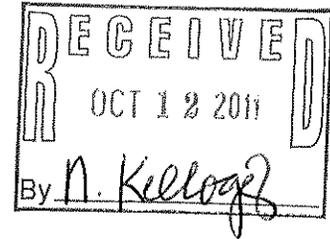


October 12, 2011



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

Dear Certificate of Need Commission:

This letter is written as formal testimony pertaining to the C.O.N. Review Standards for Bone Marrow Transplantation Services, Heart/Lung Transplantation Services, Magnetic Resonance Imaging (MRI) Services, Pancreas Transplantation Services, and Psychiatric Beds and Services, which are scheduled for review in 2012.

Bone Marrow Transplantation (BMT) Services:

Beaumont recommends the removal of BMT services from CON regulation or, at a minimum, mandate an institution specific methodology for BMT or autologous-only BMT. For the third time, Beaumont is formally requesting that BMT standards be modified or removed to allow large cancer centers to offer this service. The other two times, in 2006 and 2009, existing providers used the C.O.N. process to block patient access to BMT services even though need was shown using data. This is unacceptable: it is an abuse of the C.O.N. process and it threatens patient care.

The arguments supporting expanded BMT access are summarized in the attached letter from Beaumont's Chief of Oncology, which was sent prior to the 2009 SAC report to the Commission. We urge you to read and consider the arguments, which are supported by data. Note that since 2009, MDCH data shows that demand for BMT has gone up in Michigan.

We ask the Commission to remove BMT from C.O.N. coverage, which is authorized under Section 22215(1)(a) of PA 619. If the Commission chooses to retain BMT as a covered clinical service, we suggest that the Commission not establish another SAC, but utilize the Department or an unbiased consulting group to recommend an institution specific approach for establishing BMT or autologous-only BMT services (as provided for in Section 22215(1)(n) of PA 619).

Heart/Lung Transplantation Services:

Beaumont supports the continued regulation of heart/lung transplantation services. Beaumont recommends that the Commission consider an institution specific methodology for initiation of Heart/Lung transplantation services in lieu of comparative review.

Corporate Administration
3711 W. Thirteen Mile Rd.
Royal Oak, MI 48073-6769

Magnetic Resonance Imaging (MRI) Services:

Beaumont supports the continued regulation of magnetic resonance imaging services. Beaumont recommends that the Commission consider streamlining the process for documenting actual MRI utilization (Section 14) to make it more efficient for the applicant to comply.

Pancreas Transplantation Services:

Beaumont supports the continued regulation of pancreas transplantation services. These review standards have already been updated to be institution specific, so no further changes are recommended at this time.

Psychiatric Beds and Services:

Beaumont supports the continued regulation of psychiatric beds and services. No specific changes to these standards are recommended at this time.

Thank you for the opportunity to provide comment on these C.O.N. Review Standards.

Sincerely,



Patrick O'Donovan
Vice President, Planning

December 8, 2009

Certificate of Need Commission
201 Townsend
7th Floor, Capitol View Building
Lansing, MI 48913

Dear Commissioner:

I have closely followed the activities of the bone marrow transplant (BMT) standard advisory committee (SAC) and am distributed and disappointed with both the process and the results.

Since 2005, Beaumont Hospitals has been advocating that the Certificate of Need Commission loosen its 23-plus-year-old regulations on bone marrow transplants in order to allow for much needed access to this standard of care for patients in the state. Beaumont and St. John were both represented by physicians on the BMT SAC (Dr. Adil Akhtar from Beaumont; Dr. Michael Wiemann from St. John). It was clear from the first meeting that the SAC was not interested substantive discussion, as evidenced when a “straw vote” on whether to continue regulation (the first charge) was made within the first 15 minutes of the first SAC meeting. Despite the “writing on the wall”, Beaumont and St. John continued to make the case for improved BMT access for cancer patients, which was supported by data at every turn.

Beaumont and St. John demonstrated through the nationwide BMT data that CON regulation is not needed in the state of Michigan.

- Only nine states have any type of BMT regulation and only Michigan has a cap on the number of programs.
- The National Marrow Donor Program (NMDP) data shows that there is no difference in the number of programs per million people for states with and without BMT CON regulation, nor differences in patient outcomes.
- If BMT was not already a covered clinical service nobody would suggest, or be able to make a credible case, that it be added.

The SAC voted to continue to regulate BMT. Subsequently, Beaumont and St. John proposed an institution-specific methodology. Our goal was to provide the needed access for our patients, while using a data driven methodology for determining need. Many SAC members looked at “capacity” of existing programs (not a criteria in other CON-covered services) or the one dimensional characteristic of distance when considering access. Yet the data that we brought indicates there is an access problem throughout the entire state, not just the west side of Michigan.

- A 2006 New England Journal of Medicine article, which nobody on the SAC refuted, concluded that there is a BMT access problem by virtue of the fact that BMT is broadly underutilized, suggesting that BMT acc is compromised.
- BMTs are increasing worldwide. See figure 1.
- Older patients are becoming eligible for BMTs, and the number of elderly people in our state is increasing, therefore leading to increased demand for the service. See figures 2 and 3.
- The number of BMTs is increasing in Michigan. See figure 4.

- Compared to other states, Michigan ranks high in BMT eligible cancer incidence -- and has higher death rates – supporting the need for more access. See figures 5 and 6.
- BMTs are no longer experimental, they are standard of care as substantiated by comments made by a prominent University of Michigan (UofM) stem cell researcher on 760 WJR radio. (Dr. Eva Feldman, Director of the A. Alfred Taubman Medical Research Institute, December 1, 2009).
- Based on 2007 tumor registry data, Beaumont and St. John are behind only UofM in the number of new cancer cases diagnosed, and ahead of both Henry Ford and Karmanos.
- Capacity does not equal access. Beaumont and St. John physicians repeatedly discussed the importance of the doctor-patient relationship, especially for cancer patients. A Beaumont oncology nurse testified as to the strong bond that cancer patients develop with their oncologist, and that patients are often reluctant to leave their oncologist. There is no reason to disrupt the relationship at large cancer center capable of offering BMT. As a cancer physician this is clear to me but the SAC gave this little, if any, weight.

Despite the evidence showing need for more access, the SAC voted to continue the cap. SAC members continued to argue that because existing programs could take on additional patients there was no access problem in southeast Michigan. More troubling is the fact that no methodology at all was discussed to substantiate 3 programs on the east side of the state or the addition of 1 program on the west side of the state.

Determined to secure for our patients same additional access to this life-saving treatment, Beaumont and St. John came to the SAC with a proposal allowing autologous-only programs in Michigan:

- Autologous BMTs are a standard of care for multiple types of cancer. They are less risky and are less costly as compared to allogeneic because most are done on an outpatient basis.
- The autologous program offers the ability for collaboration and sharing of resources. Part of the SAC's charge was to discuss possible consortium approaches.
- The costs of autologous BMT are similar to chemotherapy, which is not even covered by CON.
- All large cancer programs already offer induction therapy with chemo drugs – autologous BMT is no different.
- The SAC not only voted against this approach, but established new volume requirements that exceed professional guidelines and make it impossible for a new program to perform autologous only BMTs. No such regulation exists anywhere in the U.S.
- Furthermore, without justification BMT is being treated differently than other covered clinical services, other transplant standards. For example, kidney transplants are not covered by CON at all, and pancreas has institution specific methodology based on the number of transplants performed.

The SAC is going to recommend we continue continuing the arbitrary cap of 3 programs in southeast Michigan. No one even knew how or why this number got to be 3. The SAC missed an important opportunity (and obligation) to use the expertise of members in order to establish a methodology based on data and need. The SAC will also assert that there is no access problem in southeast Michigan. This is a troubling notion to patients and families who, in one of the most stressful times of their lives, must leave their cancer treatment team. If CON loosened their restrictions on BMTs, there would not be an explosion of programs in the state. This could be assured through application of institution specific methodology with a sufficiently high threshold.

Note that at Beaumont, its capital cost to establish BMT is \$1.3 million, far less than the cost of many other, unregulated services.

The Commission should be concerned about the SAC process and the message it sends about the integrity of the CON program, and the impact on patients. Due to the composition, the outcome of the BMT SAC was predetermined and predictable, despite provision of data supporting the need for increased access, as well as good faith offer of compromise. We respectfully ask that the Commission remove BMT from CON coverage or, at a minimum, agree to quickly consider an institution specific methodology for BMT in total or for autologous-only BMT.

Sincerely,

Frank Vicini, MD
Corporate Chief of Oncology

Appendix:

Figure 1: Bone Marrow Transplants are Increasing Worldwide

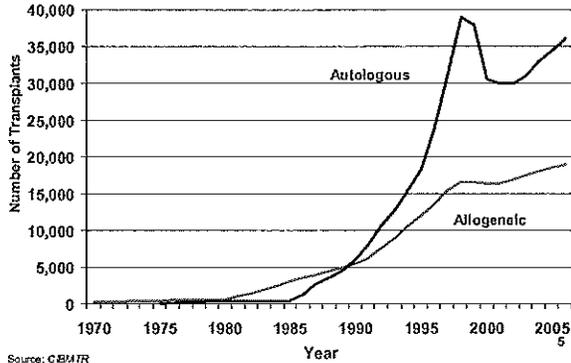


Figure 2: Older Patients Increasingly Eligible for BMT

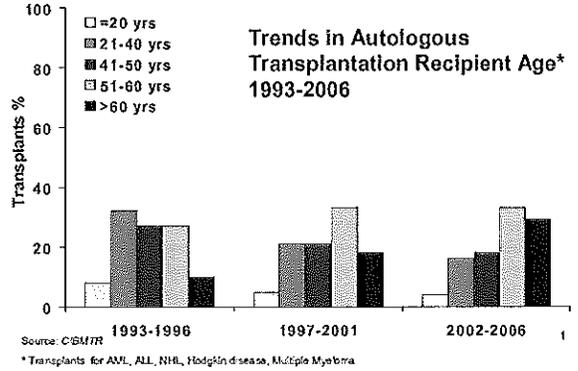


Figure 3: Older Patients Increasingly Eligible for BMT (Continued)

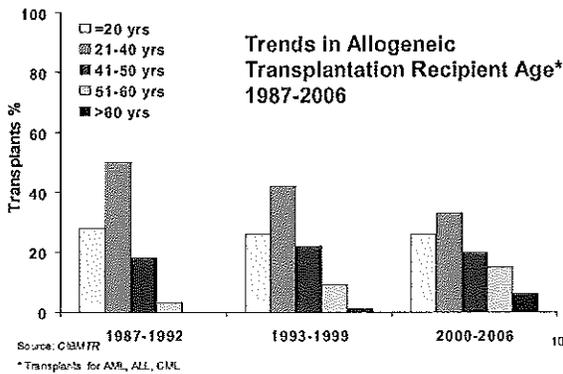


Figure 4: BMTs are Increasing in Michigan

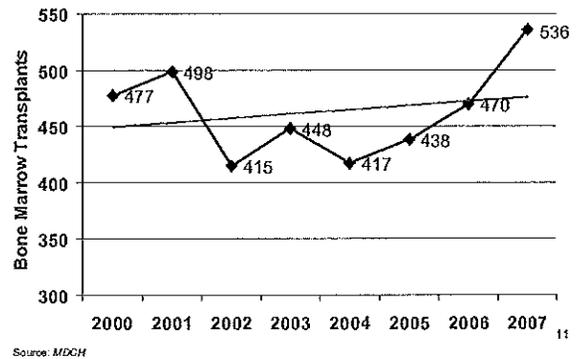
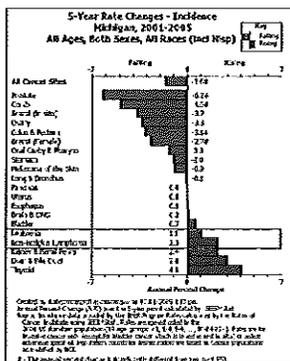


Figure 5: Annual Percentage Change in Cancer Incidence



Michigan experiencing rising rates of Leukemia and Non-Hodgkin Lymphoma

Figure 6: Michigan Ranks High in BMT Eligible Cancer Incidence & Death Rates

	Incidence Rates*			
	Michigan	Nation	Diff	Rank
Hodgkin's Lymphoma	3.2	2.8	0.4	11
Non-Hodgkin's Lymphoma	21.4	18.9	2.5	3
Leukemia	13.6	11.6	2.0	7
Myeloma	6.0	5.4	0.6	10

	Death Rates*			
	Michigan	Nation	Diff	Rank
Hodgkin's Lymphoma	0.5	0.5	0.0	10
Non-Hodgkin's Lymphoma	8.2	6.9	1.3	1
Leukemia	8.0	7.2	0.8	8
Myeloma	3.8	3.6	0.2	18

*Rates are per 100,000
Source: Centers for Disease Control and Prevention and National Cancer Institute, 2005 data

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734)647-1163
4. Email: sszelag@umich.edu
5. Standards: MRI
6. Testimony:

Content-Length: 19477



University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
Certificate of Need (CON) Review Standards for
Magnetic Resonance Imaging Services
October 19, 2011

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments relating to the Certificate of Need (CoN) review standards for Magnetic Resonance Imaging (MRI) Services.

UMHS supports the overall Michigan Department of Community Health (Department) regulations for this service; however, there are several points that should be addressed during the next review of the MRI Standards in 2012.

To assist in improving access and safety the Department should consider lowering the MRI Adjusted Procedure volume thresholds within the CoN Standards. The Standards currently in effect require applicants to demonstrate an average of 11,000 MRI Adjusted Procedures per unit for expansion of both hospital-based and freestanding services. This is a challenging requirement for providers to achieve, thus creating capacity constraints. These MRI constraints restrict access resulting in some patients being scanned using Computed Tomography (CT), when either modality is appropriate, exposing them to unnecessary CT radiation.

To further aid access and safety improvement the Department should study the benefits of allowing greater clinical use of MRI scanners used in a hybrid configuration. The Standards currently in effect address this for Intra-Operative MRI and should be considered for other hybrid MRI modalities. These modalities include, but should not be limited to: MRIs used in conjunction with a Linear Accelerator, Positron Emission Tomography or an Electro-Physiology laboratory.

Lowering the MRI Adjusted Procedure volume threshold and allowing greater clinical use of MRIs used in a hybrid configuration would also have positive impacts on operating and capital costs. Additional capacity may reduce many providers' need to operate MRI services for extended hours and greater clinical use of MRI in a hybrid configuration would allow providers the opportunity to better utilize a high-cost, low-volume piece of equipment.

Lastly, the Department should also investigate a "system view" of imaging asset deployment. Healthcare delivery systems with multiple licensed and/or unlicensed medical facilities, under common ownership, require flexibility to improve "point-of-service" care based on changing demographics and demand. The existing CoN Standards for Replacement and Relocation are somewhat restrictive and may not adequately meet the specific needs of the applicant. Regulations currently exist for the movement of licensed medical/surgical beds between multiple licensed facilities under common ownership. Similar regulations for other CoN Covered Services would significantly improve access to healthcare.

Thank you for according us the opportunity to make this statement today.

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734) 647-1163
4. Email: sszelag@umich.edu
5. Standards: HLL
6. Testimony:

Content-Length: 17158



University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
Certificate of Need (CON) Review Standards for
Heart/Lung & Liver Transplantation Services
October 19, 2011

My name is Steven Szlag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments relating to the Certificate of Need (CoN) review standards for Heart/Lung & Liver Transplantation Services.

With substantive changes to the standards, allowing for an incremental program, approved by the CON Commission in March of 2010, it is too early to objectively evaluate the effects these changes are having on cost, quality and access. UMHS recommends not making any revisions to the current standards and waiting until the next review cycle in 2015.

Thank you for according us the opportunity to make this statement today.

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: (734) 647-1163
4. Email: sszelag@umich.edu
5. Standards: BMT
6. Testimony:

Content-Length: 17730



University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
Certificate of Need (CON) Review Standards for
Bone Marrow Transplantation Services
October 19, 2011

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments relating to the Certificate of Need (CoN) review standards for Bone Marrow Transplantation (BMT) Services.

UMHS believes the CoN Standards for BMT should not be re-opened at this time. Based on expert clinical opinion, capacity in Michigan appears to be adequate and forecasts indicate no drastic change in the number of patients requiring this therapy. Continued replication of this high cost, low volume service at additional locations within the State could adversely impact quality and research potential by diluting the available patient population, yet would not yield any significant access benefits.

Also, with substantive changes to the CoN standards, allowing for an incremental program, approved by the CON Commission in March of 2010, it is too early to objectively evaluate the effects these changes are having on cost, quality and access. UMHS recommends not making any revisions to the current standards and waiting until the next review cycle in 2015.

Thank you for according us the opportunity to make this statement today.

1. Name: Loren Rhoad
2. Organization: Alliance-HNV
3. Phone: (269) 329-3501
4. Email: rhoadl@hmv-hnhs.com
5. Standards: MRI
6. Testimony: As one of the largest mobile MRI service companies operating in the State of Michigan, Alliance-HNV has applied nearly every section of the MRI CON Review Standards. Because of the diverse nature of our operations across the State we have experienced many outcomes when applying the standards û both foreseeable and unforeseeable.

The largest issue our customers have experienced of late revolves around minimum volume requirements. A large number of host sites and mobile units are operating below the minimum volume requirements. The Department has taken steps with other sets of CON Standards to reduce or eliminate the minimum volume requirement for replacement so that state of the art equipment is available across the board. The MRI Standards should be adjusted to be consistent with the policy premise articulated in the CT and PET Standards. In our experience, new initiations continue to be filed at the expense of existing operators. Because of the overlay of Federal Stark and anti-kickback laws, minimum volume requirements are unattainable in some replacement scenarios. Consequently new initiations by unproven entities can purchase new equipment, but existing operators with a proven track record cannot replace equipment.

Another area of concern weÆve encountered relates to upgrades and repairs. Applicants requesting an upgrade below the existing upgrade threshold shouldnÆt be subject to the replacement standards in order to utilize a temporary mobile unit. If the project costs (including lease of a temporary mobile) are less than \$750,000 the entire project should be considered part of the upgrade.

In summary, we recommend evaluation of the threshold for initiation û taking into consideration the existing services in a community that is proposing new equipment. We also recommend review of a volume requirement for replacement. Finally, we recommend modification of the upgrade language to allow for utilization of a temporary mobile in the event the entire project is less than \$750,000.

As always we appreciate the time and consideration the CON Commission and Department of Community Health take in reviewing CON covered clinical services. We will make ourselves available to participate in whichever process the Commission deems appropriate in addressing the MRI Standards.

7. Attachment:

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: 616-391-2779
4. Email: bob.meeker@spectrumhealth.org
5. Standards: MRI
6. Testimony:

Content-Length: 34903



Spectrum Health Butterworth Hospital
100 Michigan Street NE
Grand Rapids, MI 49503-2560
616.391.1774 fax 616.391.2745
spectrum-health.org

October 19, 2011

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

Dear Commissioner Falahee,

This letter is written as formal testimony for the CON Review Standards for Bone Marrow Transplant Services. It is the position of Spectrum Health that the Bone Marrow Transplant Services Standards should not be opened for review at this time. The CON Review Standards for Bone Marrow Transplant were thoroughly discussed and revised three (3) years ago, and they are serving the state very well. As a result, we believe that these standards do not require further revision.

Spectrum Health appreciates the opportunity to present our comments about the CON Review Standards for Bone Marrow Transplant Services.

Sincerely,

A handwritten signature in blue ink, reading "Robert A. Meeker". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Robert A. Meeker
Strategic Program Manager
Spectrum Health

Spectrum Health Butterworth Hospital
100 Michigan Street NE
Grand Rapids, MI 49503-2560
616.391.1774 fax 616.391.2745
spectrum-health.org

October 19, 2011

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

Dear Commissioner Falahee,

This letter is written as formal testimony for the CON Review Standards for MRI Services. It is the position of Spectrum Health that the MRI Services Standards should be opened for review at this time. Although we believe that the CON Review Standards for MRI Services have served Michigan based hospitals and healthcare organizations very well it is our position that the MRI data reporting system is burdensome to both the providers in the state and to the state itself to administrate. With that being said we propose that an evaluation of the MRI data reporting system should be conducted at this time. In the pursuit of the reduction of inefficiencies for providers and the MDCH it is our recommendation that the MRI data reporting requirements be reviewed for opportunities to streamline some of the processes involved in the reporting of MRI data to the MDCH.

Spectrum Health appreciates the opportunity to present our comment and to offer our assistance in the review of the current CON Standards for MRI Services.

Sincerely,



Manager, Strategic Programs
Spectrum Health

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: 616-391-2779
4. Email: bob.meeker@spectrumhealth.org
5. Standards: HLL
6. Testimony:

Content-Length: 33787

Spectrum Health Butterworth Hospital
100 Michigan Street NE
Grand Rapids, MI 49503-2560
616.391.1774 fax 616.391.2745
spectrum-health.org

October 19, 2011

James B. Falahee, Jr, Chairperson
Certificate of Need Commission
C/o Michigan Department of Community Health
Certificate of Need Policy Section
Capitol View Building, 201 Townsend Street
Lansing, Michigan 48913

Dear Commissioner Falahee,

This letter is written as formal testimony about the CON Review Standards for Heart, Lung and Liver Transplant Services that went into effect May 28, 2010. Spectrum Health appreciates the opportunity to comment on these Standards. The Heart, Lung and Liver Transplant Standards have served the citizens and providers in the State of Michigan very well and therefore we believe that there is no need to open the Heart, Lung and Liver Transplant Standards at this point in time.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for Heart, Lung and Liver Transplant services.

Sincerely,



Robert A. Meeker
Strategic Program Manager

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: (248) 596-1006
4. Email: Dennismccafferty@EAMOnline.org
5. Standards: Psych Beds
6. Testimony: PSYCHIATRIC BEDS AND SERVICES

We know of no issues that would warrant a review of these standards other than any technical changes recommended by the Department. We will wait until we see what issues, if any, are raised in the public testimony.

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: (248) 596-1006
4. Email: Dennismccafferty@EAMOnline.org

5. Standards: Pancreas

6. Testimony: PANCREAS TRANSPLANT SERVICES:

This standard was reviewed in 2009 and revised to allow for two additional providers to re-start their programs. The new standards now use the number of kidney transplants performed by an institution as the surrogate for proficiency in pancreas transplants. Because of the limited availability of pancreas for transplant, revising the standards to allow additional provider is unnecessary. We recommend that only technical changes recommended by the Department be considered and that a SAC need not be set-up for a review of this standard.

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: (248) 596-1006
4. Email: Dennis mccafferty@EAMOnline.org

5. Standards: MRI

6. Testimony: MAGNETIC RESONANCE IMAGING (MRI) SERVICES

The existing standards have been successful in optimizing the utilization of the MRI units in the state. Patient's concern related to the high-dose radiations levels from CT may be resulting in shifting imaging volume to MRI units. We understand that MRI technology is changing and merging with other means of diagnostic imaging technology and as a support for therapeutic procedures. We also understand that the current CON required reporting requirements for MRI services may be burdensome to the providers and should be reviewed. We would support the establishing of a SAC to review these standards.

7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: (248) 596-1006
4. Email: Dennismccafferty@EAMOnLine.org
5. Standards: HLL
6. Testimony: HEART- HEART/LUNG AND LUNG TRANSPLANT SERVICES:
This standard was reviewed in 2009 and a new adult program was added to the west-side of the state in 2010 to address perceived needs for geographical patient access. Volume is constrained by the supply of organ for transplantation and not upon any restrictions on the number of providers. We believe it is too soon to re-open these standards to consider changes that may result in more providers. We recommend that only technical changes recommended by the Department be considered and that a SAC need not be set-up for a review of this standard.
7. Attachment:

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: (248) 596-1006
4. Email: Dennismccafferty@EAMOnline.org

5. Standards: BMT

6. Testimony: BONE MARROW TRANSPLANTATION SERVICES:

This standard was reviewed in 2009 and a new, 4th adult program was added to the west-side of the state to address perceived needs for geographical patient access. This program didn't get started until 2010. Volume has increased only slightly since Karmanos implemented their program in 2007. The arguments for Autologous only programs were thoroughly reviewed during this most recent review and were rejected. Unless there is new compelling evidence that would alter this discussion, re-visiting this argument would not be fruitful. We believe it is too soon to re-open these standards to consider changes that may result in more providers. We recommend that only technical changes recommended by the Department be considered and that a SAC need not be set-up for a review of this standard.

7. Attachment:

1. Name: Karen Kippen
2. Organization: Henry Ford Health System
3. Phone: 313-874-6985
4. Email: kkippen1@hfhs.org
5. Standards: Psych Beds
6. Testimony:

Content-Length: 327698



Karen E. Kippen
Henry Ford Health System
Director, Strategic Planning
One Ford Place
Detroit, MI 48202
October 15, 2011

Corporate Planning

1 Ford Place, 3B
Detroit, MI 48202-3450
(313) 874-5000 Office
(313) 874-4030 Fax

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

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

HFHS strongly supports the continued regulation of Psychiatric Beds and Services. We also support the creation of a Standard Advisory Committee (SAC) to review, update and clarify current standards. Proposed areas of focus:

- Review /revise the appropriate time period for calculation of average daily occupancy for both adult and child beds. Currently the 24 month period does not allow flexibility to allow for changes in physician staffing and patient populations.
- Review the impact of the current average occupancy rate percentages on patient access and providing service in a changing market for both adults and children.
- Clarify language relating to replacement and relocation of beds to facilities within planning areas. This may be an opportunity to standardize language between hospital bed services (currently under review) and psychiatric bed services.

We look forward to working with the Commission and the Department and believe a SAC would be the most appropriate way to address these issues.

Respectfully,

A handwritten signature in blue ink that reads "Karen E. Kippen".

Karen Kippen
HFHS, Corporate Planning

1. Name: Karen Kippen
2. Organization: Henry Ford Health System
3. Phone: 313-874-6985
4. Email: kkippen1@hfhs.org
5. Standards: Pancreas
6. Testimony:

Content-Length: 299331



Karen E. Kippen
Henry Ford Health System
Director, Strategic Planning
One Ford
Detroit, MI 48202
October 15, 2011

Corporate Planning

1 Ford Place, 3B
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(313) 874-4030 Fax

James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on the following Certificate of Need (CoN) review standards:

- Pancreas Transplantation Services
- Heart/Lung and Liver Transplantation Services
- Bone Marrow Transplantation Services

HFHS strongly supports the continued regulation of all the above transplantation services and supports those regulations in their current form without revisions.

Two of the review standards, Heart/Lung and Liver and Bone Marrow, had Standard Advisory Committees (SACs) created to update and revise the standards after extensive research and thorough consideration by experts, payors and consumers in 2010. The Pancreas Transplant Standards were reviewed and revised by a workgroup in 2009.

The revisions made during that work and approved by the Commission have enabled service providers to effectively meet the transplantation needs of the people of Michigan providing timely access, high quality and low cost services.

Respectfully,

A handwritten signature in blue ink that reads "Karen E. Kippen".

Karen Kippen
HFHS, Corporate Planning

1. Name: Karen Kippen
2. Organization: Henry Ford Health System
3. Phone: 313-874-6985
4. Email: kkippen1@hfhs.org
5. Standards: HLL
6. Testimony:

Content-Length: 299331



Karen E. Kippen
Henry Ford Health System
Director, Strategic Planning
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Detroit, MI 48202
October 15, 2011

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James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on the following Certificate of Need (CoN) review standards:

- Pancreas Transplantation Services
- Heart/Lung and Liver Transplantation Services
- Bone Marrow Transplantation Services

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The revisions made during that work and approved by the Commission have enabled service providers to effectively meet the transplantation needs of the people of Michigan providing timely access, high quality and low cost services.

Respectfully,

A handwritten signature in blue ink that reads "Karen E. Kippen".

Karen Kippen
HFHS, Corporate Planning

1. Name: Karen Kippen
2. Organization: Henry Ford Health System
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5. Standards: BMT
6. Testimony:

Content-Length: 299331



Karen E. Kippen
Henry Ford Health System
Director, Strategic Planning
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Detroit, MI 48202
October 15, 2011

Corporate Planning

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James B. Falahee, Jr, J.D.
CoN Commission Chairperson
Capital View Building
201 Townsend Street
Lansing, MI 48913

Dear Commissioner Falahee:

Henry Ford Health System (HFHS) would like to offer comments on the following Certificate of Need (CoN) review standards:

- Pancreas Transplantation Services
- Heart/Lung and Liver Transplantation Services
- Bone Marrow Transplantation Services

HFHS strongly supports the continued regulation of all the above transplantation services and supports those regulations in their current form without revisions.

Two of the review standards, Heart/Lung and Liver and Bone Marrow, had Standard Advisory Committees (SACs) created to update and revise the standards after extensive research and thorough consideration by experts, payors and consumers in 2010. The Pancreas Transplant Standards were reviewed and revised by a workgroup in 2009.

The revisions made during that work and approved by the Commission have enabled service providers to effectively meet the transplantation needs of the people of Michigan providing timely access, high quality and low cost services.

Respectfully,

A handwritten signature in blue ink that reads "Karen E. Kippen".

Karen Kippen
HFHS, Corporate Planning

1. Name: Azzam S. Kanaan, M.D.
2. Organization: Southwest Michigan Imaging Center, L.L.C.
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4. Email: hbo@kniimaging.com
5. Standards: MRI
6. Testimony: Please see attached PDF document

Content-Length: 58088

October 13, 2011

Brenda Rogers
Lewis Cass Building
320 S. Walnut
Lansing, MI 48913

VIA email: RogersBre@michigan.gov

Dear Ms. Rogers:

Currently, in addition to other requirements, the MRI Standards specify utilization thresholds applicable to replacement of mobile units. As a mobile provider to many smaller rural hospitals we have a concern regarding the utilization requirements. We would like to have our comments in this letter entered into the Public Hearing from October 12, 2011 pursuant to the upcoming review of the MRI Standards scheduled for 2012.

As a mobile provider to many smaller rural community hospitals, we are concerned regarding the utilization threshold requirements.

All of our mobile MRI units are well maintained and upgraded to the most current software release. Nevertheless, several of our mobile units will be reaching the end of their technical life (as specified by their vendors) in late 2011 and 2012. This means that within the next three to five years support from the original manufacturer will no longer be available and replacement parts may eventually not be obtainable.

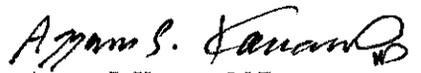
Most of the large hospital sites that we previously served have been able to convert to fixed units and we are now serving only the smaller, low volume community hospitals. It is these hospital sites that have us concerned. Their volumes do not meet the current regulation thresholds for replacement. However, MRI has become a standard of care for most hospitals. Not being able to replace these units due to low volume, will leave the small hospitals with technologically inferior equipment and eventual complete loss of service.

This issue, of course, is an issue for any mobile MRI provider, not just Midwest Mobile Diagnostic Imaging.

We are aware that the CON Commission approved new replacement language for PET and CT that address the threshold utilization concern. We would like to urge the Department to draft similar language for MRI replacement when the MRI standards are reviewed in 2012. We are supportive of using the same Language for all covered clinical equipment standards to prevent interruption or loss of service to smaller communities.

We urge your support to use the new Language for the PET and CT Standards for replacement, for MRI equipment replacement when the MRI standards are reviewed in 2012.

Sincerely,


Azzam S. Kanaan, M.D.
C.E.O.

cc: Scott Blakeney
Sally Flanders

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: BMT
6. Testimony: Dear Chairman Falahee and Con Commisioners:

Thank you for the opportunity to submit comments on behalf of Ascension Health - Michigan to modify CON BMT standards. AH-MI recommends the separation of Allogenic and Autologous BMT services. It is further strongly recommended that the Commission consider the removal of Autologous BMT as a CON covered service. As of 2009, only eight (8) states regulated BMT and no state, other than Michigan has a cap on the number of BMT programs. There is no difference in the numbers of BMT programs per population between regulated and non-regulated states. There is no correlation between mortality and whether BMT programs are regulated or not regulated. Costs of BMT services are no more than other cancer treatments and Autologous stem cell transplants are no more complicated than induction chemotherapy for acute leukemia.

A 2006 New England Journal of Medicine article stated the BMT is a widely underutilized procedure. Michigan has among the highest cancer incidence rates and cancer death rates for cancers that could be treated by BMT

Although BMT does not guarantee an eradication of the disease, transplants have been shown to increase the likelihood of prolonged survival if not a cure. Advancements behind the science of BMT have opened the door for a wide array of diseases potentially eligible for transplantation, thus improving the treatment options to patients with hard to treat diseases like lymphoma and leukemia. Today, the majority of care provided on pre-procedural basis as well as the follow-up care can be provided in an outpatient setting. This limits the length of hospitalization and the costs associated with delivering this service.

The rationale for separating and eliminating Autologous BMT services can be explained as follows:

- ò Costs associated with alternative therapies are more expensive than the BMT procedure and follow-up treatment
- ò Quality related to BMT programs and practitioners is determined and monitored by a well-regarded accrediting body, the Foundation for the Accreditation of Hematopoietic Cellular Therapy (FAHCT)
- ò Access to BMT should be made available at community cancer centers where earlier treatment of cancer patients has shown to improve survival rates.

Should the Commission see a need for retaining Autologous BMT services as a CON covered clinical service, we request that the Commission establish distinct standards applicable for Autologous only BMT programs. These standards should include an institution specific need methodology, no limit to the number of

programs in the planning areas and a requirement that the program become accredited by the Foundation for the Accreditation of Hematopoietic Cellular Therapy (FACHT).

Thank you for the opportunity to comment.

7. Attachment:

1. Name: Carol Christner
2. Organization: Barbara Ann Karmanos Cancer Institute
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5. Standards: BMT
6. Testimony:

Content-Length: 646232

Certificate of Need Commission 2012 Workplan Public Hearing

Comments Regarding: CON Review Standards for Bone Marrow Transplantation
Comments Submitted by: Joseph Uberti, M.D., Ph.D.
Service Chief, Department of Hematology and Oncology
Co-Director, Blood and Marrow Stem Cell Transplant
Barbara Ann Karmanos Cancer Institute

On March 25, 2010, the CON Commission adopted newly revised standards for Bone Marrow Transplantation (BMT) that allowed for the addition of a new planning area, with one adult program in western Michigan, based on the planning zones for pediatric BMT services. The new standards also continued regulation of BMT services and required adult services to perform a minimum of 30 transplants, of which at least 10 must be allogeneic.

The Barbara Ann Karmanos Cancer Institute supports the standards approved by the Commission less than 18 months ago; there have been no significant changes in the field of BMT that would warrant revisions to the standards in 2012. There has been no significant change to the number of transplants conducted, geographic barriers have been addressed, and there continues to be excess bed capacity.

In past years, others have maintained that a needs based methodology for BMT is preferred to a planning area threshold. The rationale for this methodology has been repeatedly disproven and continues to hold no merit when BMT standards are reviewed. This methodology is an attempt to predict the number of transplants based on the number of cancer patients seen in any area. To be effective, a needs based methodology must rely on an accurate assessment and estimation of the number of patients requiring a transplant. Presentation and discussion during the 2006 workgroup and the 2009 SAC indicated how difficult this estimation would be. The number of cancer cases seen at any individual center has no correlation to how many patients would ultimately require a transplant. Bone Marrow Transplant is often used in patients who have either advanced disease, relapsed disease or have failed several therapies. This data is not captured by any needs based methodology of cancer cases seen in any area. In addition, the use of transplantation as a therapeutic modality is altered by new results and newer therapies. As an example, the Karmanos Cancer Center has seen the number of transplants for breast cancer go from a high of 152 in a year to one to two per year. These changing practice patterns make long term predictions difficult.

The Standards approved in 2010 address all three major tenets of CON:

COST

Michigan's existing BMT programs provide a stable environment for patients, payers and providers. Establishing a BMT program is an extremely expensive undertaking. In March 2009, the Advisory Board projected that an average size unit would require start-up and maintenance costs of \$1,300,000. This amount does not take into consideration nursing and patient care expenses which cost Karmanos in excess of \$7,000,000 annually.

Transplantation is an extremely expensive procedure, sometimes requiring a 30 day hospitalization for many of our autologous patients. While some of these transplants may start as an outpatient

procedure, they are often accompanied by prolonged hospitalizations due to toxicity from high dose chemotherapy, infections or bleeding, and may ultimately result in death.

Quality

Michigan's four existing adult programs provide outstanding quality. To maintain the quality patients deserve and BMT guidelines require, experienced staff is needed. Shortages of transplant physicians, physician assistants, nurse practitioners, nurses and the support personnel who are needed to take care of transplant patients continue to be an obstacle in the field of BMT. Adding more programs will simply result in the cannibalization of existing programs, effectively decreasing their quality.

It has previously been argued that new BMT programs in the state are needed to allow patients to remain under the care of their current oncologist. All patients referred to Karmanos for BMT continue to have close contact with their referring physician. The BMT multi-disciplinary team at Karmanos is committed to developing a strong working relationship with referring physicians to help ease the patients' transition to our facility for transplantation. Pre and post treatment tests are performed by the referring physician as frequently as possible, eliminating duplicity or added burden for the patient. Patients return to their original physician as soon as possible after transplantation for additional care.

It has also been argued that Karmanos has turned away patients in need of transplantation. This is true. There are patients referred to us who potentially would benefit from transplantation, however, underlying medical conditions such as heart or lung problems may not make them a viable candidate. This is in keeping with the highest standards of medical care that any credible hospital would adhere to.

Access

There continue to be no barriers to access for BMT. The existing programs have sufficient capacity to address the needs of the patient population and the addition of an adult program in Grand Rapids has answered concerns related to geographic barriers.

Previous arguments for more programs indicated that there is an underutilization of transplantation due to access issues, however there has never been any evidence that any alleged underutilization was due to a lack of capacity or sufficient transplant centers. What does effect underutilization, according to the NEJM, are poor insurance, poor socioeconomic issues and poor referral patterns.

These issues are not rectified by opening up more programs but by better physician and patient education, better insurance and a better economy. These issues would also be improved by increasing the number of available donors. However to increase the number of transplants by 1% we would need to add an additional 7,000,000 donors to the registry.

CONCLUSION

The Barbara Ann Karmanos Cancer Institute believes there is no need for the Commission to review the Bone Marrow Transplant Standards in 2012. Doing so will simply lead to recirculation of the same arguments that were disproven during the 2006 workgroup, the 2009 SAC and the continued testimony that lasted until the final approval of the SAC's recommendations which took effect less than 18 months ago.

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5. Standards: Pancreas
6. Testimony:

Content-Length: 17126



University of Michigan Health System
1500 East Medical Center Drive
Ann Arbor, MI 48109

Public Testimony
Certificate of Need (CON) Review Standards for
Pancreas Transplantation Services
October 19, 2011

My name is Steven Szelag and I am a Strategic Planner at the University of Michigan Health System (UMHS). UMHS wishes to take this opportunity today to offer comments relating to the Certificate of Need (CoN) review standards for Pancreas Transplantation Services.

With substantive changes to the standards, allowing for incremental programs, approved by the CON Commission two years ago, it is too early to objectively evaluate the effects these changes are having on cost, quality and access. UMHS recommends not making any revisions to the current standards and waiting until the next review cycle in 2015.

Thank you for according us the opportunity to make this statement today.