From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 4:41 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: 734-647-1163
4. Email: sszelag@umich.edu
5. Standards: Psych
6. Testimony: My name is Steven Szelag and I am a Senior Health System 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 Psychiatric Beds & Services.

With substantive changes approved by the CON Commission less than one (1) year ago, it is probably too early to objectively evaluate the effects the changes are having on cost, quality and access. UMHS recommends not making any changes to the current standards and waiting unit the next review cycle in 2012.

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

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/14/2008 4:26 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Meg Tipton
2. Organization: Spectrum Health Hospitals
3. Phone: 616-391-2043
4. Email: meg.tipton@spectrum-health.org
5. Standards: MRI
6. Testimony: October 16, 2008

Edward B. Goldman, Chair
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 Goldman,

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 not be opened for review at this time. We believe that the CON Review Standards for MRI Services have served Michigan based hospitals and healthcare organizations very well. These standards have assured the availability of sufficient MRI services to meet the needs of Michigan citizens, while enabling MichiganÆs health care organizations to provide quality care to their patients and therefore we do not suggest revisions or review of the current CON Review Standards for MRI Services.

Spectrum Health appreciates the opportunity to present our comment on the current CON Standards for MRI Services.

Sincerely,

Meg Tipton
Strategic Regulatory Associate
Spectrum Health

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/17/2008 10:17 AM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Rob Covert
2. Organization: Oaklawn Hospital
3. Phone: (269) 789-3924
4. Email: kcrowell@oaklawnhospital.com
5. Standards: MRI
6. Testimony: October 16, 2008

Mr. Edward B. Goldman, J.D.
Chairman
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend Street, 7th Floor
Lansing, Michigan 48913

Dear Chairman Goldman,

On behalf of Oaklawn Hospital in Marshall, Michigan, we appreciate this opportunity to provide comments on the MRI standards up for review in 2009. Oaklawn Hospital is a 94-bed hospital with more than 800 employees and 90 active staff physicians providing 30 specialties. We have received the GovernorÆs Award of Excellence, and we were recently named as one of the 100 Best Places to Work in Healthcare in the nation by Modern Healthcare magazine. In CMSÆ most recent release of patient satisfaction data, Oaklawn Hospital was above state and national averages in all ten categories.

Some of our recent clinical accreditations and recognitions include:
ò Joint Commission, full, unconditional accreditation, June 2008
ò Cardiopulmonary Services Department, Quality Respiratory Care Recognition by the American Association for Respiratory Care, a designation given to just 10% of hospitals nationally.
ò Laboratory maintains accreditation by the Commission on Laboratory Accreditation of the College of American Pathologists (CAP), the most stringent accreditation available.
ò Radiology Department maintains accreditation by the American College of Radiology.
ò OaklawnÆs joint replacement program has earned a 2009 Top 5% in the Nation designation by HealthGrades for clinical outcomes.

Oaklawn has been providing mobile MRI service since 1991. We currently receive mobile service five days per week and have considered increasing to seven days per week. However, in considering our options, it has become clear to us that our hospital

needs a fixed MRI unit available 24 hours per day, not 7 days per week of mobile service available only 12 hours per day.

Our Emergency Department sees more than 20,000 patients each year, with patients arriving during all hours of the day and night. From a practical standpoint, when we purchase mobile MRI service, it is available from 7:00 am to 7:00 pm, leaving our nighttime patients unserved by MRI until the next morning. Although we have a fixed CT scanner which provides us with a diagnostic tool to care for most of our emergency patients, there are still numerous patients who arrive at our Emergency area with conditions requiring MRI for optimum diagnosis and we are unable to provide that tool.

With recent literature confirming the superiority of MRI over CT in detecting acute strokes, especially in ischemic strokes which can be treated within the first three hours of symptoms with Thrombolytic therapy resulting in improved patient outcomes, the need for a fixed MRI becomes even more apparent. (See attached article from The Lancet, January 27, 2007.) For example, when patients arrive who are exhibiting symptoms of stroke, we would be able to diagnose the stroke, analyze the size, and determine if the use of TPA is appropriate with an MRI scan. However, if that patient arrives when the mobile trailer is not parked at our facility, we must instead turn to other, less precise, methods of diagnosis.

Reducing exposure to radiation, especially in adolescent patients, is also a significant goal. While certain conditions require CT for diagnosis, there are many other conditions that could be diagnosed with MRI rather than CT as a way to reduce exposure to radiation. It is important to remember that MRI utilizes magnetic fields to create diagnostic images, whereas CT uses radiation. Exposure to radiation through the use of diagnostic CT was an issue raised at the CT Standards Advisory Committee last year. On October 10, 2007, Tom Slovis, MD, from the Detroit Medical Center, presented the SAC with evidence connecting pediatric exposure to CT with adult onset of cancer. Dr. SlovisÆ testimony reported that between 1 in 2,000 and 1 in 10,000 children receiving head or abdominal CT end up with cancer. He added, ôConsidering we are doing over 3 million CTs per year on children, this is a large public health problem.ö

Because any radiation exposure can cause cancer, according to Dr. Slovis, no dose of radiation can be considered safe, and therefore we must look for alternative modalities for diagnosing patients. Having these other modalities available is crucial. As Dr. Slovis put it, ôIf your only tool is a hammer, you use it for inserting nails, screws, or fixing things. If you only have CT available 24/7, then thatÆs what youÆll use when nothing else is available.ö This ever-increasing exposure to radiation through diagnostic studies needs to be of major concern, and we must look for ways to reduce radiation exposure; utilizing MRI in place of CT as a diagnostic tool should be encouraged whenever it is appropriate.

We understand that the purpose of Certificate of Need is to ensure quality and access, while restraining the rising cost of health care. Having addressed access and quality above, this leaves us only to look at cost. Based on our current costs for obtaining

service from existing mobile MRI routes, we have determined that it is less expensive for us to acquire a fixed MRI unit rather than pay for mobile service seven days per week.

More specifically, assuming the cost of mobile service stays consistent with current contracts and a $2 million price tag for a fixed MRI unit, our hospital would save in excess of $1 million by replacing our mobile MRI service with a fixed MRI unit. Additionally, as already noted above, seven day per week mobile service would not give our patients round-the-clock access.

We do recognize that Michigan cannot afford for every hospital with an Emergency Department to have a fixed MRI. However, we do believe it is a vital diagnostic tool for an emergency department with significant volume that is located a fair distance from another emergency department with fixed MRI service. Since most hospitals with busy emergency departments already have fixed MRI service, this would only allow for those few hospitals that donÆt. Therefore, I am asking that the CON Commission modify the MRI standards to accommodate for these limited circumstances and have attached potential language modifications that would do so.

I appreciate your time in considering this matter and look forward to continued discussions as you review these standards early next year, and urge that you take up this matter in as expedited and efficient manner as possible. Please feel free to contact me directly at (269) 789-3924.

Sincerely,
Rob Covert
President and CEO

Note: A hardcopy of this letter and all referenced attachments have been mailed to MDCH for inclusion in the record.

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 4:27 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

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: My name is Steven Szelag and I am a Senior Health System 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 does not believe that these CON standards need to be re-opened at this time.

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

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/26/2008 9:47 AM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Yahya M. Basha, M.D.
2. Organization: Basha Diagnostics, P.C.
3. Phone: 248-435-8066
4. Email: bashadiagnostics@aol.com
5. Standards: MRI
6. Testimony: October 22, 2008

Mr. Edward B. Goldman, J.D.
Chairperson
Certificate of Need Commission
Michigan Department of Community Health
201 Townsend Street, 7th Floor
Lansing, Michigan 48913

Dear Chairperson Goldman,

As the president of Basha Diagnostics, based in Royal Oak, I appreciate this opportunity to provide comments on the MRI standards up for review in 2009. I am a board certified Radiologist providing ambulatory diagnostic services in southeast Michigan. Basha Diagnostics has locations in Sterling Heights, Dearborn, and Royal Oak. We are part-owners of a mobile MRI network and expect to receive approval for our first fixed MRI unit in the coming weeks.

I have been providing care to indigent patients that are referred by free-clinics and other charity-based health care service providers in the Detroit area. As MichiganÆs economy continues on its downward spiral, the need for low-cost and free healthcare is reaching an all-time high. Requests for charity care come at an alarming rate. I come to you today asking that, as you review the MRI standards this next year, you look at ways to encourage the provision of charity care to those in need, and specifically to create incentives and opportunities for those providers willing to take on this challenge.

I would appreciate an opportunity to work with you and the Department of Community Health to explore ideas and options to address this issue. I thank you for your time in considering this request and would be happy to talk with you directly. You can reach me at (248) 435-8066.

Sincerely,
Yahya M. Basha, M.D.
President

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/22/2008 2:27 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Darla Granger, MD
2. Organization: St John Hospital and Medical Center
3. Phone: 313-343-3048
4. Email: darla.granger@stjohn.org
5. Standards: Pancreas
6. Testimony: I am writing on behalf of St John Hospital and Medical Center where I am a transplant surgeon.

Last year, St John ôvoluntarily surrenderedö our certificate of need based on the fact that our center was reaching lower than expected volumes for pancreas transplants. We would like to discuss the reasons why we believe our certificate of need should be reinstated.

Quality of care must be the overriding concern of the Commission. Others have provided data from the Scientific Registry of Transplant Recipients (SRTR). As the SRTR data demonstrates, larger center volume does not improve outcome, as it does in other procedures. This may be related to the fragility of pancreas graft itself. We could increase our numbers at St John but it would mean using more marginal organs, and therefore decreasing our graft and recipient survival. Our graft and patient survival was equal or better than our peers at the time of our ôsurrenderö.

Cost issues are immaterial to the discussion of pancreas transplantation. Once the infrastructure exists for a busy kidney transplant program, adding pancreas transplant adds nothing to the cost either in personnel or capital outlay.

The largest issue to be addressed by the Commission with regards to pancreas transplant is access to care. The people considered for pancreas transplant are our most fragile. In addition to their kidney problems, they usually suffer from vision and mobility issues. The potential recipients have many other medical problems and become our ôfrequent fliersö with complicated health histories and extensive use of our medical facilities. We know these people well, and they know us. Rather than transfer their care to other instate transplant programs, 10 of the 12 people on our list for a pancreas at the time of our ôsurrenderö opted to stay on our list for a kidney only. This is despite extensive individual counseling to seek pancreas transplant elsewhere. It is frustrating to see diabetics receiving suboptimum therapy for their disease process because they cannot logistically transfer their medical care to other centers due to transportation difficulties or because they are
unwilling to start over with another health system.

Our transplant center, working with our past recipients, does extensive fundraising simply to provide gas cards to patients to come to appointments. Most of our potential pancreas recipients are unable to drive secondary to vision problems or labile blood

sugars. Medicaid drivers or family members must bring them to appointments. Asking these people to travel greater distances is particularly onerous.

We appreciate the CommissionÆs review of the volume standards for pancreas transplantation and look forward to working with the Commission to improve the care of brittle diabetics in the east Metro area.

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 10:23 AM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Richard E Pietroski
2. Organization: Gift of Life Michigan
3. Phone: 800 482 4881
4. Email: rpietroski@giftoflifemichigan.org
5. Standards: Pancreas
6. Testimony: Certificate of Need Commission:

I would like to begin by thanking the Certificate of Need Commission and administrative staff for the assistance your organization has given Gift of Life Michigan in fully understanding the process to effect change in the pancreas transplant standards.

After months of deliberation and study of this topic, research that is contained at the end of this introductory letter, Gift of Life Michigan supports a two-pronged approach to addressing the current flaws in the certificate of need standards for pancreas transplants:

1. A hospital will qualify to provide pancreas transplant services through the establishment of an on-site renal transplant service that has performed a minimum of 80 kidney transplants in any 24 consecutive months in the most recent three years for which data are available.

2. A hospital will be considered to be active by performing at least one pancreas transplant in a six month period, otherwise the center must submit any required federal OPTN center status review documents for examination and center certificate disposition by the CON Commission.

We believe the approach outlined above will, first, guarantee quality of service, as a center must be an active renal transplant center in order to be able to perform pancreas transplants. Second, the approach allows for patient access to care as the minimum volume standards would be reduced. Finally, as there are no additive costs for pancreas transplants on top of an active renal transplant program, cost is not an issue.

The current CON annual volume requirement affects not only patients and transplant centers, but also Gift of Life Michigan directly. As a certified organ procurement organization, we are expected to maintain a certain number of organs transplanted per donor. Should we fall more than one standard deviation below the national mean, Gift of Life would be decertified. Should this happen in Michigan, the 36-year institution of Gift of Life Michigan would cease operations, and organ recoveries would be performed by another organization from a different state, an unintended outcome of the CON requirement. The threat of this situation is real if there are insufficient transplant programs in Michigan to service the population. We believe that having only one or two pancreas transplant programs does under serve the Michigan population, and therefore

poses a threat to Gift of Life MichiganÆs survival, as well as the health of those patients in need of a transplant.

Thank you again for the opportunity to review our concerns and to propose a solution to the current needs of Michigan patients with regards to pancreas transplants. I look forward to finding a solution to modify the pancreas CON requirement for the benefit of Michigan patients.

Richard E. Pietroski
Executive Director
Gift of Life Michigan

Gift of Life Michigan
Position Statement on the State of MichiganÆs Certificate of Need (CON)
For Pancreas Transplantation: Requirements for Performing 12 Cases/Year

It is the position of Gift of Life Michigan, the organ procurement organization federally designated by the United States Department of Health and Human Services and as a member of the federal Organ Procurement and Transplantation Network (OPTN), that the State of Michigan's CON requirement for a transplant center to perform 12 pancreas transplants annually in order to remain in compliance is without scientific, medical, and regulatory rationale. The following information is in support of this position:

(1) In calendar years 2005, 2006, and 2007, respectively 39 (28%), 38 (28%), and 33 (23%) of the 145 OPTN approved and active pancreas transplant programs in the country performed 12 or more cases (OPTN; www.optn.org/latestdata). Furthermore, the fraction of programs in the country performing 12 or more cases per year has not significantly increased from calendar years 1999 and 2000 (when it was 25%) and has essentially remained flat. Finally, the total number of pancreas transplants performed in the nation actually decreased from 1,444 in 2005, to 1,387 in 2006, and 1,267 in 2007, reflecting the aging donor population and the decreased quality of available organs.

Table I contains a summary of the level of pancreas transplant activity for those centers located in the four other states that have minimum volume requirements for pancreas transplants (OPTN; www.optn.org/latestdata/). The remaining 45 states do not set minimum volume requirements for pancreas transplants. The data covers the time period 2003-2007. No one state had all of their centers meet the CON requirements over five years and, out of 19 centers, only four total met their stateÆs CON requirements annually.

Table I. States where CON Requirement Exists and Volume of Center Transplants

State: Maryland (CON=12)
No. Active Pancreas Transplant Centers in State: 2
Percent of centers in Maryland that met CON Pancreas Transplant Requirement:
2003 50%

2004 100%
2005 100%
2006 100%
2007 100%

State: New Jersey (CON=15)
No. Active Pancreas Transplant Centers in State: 5
Percent of centers in New Jersey that met CON Pancreas Transplant Requirement:
2003 20%
2004 20%
2005 0%
2006 0%
2007 0%

State: North Carolina (CON=10)
No. Active Pancreas Transplant Centers in State: 4
Percent of centers in North Carolina that met CON Pancreas Transplant Requirement:
2003 50%
2004 50%
2005 50%
2006 50%
2007 50%

State: Virginia (CON=12)
No. Active Pancreas Transplant Centers in State: 4
Percent of centers in Virginia that met CON Pancreas Transplant Requirement:
2003 0%
2004 25%
2005 25%
2006 25%
2007 25%

(2)The following tables of the most recent data available obtained from the 2006 OPTN/Scientific Registry of Transplant Recipients (SRTR) [www.ustransplant.org/annual.reports/current] indicate that across the nation, there is no correlation between the annual number of pancreas transplants performed by a transplant center and outcomes, as measured by 1-, 3-, and 5-year patient and pancreas graft survival rates, for all three types of pancreas transplant procedure: simultaneous pancreas/kidney (SPK), pancreas after kidney (PAK), and pancreas transplant alone (PTA). Pancreas transplant centers performing <12 cases per year did not have outcomes significantly different from those performing ≥12 cases per year:

Note: Tables II û VII refer to % patient/graft survival current to 2004. 1YR = transplanted in 2003. 3YR = transplanted in 2001. 5YR = transplanted in 1999. ACV refers to Annual Center Volume

Table II. U.S. SPK Patient Survival v Annual Transplant Volume

ACV	1YR	3YR	5YR
0-3	93.2	89.9	84.3
4-6	96.3	90.3	83.4
7-9	96.4	92.7	89.0
10-16	94.2	91.0	87.6
17+	95.8	90.4	84.8

Table III. U.S. SPK Pancreas Graft Survival v Annual Transplant Volume

ACV	1YR	3YR	5YR
0-3	82.4	77.5	70.7
4-6	84.2	79.8	72.1
7-10	83.0	76.2	66.8
11-17	83.7	80.8	72.6
18+	87.1	79.3	71.2

Table IV. U.S. PAK Patient Survival v Annual Transplant Volume

ACV	1YR	3YR	5YR
0-4	93.9	89.5	77.1
5-7	96.3	91.4	94.3
8-11	100.0	94.5	85.0
12-19	93.6	90.6	85.2
20+	95.0	87.9	82.2

Table V. U.S. PAK Graft Survival v Annual Transplant Volume

ACV	1YR	3YR	5YR
0-4	64.0	61.0	50.1
5-7	77.1	68.9	63.1
8-11	72.6	65.8	56.8
12-19	77.3	68.3	58.6
20+	84.7	68.8	56.5

Table VI. U.S. PTA Patient Survival v Annual Transplant Volume

ACV	1YR	3YR	5YR
0-4	100.0	100.0	94.4
5-7	100.0	100.0	100.0
8-11	92.9	94.1	98.4
12-19	97.4	91.3	88.4
20+	94.0	90.3	89.4

Table VII. U.S. PTA Graft Survival v Annual Transplant Volume

ACV	1YR	3YR	5YR
0-4	80.0	65.6	33.3
5-7	75.0	69.4	59.2
8-11	64.3	59.9	68.0
12-19	79.4	69.8	61.9

20+ 71.6 55.0 52.3

(3) Table VIII below gives the total number of pancreas transplants performed by each program in the state of Michigan over the past three years:

Table VIII. 2005 thru 2007
Michigan Pancreas Programs
Harper University Hospital **
2005: 1 2006: 5 2007: 2
Henry Ford Hospital
2005: 12 2006: 15 2007: 6
St. John Hospital **
2005: 1 2006: 2 2007: 1
University of Michigan
2005: 17 2006: 29 2007: 15
Totals
2005: 31 2006: 51 2007: 24
** Programs now inactive due to state CON requirement

The table illustrates volatility in the annual number of pancreas transplants performed by Michigan centers, and it may come to pass that all Michigan centers will be closed due to the artificial CON metric of requiring a minimum of 12 pancreas transplants per year. While these centers are somewhat geographically diverse, their patient populations for receiving end-stage renal disease treatment are well established, but disadvantaged for receiving treatment of type I diabetes.

The volume level established by the CON has no scientific basis for its determination, and appears to have been established arbitrarily. There is national evidence to support a decrease or elimination of this requirement, namely:
ò The federal OPTN, under control of the U.S. Department of Health and Human Services (DHHS), which oversees and regulates all solid organ transplant programs in the United States, does not impose any volume requirement.
ò The only center level volume requirement which exists is in the OPTN Membership and Professional Standards Committee (MPSC) bylaws involving a formal review of centers that have not transplanted at least one pancreas in a six month period.
ò The national median number of pancreas transplants performed per center is six.

(4) One of the possible reasons for having a CON for pancreas transplantation, besides attempting to maintain quality outcomes, is to use resources efficiently and minimize cost. There are no relevant major capital or equipment expenditures necessary for pancreas transplantation than that also required for renal transplantation. This also holds true in terms of personnel required to manage a pancreas transplant program, above and beyond, that which is required for renal transplantation alone. The same pre- and post-transplant coordinators, social workers, nutritionist, pharmacist, financial coordinator, clinic staff, nurses, nephrologists, and surgeons who are involved with the kidney

transplant program also handle the comparatively smaller volume pancreas transplant program numbers, so no additional costs are incurred.

(5)Given all of the above evidence, there is no scientifically based reason for causing Michigan renal transplant centers to close their pancreas programs and have their patients seek pancreas transplant services elsewhere due to local access issues. Patient access to dialysis, prior general surgical, and other medical care locally, should not be forced through a CON process, especially in light of all Michigan transplant centers being federally designated under a fully functional and efficiently regulated national procurement and transplant system.

(6)Gift of Life Michigan, is one of the nation's 58 federally designated organ procurement organizations (OPOs) under DHHS, and is held to meeting performance measures developed by the Centers for Medicare and Medicaid Services (CMS) in order to not become decertified. One of the CMS performance measures involves each OPO achieving a number of organs transplanted per donor within one standard deviation of the national mean. With local centers being restricted to perform pancreas transplants under the Michigan CON process, along with logistical and medical issues making the exportation of pancreata out of Michigan difficult, Gift of Life Michigan is disadvantaged in its efforts to meet CMS performance measures compared with the other OPOs not faced with similar state regulations.

In summary, Gift of Life Michigan supports a decrease in or elimination of the annual pancreas transplant volume requirement for Michigan transplant centers. There are no cost or quality benefits to waiting transplant patients in reducing the number of centers providing this service. Access to care is compromised for every patient as they are forced to seek pancreas transplant care from a center out-of-area while receiving renal transplant care at a center locally. Finally, a reduction of pancreas transplant centers directly affects the ability of Michigan to continue to be a leader in donation and transplant services in the country.

October 2008

Please direct questions to:
Richard Pietroski, Executive Director, rpietroski@giftoflifemichigan.org, Gift of Life Michigan, 800.482.4881

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 4:41 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: 734-647-1163
4. Email: sszelag@umich.edu
5. Standards: Pancreas
6. Testimony: My name is Steven Szelag and I am a Senior Health System 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.

UMHS does not oppose the modification of Pancreas Transplant Standard to reflect a lower requirement for annual pancreas transplant volume. We recognize that Gift of Life Michigan is under a federal mandate to maximize pancreas utilization in its service area.

However, UMHS continues to support the existing quantitative Kidney Transplant volume prerequisite for approval of a Pancreas Transplant program.

Thank you for according us the opportunity to make this statement today. We stand ready to work with you and with the Department on this important matter.

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/16/2008 6:28 AM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Andrew C Chang, MD
2. Organization: University of Michigan, Transplant Center
3. Phone: 734.763.7418
4. Email: andrwchg@umich.edu
5. Standards: Heart
6. Testimony: Dear Members of the Certificate of Need Commission:

At the University of Michigan, as of October 15, 2008, 425 patients have undergone lung transplantation since thoracic organ transplantation began at our institution in 1984. As might be expected, a large team of professionals, including transplant surgeons, internists, anesthesiologists, nurses and other health specialists work together for our patientsÆ well-being. Since 2003, when Dr. Andrew Chang, the current surgical director, and Dr. Kevin Chan, medical director, were appointed, and in close coordination with Gift of Life of Michigan and other regional organ procurement organizations (OPO), 138 patients have undergone lung transplantation at our program.

We are writing this letter to express our concerns regarding several inconsistencies and possible misconceptions regarding the ôCertificate of need (CON) review standards for heart/lung and liver transplantation services,ö particularly in reference to lung transplantation.

Section 4.

Item 1 combines heart, heart/lung and lung transplant programs together, with the presumption that these operations and organ transplants are done by the same team of physicians. These are actually distinct procedures, and lung transplantation in particular is performed not only by cardiac or cardiothoracic surgeons but also general thoracic surgeons (see comments regarding section 9 below).

Section 8. Additional terms of approval...

"requires presence of a cyclosporine assay availability with results available on the same day" is outdated and too specific. Immunosuppression regimens will change and are already changing. This section should include monitoring of tacrolimus levels, or be reworded to ômonitoring of immunosuppression drug levels including calcineurin inhibitors such as cyclosporine and tacrolimus.ö

Section 9. Additional terms of approval (regarding team composition)

Item 9.1.a. should include: ôpulmonologists and surgeons trained in bronchoscopy and transbronchial techniques including biopsy and stent placementö

Item 9.1.b. should read: ôcardiologists, pulmonologists and surgeons trained in immunosuppression techniquesö

Item 9.1.c. should include ôboth adult and pediatric, as appropriate, cardiologists, pulmonolgists and surgeons.ö

Item 9.1.d. cardiac and thoracic surgeons should have demonstrated capability of successfully performing orthotopic cardiac or lung transplantation, in accordance with United Network for Organ Sharing (UNOS) guidelines. These guidelines require documentation of satisfactory training in transplantation in patient settings. Any simulation (animal or computer modeling) of human transplantation as sole criteria for establishing competency in performing transplantation would not be satisfactory for medical specialty board certification let alone UNOS certification.

Item 9.1e. "two cardiac transplant surgical teams with a total of at least 3 trained cardiac surgeons..." is inaccurate in that, in practice, there exists a distinction between cardiac surgery, general thoracic surgery and cardiothoracic surgery. The statement as currently worded assumes that the same surgical teams perform both heart and lung transplantation and include cardiac surgeons only. There should be a separate statement regarding availability of surgical team (cardiothoracic and/or general thoracic) for lung transplantation. Not only cardiac surgeons but also general thoracic (American Board of Thoracic Surgery-certified) surgeons are capable of performing such procedures safely and with excellent outcomes. Several of the largest lung transplant programs are directed by general thoracic surgeons, most notably Dr. G. Alex Patterson at Barnes Hospital, Washington University in St Louis, MO and Dr. Shaf Keshavjee at Toronto General Hospital, Toronto Canada. Both
of these general thoracic surgeons are recognized internationally as leaders and authorities not only on pulmonary transplantation but also in the field of thoracic surgery.

Item 9.1.f. should include a pathologist capable of diagnosing pulmonary allograft rejection on lung biopsy specimens.

Item 9.1.g. should include anesthesiologists trained in open heart surgery and/or general thoracic surgery.

Item 9.2. Cardiac transplant survival benchmark should also be adjusted to what is reported in OPTN, not absolute numbers that are at risk of becoming outdated.

Item 10.2.a. should read ôradionuclide HIDA biliary scan,ö rather than ônuclear HID biliary scanö

We support strongly the need for oversight of complex operations such as cardiac and lung transplantation. Certificates of Need provide one important avenue to standardize care of patients in need of these operations. We hope these comments help clarify the

standards for lung and cardiac transplantation so as to serve the Michigan community better.

Thank you for your attention and consideration.

Sincerely,

Andrew C. Chang, MD
Kevin M. Chan, MD
Co-Directors, Pulmonary Transplantation
University of Michigan Medical Center
Ann Arbor, MI

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/21/2008 12:17 PM
Subject: October 16, 2008 HB Public Hearing Written Testimony (ContentID - 196938)

1. Name: Dennis McCafferty
2. Organization: Economic Alliance for Michigan
3. Phone: 248-596-1006
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5. Testimony: The Economic Alliance for Michigan

Public Comments û October 16, 2008
Regarding the 2009 CON Work Plan
By Dennis McCafferty

Transplant services (BMT, Heart, Lung, Liver and Pancreas)
The Economic Alliance for MichiganÆs positions on transplant services has always been that unless new, compelling evidence can be presented, additional Transplant service capacity is not needed in Michigan. Our memberÆs Health Staff Group and the EAM Board recently reaffirmed this position.
Data provided by the MDCH (see table) shows that over the last eight years, some yearÆs annual volumes are higher and some yearÆs are lower. In 2007, the annual volumes for most CON-Regulated Transplant Services were close to the average annual statewide volume for the last eight years. The one exception being Bone Marrow Transplant and almost all of this increase is attributable to a large increase at Karmanos. The Economic Alliance remains open to the need for greater geographic distribution of Bone Marrow Transplant services. Potentially there is a need for two planning areas, one on the east side and a second on the west side of the state. However, additional access to Bone Marrow Transplant services in Southeast Michigan does not seem to be an issue. We are also open to new information regarding the possibility that access concerns may be depressing the volume of Pancreas transplants. In response to these concerns we have invited interested parties, to present their position to our memberÆs prior to the CON Work Plan meeting in January.

MRI Services

The Michigan CON standards for MRI services have resulted in lowering the 3 domestic auto companiesÆ cost per covered person for MRI services by 20%. This study of their combined 2006 claim data compared Michigan to 9 other states where the 3 autos collectively have large covered populations. None of these 9 other states have CON standards that are as effective in holding down costs as the Michigan CON standards. We have canvassed a number of radiologist and other imaging professionals and we have not learned of any pressing issues that would warrant re-opening of these standards. We are, however open to new, compelling information that supports changing the standards to improve access and quality or to lower the cost.

Psychiatric Beds

These standards were reviewed in 2007 and took effect in February of this year. This effort was headed up by Commissioner DeRemo. We would like to commend

Commissioner DeRemo and the SAC for their efforts on these new standards and see no reason for re-opening them in 2009.

Hospital Beds

We would like to commend the Commission and Department for their work on the technical updates to the hospital bed standards. We would also like to go on record to say that we know of no other reason for these standards to be re-opened in 2009. From March 2002 to March 2007 there were 4 separate efforts to review these standards and a total of 60 public meeting were held. The issue of relocation of existing hospitals was specifically addressed and four times the Commission decided that this part of the standard should not be changed.

However, during this period the standards for access have been relaxed. The definition for full occupancy has been reduced from 90% to 85% to 80%. Other exceptions have also been made in determining high occupancy. This has resulted in the ôHospital Bed Needö in Michigan increasing from 17,000 to over 20,000 when the stateÆs population has been static or decreasing. In spite of these changes, recent data shows that there are over 26,000 licensed hospital beds (30% more than need) and in every sub-area in the state, there are licensed beds in excess of hospital bed needs. Our members would oppose any efforts to further loosen these standards.

CT Imaging

The Economic Alliance supports the migration of advance imaging technology to physician offices when there is strong medical evidence that this is in the best interest of the patients. Currently, patient access to advance imaging service is not an issue. We continue to be open to information that demonstrates that office-base advance imaging is a cost effective, high quality alternative to current imaging center based technology. We have continued to participate in the MDCH workgroup that is examining this question for ENT and dental office-based CT. It is our hope that reasonable accommodations can be reached to allow this new technology to benefit patients.

CON-REGULATED TRANSPLANT SERVICES **2000 through 2007**

									EAM Staff Analysis		
Bone Marrow	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Average**	**2007 vs. Average**	**COMMENT**
Children's- Peds								2	NA	NA	
Karmanos - Adult/Peds	189	211	123	112	125	155	187	233	167	66	
Henry Ford – Adult	38	35	36	52	49	43	43	38	42	-4	
Oakwood Adult	21	14	11	15	11	17	3	0	12	-12	2006: Hospital ended service due to low volume
Spectrum (Butterworth) – Peds	14	17	13	12	14	15	13	15	14	1	
U of Michigan – Adult/Peds	215	221	232	257	218	208	224	248	228	20	
Totals	**477**	**498**	**415**	**448**	**417**	**438**	**470**	**536**	**462**	**74**	2007: gain nearly all due to Karmanos
Heart, Heart & Lung, Lung	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Average**	**2007 vs. Average**	
Children's	2	4	4	3	8	10	9	6	6	0	
Henry Ford	44	36	31	25	18	19	25	22	28	-6	
University of Michigan	57	81	56	44	56	64	64	55	60	-5	
Totals	**103**	**121**	**91**	**72**	**82**	**93**	**98**	**83**	**93**	**-10**	
Liver Transplants	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Average**	**2007 vs. Average**	
Henry Ford	46	71	58	58	120	109	84	114	83	32	
University of Michigan	69	57	89	86	86	87	106	71	81	-10	
Totals	**115**	**128**	**147**	**144**	**206**	**196**	**190**	**185**	**164**	**21**	
Pancreas Transplants	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Average**	**2007 vs. Average**	
Harper	started in 2003			1	0	1	5	2	2	0	Both hospitals ended program in '07 due to low volume; never even half minimum volume
St. John - Detroit	2	4	1	1	4	1	2	1	2	-1	
Henry Ford	started fall '02		3	3	7	13	15	6	8	-2	Approved under old Std's limit of 3 statewide.
University of Michigan	14	14	22	14	24	17	29	15	19	-4	
Totals	**16**	**18**	**26**	**19**	**35**	**32**	**51**	**24**	**28**	**-4**	Volumes gyrated;'06 very high at H.Ford & UM.
Kidney Transplants	**2000**	**2001**	**2002**	**2003**	**2004**	**2005**	**2006**	**2007**	**Average**	**2007 vs. Average**	No CON required. Data kept to vreify hospital has 80 kidney transplants in 24 months required to get pancreas CON.
Children's	7	6	8	9	8	12	15	8	9	-1	
Harper University	23	25	60	39	99	43	30	39	45	-6	
Henry Ford- Detroit	58	83	102	102	117	106	102	81	94	-13	
Hurley Medical Center	11	21	0	0	0	25	13	11	10	1	
St. John's – Detroit	61	65	49	48	47	51	51	55	53	2	
St. Mary's – Grand Rapids	58	71	79	81	66	81	63	87	73	14	
University of Michigan	227	189	194	200	233	225	291	259	227	32	
Spectrum Health Butterworth	prog m started in 2007							5	NA	N/A	
Wm. Beaumont – Royal Oak	59	64	60	65	53	49	50	48	56	-8	
Totals	**504**	**524**	**552**	**544**	**623**	**592**	**615**	**593**	**568**	**25**	

Corrections to St John data
Revised 2002, 2003

DATA SOURCE:MDCH 9-26-08

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/21/2008 12:37 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Barbara Winston Jackson
2. Organization: BCBSM/BCN
3. Phone: 248.448.2710
4. Email: bjackson3@bcbsm.com
5. Standards: BMT
6. Testimony: Blue Cross Blue Shield of Michigan/Blue Care Network
Public Hearing
October 16, 2008

On behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN), I would like to thank the Commission for this opportunity to testify. BCBSM and BCN continue to support the Certificate of Need (CON) program, which is designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

Hospital Beds
As we stated at the September 16th CON commission meeting, BCBSM and BCN supported updating the Hospital Bed Review Standards and applauded the CommissionÆs proposed action to do so. These proposed standards serve an important function by clarifying and updating the language including a recalculated hospital bed need based on more current conditions. Keeping the standards as relevant as possible by using current data is vitally important. We commend the CON Commission for moving this updated language forward for proposed action.

Bone Marrow Transplant Services
Fro the reasons listed below, BCBSM/BCN believes that there is no need to formally address the Bone Marrow Transplant (BMT) Service standards at this time:
ò An informal BMT work group, facilitated by CON Commissioner Dr. Michael Young, met multiple times during 2006. The workgroup was comprised of expert physicians, providers and purchasers. The majority of workgroup members requested that the Commission determine whether a standard advisory committee (SAC) should be appointed, however, a very vocal minority indicated there was no need. Ultimately the Commission did not appoint a SAC, as they didnÆt feel it was necessary at that time.
ò Since the BMT work group was convened, public testimony has been given almost routinely at Commission meetings by providers interested in initiating new BMT programs. No compelling evidence, however, has been provided as to the need for additional programs; rather only anecdotal accounts have been described.
ò While the geographic distribution of existing programs may not be perfectly distributed, the current programs appear sufficient to support current patient volumes.
ò Annualized state-wide bone marrow transplant service trends indicate that the volume of these procedures has stabilized with some decreases in volumes observed. Due

to low patient volumes, Oakwood Health Care voluntarily surrendered its BMT program CON.

ò Opening up the standards for review could result in more programs, which could seriously deplete existing programsÆ patient volumes and staffing; reduce the quality of care and increase health care costs.
ò The recent Commission action to modify the BMT standards allowed for an expedient technical solution. This action allowed the retention of a highly regarded BMT program with a long history of service to residents throughout the State of Michigan.

BCBSM/BCN, however, would consider supporting a review of the BMT standards if compelling evidence of community benefit, in terms of cost, quality and/or access concerns, were provided.

Heart/Lung and Liver Transplantation Services
A review of state-wide transplant services data for heart, lung and liver transplants shows stable individual program volumes. No evidence of a need for increased access exists. BCBSM/BCN, thus, sees no compelling need to review these standards.

MRI Services
BCSM/BCN has performed state-wide reviews of MRI access over the past few years and found no access to care issues. We are also not aware of any compelling new applications or scientific evidence that would merit a complete review of these standards. Additionally, based on the CommissionÆs ability to address issues on an ad hoc basis, a potential problem was addressed expeditiously that allows the use of intra-operative MRI units (IMRI) in the acute care setting. BCSM/BCN strongly supported the CommissionÆs action that allowed for this new application of MRI technology. This quick action results in improved patient safety and quality of health care.

Pancreas Transplantation Services
A review of state-wide pancreas transplant data shows relatively consistent individual program volumes for these services. In fact, due to low patient volumes, Harper and St. John Hospitals voluntarily surrendered their CONs for this service. BCBSM/BCN is not aware of any access issues and, thus, sees no reason to review these standards.

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 4:41 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Steven Szelag
2. Organization: University of Michigan Health System
3. Phone: 734-647-1163
4. Email: sszelag@umich.edu
5. Standards: Heart
6. Testimony: My name is Steven Szelag and I am a Senior Health System 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.

UMHS does not believe that these CON standards need to be re-opened at this time.

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

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 4:43 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Richard E Pietroski
2. Organization: Gift of Life Michigan, 3861 Research Park Drive, Ann Arbor, MI 48108
3. Phone: 800 482 4881
4. Email: rpietroski@giftoflifemichigan.org
5. Standards: Heart
6. Testimony: Certificate of Need Commission Members:

Gift of Life Michigan is the organ procurement organization federally designated by the United States Department of Health and Human Services for the state of Michigan.

As a member of the federal Organ Procurement and Transplantation Network (OPTN) and a certified organization through the Association of Organ Procurement Organizations (AOPO), we recognize the need for well-written and thoughtful regulations. As you move forward to review these standards, we welcome the opportunity to participate in on-going discussions regarding the Heart, Heart/Lung, Lung and Liver Transplantation Standards. It is our hope that we can maintain high standards in our transplant services while addressing the ever-changing medical and regulatory environment within which all transplant centers and procurement organizations function.

I wish to thank the Commission for their work on this issue and look forward to further improving transplant services for Michigan patients.

Richard Pietroski, Executive Director, rpietroski@giftoflifemichigan.org, Gift of Life Michigan, 800.482.4881

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/21/2008 2:19 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: (616) 391-2779
4. Email: robert.meeker@spectrum-health.org
5. Standards: BMT
6. Testimony: In 2006, when the Commission adopted minor changes to the BMT Standards, there was considerable discussion about the appropriate number and distribution of adult BMT programs in the state. Although there was no consensus on answers to those larger questions, the Commission did express concern about the issue of access to BMT services outside of the Detroit metropolitan area. At the request of the Commission, MDCH staff studied the question of outstate access to BMT and concluded that Michigan residents living outside of Southeast Michigan experience inadequate access to BMT services. Given that the BMT Standards were scheduled for review in 2010, MDCH recommended that any revisions to the Standards be delayed until the Commission has an opportunity to perform a complete review of the Standards. That time has now arrived.

According to data available to MDCH, the number of BMT procedures in the state has remained constant over the past eight (8) years, averaging 462 cases per year. These volumes have been well within the capacity of the existing BMT programs. Clearly, the state is not in need of a substantial increase in the number of BMT services.

However, all existing BMT programs are located in southeastern Michigan. As a result, citizens from West Michigan do not have ready access to adult BMT services. From Grand Rapids, the nearest full-service BMT program is in Ann Arbor, 125 miles away. While the cancer registry for Spectrum Health indicates that approximately forty-four (44) adults would have qualified for BMT annually over the last four (4) years, an average of less than forty (40) adult patients from West Michigan, including those from other cancer registries, received BMT services, according to the Michigan Inpatient Database (MIDB). Our concern is that cancer patients who could benefit from this treatment modality are seeking alternative treatments, due to the unavailability of adult BMT services in West Michigan.

As a possible solution to address the geographic disparity of adult BMT programs in Michigan, Spectrum Health suggests the following: redefine the planning area(s) for adult BMT to correspond to those currently defined for pediatric BMT in the Standards. In essence, this approach would subdivide the state into two (2) planning areas, and require that at least one (1) adult BMT service be located within each. According to the MIDB, seventy-five (75) adults living in Planning Area # 2 were referred for BMT in 2007. Adoption of this narrowly crafted change to the standards would address the concern for access by West Michigan residents, without changing the availability of BMT services in the eastern side of the state.

If the Commission agrees with this approach, the language changes in the Standards would be straightforward, paralleling the existing language for pediatric BMT services. As a starting point, possible language revisions are attached to this letter.

If this solution is adopted, additional changes would be required to the Comparative Review Criteria, as well. Again for reference, Spectrum Health has drafted possible language for comparative review criteria in the following areas:

- ò Distance to existing adult BMT programs
- ò Current availability of necessary support services
- ò Number of related cancer cases

Additional criteria could also be developed to distinguish among competing, qualified CON applications.

Spectrum Health appreciates the opportunity to comment on the CON Review Standards for BMT, and we urge that the CON Commission initiate a process to revise these Standards to address the issue of outstate access as soon as possible. We will be pleased to participate in this process as appropriate.

Proposed Language Changes/Additions to the BMT CON Review Standards

Section 2. Definitions

(u) ôPlanning areaö means either:

(i) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or

(ii) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.

Section 3. Requirements à to initiate a BMT service

(5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation services does not exceed two (2) in planning area one identified in Section 2(1)(u)(i) or one (1) in planning area two identified in Section 2(1)(u)(ii) and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding the need for each specific planning area.

(b) An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) in planning area one identified in Section 2(1)(u)(i) or one (1)pediatric bone marrow transplantation service in planning area two identified in Section 2(1)(u)(ii) and that approval of the proposed application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific planning area.

Section 4. Additional requirements for applications included in comparative reviews

(2)(d) A qualifying project will have points awarded based on the number of necessary support services identified in Sec. 6(1)(c)(i) which the applicant has available onsite on the date the application is submitted to the Department, as shown in the following schedule:

Number of BMT support services	Points Awarded
No support services	0
One or two support services	2
Three or four support services	4
Five or six support services	6

(e) A qualifying project will have points awarded based on the distance to the closest existing BMT program of the type applied for (adult or pediatric), as shown in the following schedule:

Distance to nearest BMT program	Points Awarded
< 60 miles	0
61 û 120 miles	3
> 120 miles	6

(f) A qualifying project for adult BMT will have points awarded based on the number of new adult cancer cases on their cancer registry in the following categories: AML, Myelodysplastic, Acute Lymphoblastic Leukemia Syndrome, Non-Hodgkins Lymphoma (large cell), Multiple Myeloma, Hodgkins Disease, & Testicular Cancer; according to the following schedule:

Number of new cancer cases of the identified types	Points Awarded
< 25	0
25 û 50	2
51-75	4
> 75	6

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 1:58 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Kenneth J. Matzick
2. Organization: Beaumont Hospitals
3. Phone: (248) 551-0680
4. Email: lboudreau@beaumonthospitals.com
5. Standards: BMT
6. Testimony: October 23, 2008

Dear Commissioner:

Since June 2005, Beaumont Hospitals has been advocating that the 20-year-old bone marrow transplant (BMT) standards be reviewed and updated to improve access to these services by going to institution-specific criteria. Beaumont provided information as to why the arbitrary limit of three BMT programs in the state was an impediment to some patients receiving timely, life-saving cancer treatment (see attached letter to CON Commission dated June 15, 2006). We also provided our rationale as to why Beaumont should be allowed to provide this service. In summary:

 Beaumont diagnoses more new cancer cases than any other hospital in the state.
 Beaumont has two BMT-trained physicians, so would not be incurring additional costs or ôrobbingö another program to provide this service.
 Beaumont provided peer-reviewed articles (New England Journal of Medicine) that said bone marrow transplant was an underutilized treatment that would be increasing with older patients and for more medical conditions.

A workgroup was established to review the BMT standards. The CON Commission listened to those facilities that had BMT programs and their rationale for not revising the standards:

 The number of bone marrow transplants in Michigan had not increased for a number of years.
 The number of BMTs would likely decrease due to new, less toxic, non-transplant targeted therapies and new chemotherapy agents that could replace transplants.
 Existing BMT programs had capacity to treat other patients (despite the fact capacity measures are not a consideration in any other CON standard).
 BMT programs are enormously expensive to initiate and maintain.

In the two years since the workgroup met and the CON Commission decided not to modify the BMT standards, the following has taken place:

 As Beaumont predicted, the number of bone marrow transplants performed in the U.S. has grown significantly due to the combination of the National

Marrow Registry Donor and cord blood stem cell banks increasingly being used for non-sibling donor matches; the use of stem cell transplants for treatments for more types of cancers and other diseases; and, older patients being successfully treated with stem cell transplants. [See the attached graphs from the Center for International Blood and Marrow Transplant Research (CIBMTR)]
 Both Karmanos and University of Michigan, which argued BMT services were in a decline, have increased the number of BMTs performed since 2004: Karmanos from 125 to 233 procedures, and University of Michigan from 218 to 248 procedures.

Comments were made at the public hearing on the 2009 Commission work plan dealing with pancreas transplants and the need for more programs in the state of Michigan. We believe the compelling arguments made for pancreas transplants hold true for bone marrow transplants:

1. There is a federal certifying organization that guarantees a level of quality for transplant programs. In the case of bone marrow transplant, it is the Foundation for Accreditation of Cellular Therapy (FACT), and all information on patient outcomes must be submitted to the CIBMTR.
2. Costs of adding a pancreas transplant program are not significant for hospitals that have kidney transplant programs. The same would be true for Beaumont establishing bone marrow transplant, in light of our other transplant programs.
3. There is no evidence to link higher volume of procedures to better outcomes, despite allegations that there needs to be a higher number of bone marrow transplants at only the existing centers in order to maintain quality.
4. Most importantly, patients who have established relationships with physicians and hospitals should not be made to go to another facility to receive life-saving treatment.

The CON Commission may be persuaded by these arguments to modify the CON criteria for pancreas transplants, and Beaumont does not see any reason that the same arguments should not apply for modifying bone marrow transplant services.

The Certificate of Need Commission may want to consider updating standards for all transplant services in view of the development of data from national organizations that does not link volume with quality; that costs of implementing transplant programs may not be significant; and, that medicine has changed in the last ten years. The most compelling argument we believe, however, is that patients are being negatively impacted if they are forced to leave their existing physician and hospital when that physician and hospital have the capability of providing the transplant service. The CON Commission has not studied increased health care costs, nor impacts on the patients, of these transfers.

Again, Beaumont Hospitals would like to request the Certificate of Need Commission appoint a Standard Advisory Committee (SAC) to revise the 23-year-old standards that no longer reflect the standard of care for bone marrow transplant services. We encourage the Commission to instruct the SAC to either recommend that BMT standards be

rescinded or develop institution-specific criteria for BMT services with minimum volume thresholds.

Given the fact that BMTs can now be performed on an outpatient basis and often cost significantly less than chemotherapy or other cancer treatments, there are now reasons for changing this standard.

Sincerely,

Kenneth J. Matzick
President and
Chief Executive Officer

Enclosures referenced above were hand delivered to Andrea Moore and are considered inclusive with these comments.

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 2:47 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Carol Christner
2. Organization: Karmanos Cancer Institute
3. Phone: 313-576-8123
4. Email: christne@karmanos.org
5. Standards: BMT
6. Testimony: The Karmanos Cancer Institute supports the Bone Marrow Transplant Standards as currently written. The standards provide for the primary tenents of CON - cost, quality and access - to be maintained. Patient needs in Michigan are well met by the three existing BMT programs.

The most recent studies on trends of transplantation have shown numbers are stabilized or declining. This is due to better and less intensive treatment available for diseases such as Multiple Myeloma, Chronic Myelogenous Leukemia and Non-Hodgkins Lymphoma. All of these diseases, which in the past were often treated with transplantation, have newer, far less toxic therapies available making transplant unnecessary. In Michigan there were seven fewer transplants performed in 2006 than in 2000 and the number of transplants for all years since 2000 has remained relatively stable. There is no data that indicates stem cell transplantation will be approved for other diseases other than the hematologic malignancies.

At present the number of transplant programs in the state adequately meets the needs of the entire state. Each program is working under capacity. There is no data to suggest patients are not transplanted because of lack of beds. There is no problem getting patients in to see physicians in the current transplantation programs in the state. Patients are referred to the programs with all testing done at their home areas. No duplication of testing is required or necessary when patients are referred to transplantation centers. We, as well as other centers, have been able to successfully partner with practices around the state for the efficient and timely movement of patients back and forth for treatment. Patients are referred back to their private hematologist and oncologist as soon as possible for follow-up care.

The financial requirement to implement quality transplantation programs is high. Not only in terms of equipment, controlled rate cryopreservation systems, liquid nitrogen freezers, HEPA filtered patient care areas but also in personnel. Nurses, pharmacistsÆ social workers, and other support staff must be trained in the area of high dose chemotherapy and transplantation. In addition the physician requirements are high. Consulting physicians such as Infectious disease, pulmonary and critical care specialist need training and experience in transplantation.

The current standards ensure that patients have access to the highest quality bone marrow transplant programs and that costs are maintained through eliminating excessive capacity. We encourage the commission to allow the BMT Standards to remain as written.

Thank you,

Carol Christner
Director, Government Relations
Karmanos Cancer Institute

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 3:47 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

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: My name is Steven Szelag and I am a Senior Health System 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. 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.

Thank you for according us the opportunity to make this statement today. We stand ready to work with you and with the Department on this important matter.

From: <DoNotReply@michigan.gov>
To: moorean@michigan.gov
Date: 10/23/2008 4:14 PM
Subject: October 16, 2008 Misc. Public Hearing Written Testimony (ContentID - 147062)

1. Name: Ayad Al-Katib
2. Organization: St. John Health
3. Phone: 313-647-3130
4. Email: ayad.al-katib@stjohn.org
5. Standards: BMT
6. Testimony: Thank you for the opportunity to comment on the need for a review of CON BMT standards. St. John Health believes that there should be a review of the CON BMT standards to ascertain access to and need for BMT programs. More specifically, St. John Health urges the CON Commission to form a Standard Advisory Committee to review CON Bone Marrow Transplant Standards to eliminate the artificial cap of three programs in Michigan and adopt an institution specific needs based methodology. Alternatively, we would urge the Commission to eliminate BMT from being a covered clinical service under Certificate of Need.

St. John Health believes there is no rationale for the current methodology that limits the number of allowed BMT services in the state. The American Society of Clinical Oncology at their 2006 annual meeting concluded that BMT has evolved from an experimental approach of uncertain promise to a widely practiced treatment with a defined place in the mangagement of malignant disease particularly hematological malignancies (2006 Educational Book, 42nd Annual meeting, June 2 - 6; pgs. 387 - 396; www.ASCO.org). BMT can be conducted in community institutions because it is now safer. ASCO cites that the safety has improved because of better supportive care, new conditioning regimens, and better management of side effects of transplantation. Michigan had an all time high of 536 BMT cases in 2007. Additionally, there has been a steady rise annually in the number of bone marrow/stem cell transplantations (SCT) performed worldwide for a variety of reasons as referenced below.

- availability of Allogeneic donors to patients who do not have a HLA - identical sibling having increased - through the use of matched unrelated donors (MUD). The National Marrow Donor program (NMDP) has stated that more than 10,000 transplants have now been done utilizing unrelated donors. There are now more than 4 million donors listed in the NMDP registry.
- Transplantation can now be done safely in older patients - due to significant advances in supportive care and the introduction of non myeloablatibe and reduced intensity conditioning regimens.
- The ASCO paper states the unfortunate fact that "not all patients with an available HLA - matched donor and an uncontroversial indication for Allogeneic SCT actually receive the treatment." So, clearly there is limite access to BMT/SCT. As a practicing hematologist/oncologist exclusively in hematological malignancies where such a procedure is considered a standard of care, I can attest that access is also limited in our state. Some of the reasons are obvious like the geographic distance from a transplant center. However there are other, no less important reasons, some of which are as follows:

--Disruption of Continuity of Care - It is far more efficient and cost effective to perform BMT in the same location where the oncologist; patient relationship has been established. When transferring a patient to a transplant center not only is continuity of care disrupted but also there are additional costs and incurred because tests are typically repeated. The oncologist has to relay all patient information to the center and agree on a path of treatment and timing for transplant. This involves careful and time consuming coordination on the part of the physicians involved. Post transplant, oncologists again need to spend time with the transplant center to understand prescribed treatment regimen and results again require time consuming coordination and fragmentation of patient care. Such an environment creates additional cost and imposes hardships on the patient and referring oncologists. As a result, community oncologists do not readily refer their patients for this proc
edure, which in essence limits access to the procedure.

-- Limiting the number of Transplant Centers greatly limits the visibility of the procedure - among community oncologists which affects the timely referral of their patients thus limiting access. For this reason, treating physicians in the community often don't seek BMT/SCT at all or not early in the course of the disease where the procedure is most effective. A transplant team on site is much more likely to advocate for the procedure to colleagues within their institution than what current transplant center experts have done or can do at community centers.

There is confusion in the use of terms like "capacity" at existing transplant centers and "access" to transplantation. While our colleagues at current transplant centers are eager to accomodate referrals from the community statewide "ie. they feel they have capacity", accessibility of transplantation depends on other factors that are not visible to the transplant centers. Making BMT/SCT available to every patient in the State of Michigan who needs it goes beyond capacity at or access to the existing transplant centers. The lack of onsite transplant service in the community and the need to refer patients outside is so burdensome for both patients and referring physicians in the current environment that the procedure is clearly not being offered to all patients who are candidates; hence we are not making this procedure available/accessible to our patients.

The relative cost of transplant has changed since the inception of CON BMT standards. The cost of this procedure has decreased at a time when new non transplant, treatments cost more than transplant. Instead of referring patients to transplant when it is most appropriate, community physicians resort to treating patients with alternative methods like multiple salvage chemotherapy regimens, radiation therapy, etc. Such practice adds to the cost of healthcare and provides suboptimum care to patients. It is more cost effective to perform BMT/SCT for a patient with lymphoma at first relapse, for example than to give one, two or three salvage regimens plus radiation therapy. This speaks strongly against the argument of adding costs to healthcare by setting up more transplant centers. Moreover, BMT/SCT is a curative modality in such a case whereas the other approach is strictly palliative.

St. John Health advocates that the CON Commission allow for review of the standards to determine an institution specific needs based methodology to support BMT centers where there is critical mass to support a program while meeting strict national and state programmatic, clinical, quality indicators for BMT. Alternatively, we recommend elimination of BMT from being a covered clinical service under the Certificate of Need program.