, 2023

James Falahee - 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 Chairperson Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Magnetic Resonance Imaging (MRI). University of Michigan Health supports the continued regulation of this covered service; however, we believe the following topics should be considered for further study by a Standards Advisory Committee or Informal Workgroup:

1. Outpatient MRI-Guided Procedures without General Anesthesia:

We recommend a revision of the CON rules in Michigan to permit outpatient or conscious sedation MRI-guided procedures that do not necessitate general anesthesia or an inpatient status. The advancements in MRI technology have significantly enhanced the precision and safety of interoperative procedures. Allowing such procedures to be conducted on an outpatient basis can result in reduced healthcare costs, shorter hospital stays, and decreased risks associated with general anesthesia. This rule change aligns with the growing trend towards minimally invasive interventions and outpatient care, ultimately improving patient outcomes and satisfaction.

2. Enhanced Weighting for MRI-Guided Procedures:

In recognition of the increasing prominence of MRI-guided procedures, we propose a modification to the CON rules that assigns a heavier weighting to MRI-guided interventions during the evaluation of CON applications. This adjustment reflects the growing importance of MRI technology in driving innovation and improving patient care. As MRI-guided procedures often offer less invasive alternatives to traditional interventions, encouraging their adoption through a weighted evaluation system can accelerate the shift towards more effective and patient-friendly treatments.

3. Integration of MRI Volume Count for PET/MRI Utilization:

We suggest a refinement to the CON certification process by considering MRI volume counts when evaluating applications involving PET/MRI technology. If a PET/MRI system is utilized alongside MRI for imaging and interventions, the combined MRI volume should be factored into the adjusted procedure volumes for CON certification. This change acknowledges the synergy between the two

imaging modalities and encourages the adoption of cutting-edge technologies that offer comprehensive diagnostic and therapeutic capabilities.

Conclusion:

These proposed rule changes align with the evolving landscape of medical technology and patient-centered care. By allowing outpatient MRI-guided procedures without general anesthesia, emphasizing the significance of MRI-guided interventions, and integrating MRI volume counts for combined modalities like PET/MRI, Michigan's CON regulations can better accommodate advancements in medical practice and enhance patient outcomes while maintaining regulatory oversight. These changes reflect a proactive approach to healthcare innovation and are well-suited to position Michigan as a leader in modern, patient-focused healthcare practices.

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

Respectfully submitted,



T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief ESG Officer
University of Michigan Health
Michigan Medicine



Vikas Gulani, MD
Fred Jenner Hodges Professor of Radiology
Chair, Department of Radiology
University of Michigan Medical School
Michigan Medicine



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October 27, 2023

Mr. James Falahee, JD
Chairperson, Certificate of Need Commission
Michigan Department of Health and Human Services
South Grand Building, 4th Floor
P.O. Box 30195
Lansing, Michigan 48909

Re: Certificate of Need Review Standards for MRI Services

Chairperson Falahee,

Thank you for this opportunity to provide public comments regarding the CON Review Standards for MRI Services. MyMichigan Health supports the continued regulation of MRI services under Michigan's CON program. However, we do feel that there is room for improvement in these standards.

Specifically, we request that the Commission form a workgroup or standards advisory committee (SAC) to review the recently added provisions requiring CON approval to simply renew a lease on existing equipment. We understand that this was supported by the most recent MRI workgroup, but in talking with several members of that group, it would appear that there was a misunderstanding regarding how the provision would be used. We ask that this future review provide an opportunity for further discussion of the necessity for this provision.

In addition, we would request a review of opportunities to improve access to MRI in rural and micropolitan statistical area counties. Need is currently defined as excess volume within a certain distance of a proposed site. However, when a proposed site is too far from an existing service it can be impossible to demonstrate need, even though that distance itself would seem to demonstrate need based on geographic access. A possible solution to discuss is to allow a health system with a proposed site in a rural or micropolitan statistical area to utilize any one of its location's available adjusted procedures and necessary professional commitments as long as they are within the same HSA.

We appreciate your time in considering our requests. We would be happy to discuss this further as well as participate in a SAC or workgroup addressing these issues in the coming year.

Respectfully,

Sunita B. Vadakath
Senior Vice President and Chief Strategy Officer
MyMichigan Health

Psychiatric Beds (PB)



Ascension

October 20, 2023

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairperson Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2024: Psychiatric Beds and Services.

Ascension Michigan supports the continued regulation of Psychiatric Beds and Services and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards for review in 2024. We look forward to working with the Commission this, and the coming year.

Sincerely,

Douglas J. Apple, MD, MS, FHM
Chief Clinical Officer, Ascension Michigan

October 18, 2023

Chairperson James “Chip” Falahee
Certificate of Need Commission
c/o Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

Dear Chairperson Falahee,

Corewell Health appreciates the opportunity to provide written testimony on the CON Review Standards for Psychiatric Beds and Services (the standards).

Over the last few years, the standards have gone through two workgroups with numerous positive changes made. During the last workgroup, one minor change was recommended during the final meeting. Beds approved under the addendum for special population groups are required to maintain an 80 percent average annual occupancy. This is an unreasonable requirement.

When a patient is discharged from an inpatient unit any time prior to midnight and the next patient does not get admitted into that bed until after midnight, even if it is at 1 a.m., that counts as an empty bed for purposes of calculating occupancy. More common, at least in the inpatient psychiatric space, is for a patient to be discharged near the end of the day and another patient admitted the next morning. Statewide, the average length of stay for an inpatient psychiatric patient is 9 days. Using that average, if each bed has one empty night between each patient, they are already down to an average occupancy of 89 percent even if a patient was in the bed every day.

This phenomenon is more acutely felt in smaller units where those empty bed overnights reduce percentages at a faster rate. Most of these special pool units are smaller in size. Furthermore, for general inpatient psych beds (not special pool) the standards indicate that a unit operating at 75 or 80 percent occupancy, depending upon the size of the unit, can be added, recognizing that 75-80 percent occupancy is very high.

During the last workgroup meeting, there was unanimous agreement that the 80 percent occupancy requirement should be reduced to 60 percent. However, the Department raised concerns about the process of lowering the occupancy during the last meeting of the workgroup and wanted to make sure all stakeholders had the opportunity to weigh in on such a change.

As such, Corewell Health respectfully recommends that the Commission not try and seat a Standard Advisory Committee (SAC) or form a workgroup to address this issue. Rather, we recommend the Commission direct the Department to draft language to amend Section 9 of the Addendum for Special Population Groups to reduce the occupancy requirement for special pool beds from 80 percent occupancy to 60 percent occupancy. All major stakeholders are already aware of this proposed change from the workgroup and had the opportunity to raise concerns then and will again during the public comment period should this change move forward.

Opening a SAC or workgroup for such a widely supported and minor change would be a waste of resources and an inefficient way to address this issue. However, if concerns are raised during public comment, we would urge the Commission to form a workgroup rather than a SAC to review the issue.

While we are aware that the Department has never taken compliance action against a facility that was below 80 percent occupancy, we would feel more comfortable if the regulatory requirements reflected current practice.

We appreciate the Commission's consideration of our comments. Should you have any questions regarding these comments or if you would like any additional information, please contact David Walker, Public Policy Advisor, Corewell Health Government Relations & Public Policy, David.Walkerii@corewellhealth.org.

Sincerely,

A handwritten signature in black ink, appearing to be 'SJ', with a stylized flourish extending from the end.

Dr. Subodh Jain
Vice President, Department Chief, Behavioral Health
Corewell Health

October 16, 2023

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

Dear Commissioner Falahee,

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

HFHS appreciates the work the Workgroup did in 2022 and into 2023. HFHS supports the CON Commission's vote to support the recommended changes to the standards in 2023. We support the continued regulation of Psych Beds and Services and do not believe there are any additional changes to the standards currently.

Respectfully,



Denise Brooks-Williams
Executive Vice President & CEO
Clinical Delivery Service Operations



Lake Huron Medical Center

October 20, 2023

Mr. James Falahee, JD

Chairperson, Certificate of Need Commission

Michigan Department of Health and Human Services

South Grand Building, 5th Floor.

333 S. Grand Ave.

Lansing, Michigan 48933

Re: Certificate of Need Review Standards for Psychiatric Beds and Services

Chairperson Falahee,

Thank you for this opportunity to provide public comments regarding the CON Review Standards for Psychiatric Beds and Services. I am writing to request the Commission consider redistributing a portion of the unused special pool psychiatric beds from less utilized categories to the categories that have fewer beds available.

The Addendum for Special Population Groups sets aside 1,210 additional inpatient psychiatric beds to be distributed between several patient categories, both adult and child/adolescent. Of those categories, there are some that have been fully utilized and others that have experienced little interest. More specifically, there are two categories with more than 100 beds available consistently – Adult Developmental Disabilities currently with 173 available beds and Adult High Acuity with 234 available beds. We would request that the Commission consider taking some of the available beds from these categories and redistributing them to other adult categories to help improve access to needed inpatient psychiatric services.

I appreciate your time in considering this request and would be happy to discuss this further at the January CON Commission meeting.

Respectfully,

Jose Kottoor, CEO

October 20, 2023

James Falahee
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
MDHHSConWebTeam@michigan.gov

Re: Public Comments Re CON Review Standards for Psychiatric Beds and Services

Dear Mr. Falahee:

I am writing on behalf of Universal Health Services, Inc. (“UHS”), which operates Cedar Creek Hospital, Forest View Psychiatric Hospital, Havenwyck Hospital and Beaumont Behavioral Health, in response to the Notice of Public Comment Period posted by the Michigan Department of Health and Human Services (the “Department”) relating to the Certificate of Need (CON) Review Standards for Psychiatric Beds and Services (the “Psych Standards”). UHS thanks the Department and the CON Commission for their continued hard work in developing the Psych Standards.

UHS supports continued regulation of Psychiatric Beds and Services. However, UHS requests that the CON Commission form an Informal Workgroup to consider revisions to the definition of flex bed to allow for the conversion of an existing child/adolescent psychiatric bed to an adult psychiatric bed in an existing adult psychiatric service to improve flexibility in the use of flex beds to accommodate adult patients during peak periods and to meet adult patient demand. Specifically, UHS proposes that the CON Commission adopt the following charge for an Informal Workgroup to address:

Review and revise the definition of flex bed, the requirements for approval for flex beds, and the average occupancy rate calculations for a facility with flex beds, to allow for conversion of an existing child/adolescent psychiatric bed to an adult psychiatric bed in an existing adult psychiatric service to improve flexibility in the use of flex beds to accommodate adult patients during peak periods and meet adult patient demand when child/adolescent demand is low.

UHS proposes this charge because UHS facilities face a surge of adult patients during summer months and holidays when child/adolescent occupancy is low. UHS is forced to turn away adult patients that it could otherwise accommodate if it had the flexibility to utilize empty child/adolescent beds to serve adult patients.

James Falahee, Chairperson, Certificate of Need Commission

October 20, 2023

Page 2 of 2

Thank you for the opportunity to provide written comments. We look forward to working with the Department and the CON Commission in the coming year.

Sincerely,

A handwritten signature in black ink, appearing to read 'Jenifer Nyhuis', with a stylized, cursive script.

Jenifer Nyhuis
Regional Vice President
Universal Health Services

4866-6650-7912.1



UNIVERSITY OF MICHIGAN HEALTH
MICHIGAN MEDICINE

T. Anthony Denton, JD, MHSA
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October 20, 2023

James Falahee - 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 & Services - Certificate of Need Standards Review

Dear Chairperson Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need Review Standards for Psychiatric Beds & Services. University of Michigan Health supports the continued regulation of this covered service. However, with substantive revisions recently adopted by the CON Commission which went into effect March 6, 2023, and additional substantive recommendations awaiting Commission final action, we believe it is too early to objectively evaluate the impact these changes are having on cost, quality and access. University of Michigan Health recommends not reopening these standards until the next review cycle, but emphasizes its ongoing support for expanding flexibility to improve behavioral health access capacity for patients, families and communities.

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

Respectfully submitted,

T. Anthony Denton, JD, MHSA
Senior Vice-President & Chief ESG Officer
University of Michigan Health
Michigan Medicine

Gregory W. Dalack, M.D.
Chair, Department of Psychiatry
Daniel E. Offutt III Professor of Psychiatry
University of Michigan Health
Michigan Medicine