1. Name: Barbara Winston Jackson
2. Organization: BCBSM/BCN
3. Phone: 248.448.2710
4. Email: bjackson3@bcbsm.com
6. Testimony:

Blue Cross Blue Shield of Michigan/Blue Care Network
MDCH Public Hearing
February 10, 2010

Thank you for the opportunity to provide testimony on behalf of Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network (BCN). BCBSM and BCN continue to actively support the Certificate of Need (CON) program, designed to ensure the delivery of cost-effective, high quality health care to Michigan residents.

Bone Marrow Transplantation (BMT) Services Standard Advisory Committee (SAC)
BCBSM and BCN commend the work of BMT SAC members and MDCH staff during this groupÆs challenging deliberations. BCBSM/BCN was actively engaged as an open-minded participant of this process, well represented by Dr. Tom Ruane, BCBSM PPO Medical Director.

BCBSM and BCN remain unconvinced that there is a need for additional Michigan BMT programs despite the extensive information presented during the course of this SAC including presentations, discussions, statistical analyses as well as the input of clinician-specialists. Dr. Ruane stated thatöBCBSM/BCN is not convinced that the improved access that would occuràwould outweigh the problems caused by decreased volume in the existing centersà.ö

Magnetic Resonance Imaging Service Standards
BCBSM and BCN continue to oppose many proposed exemptions to CON review standards, since multiple exceptions weaken the standards as a whole and have the potential to increase costs of health care service delivery. In this case, BCBSM/BCN does not support proposed language that allows replacing mobile MRI units with fixed MRI units for freestanding for-profit imaging centers that provide at least 25% of their service to Medicaidûcovered patients. There are many questions regarding the validity of this proposal from a public policy rationale. Also, this additional capacity would be in direct competition with existing hospital-based not for profit MRI units, including for patients having coverage other than Medicaid.

Conclusion
BCBSM and BCN continue to support the CON program and the ongoing review of the standards in terms of cost, quality and/or access concerns. We applaud the CON Commission and MDCH staff as they continue to facilitate an objective review process, by eliciting in-depth clinical expertise as well as input from consumers, purchasers, and payors. BCBSM/BCN will continue to be an open-minded, active participant in these endeavors. As always, BCBSM/BCN commends the CON Commissioners and MDCH staff for their diligent efforts in maintaining CON as a strong, vibrant program, to ensure the delivery of high quality, safe and effective health care to patients across the state.

1. Name: Sean Gehle
2. Organization: Ascension Health - Michigan
3. Phone: 517-482-1422
4. Email: sean.gehle@stjohn.org
5. Standards: MRI
6. Testimony: MRI û Charity Care Proposal

My name is Sean Gehle and I am submitting comments on behalf of Ascension Health û Michigan (Borgess Health, Genesys Health system, St. John Health system, St. MaryÆs of Michigan and St. Joseph Health system). We would like to once again express opposition to proposed language that adds an exception to the criteria for conversion of a mobile to a fixed MRI for a for-profit freestanding facility with 2,000 MRI adjusted procedures and at least 25% of the MRI visits having a payor source of Medicaid and/or no charge.

While we again applaud Basha Diagnostics for its inclusion of a significant percentage of Medicaid and no charge patients in its case mix, we believe that allowing for this exception will negatively impact the private nonprofit healthcare safety net by weakening nonprofit providers and ultimately would not be in the best interest of the patients that we serve. Ascension Health û Michigan hospitals and health systems take very seriously our obligation to ensure access to Medicaid and uninsured patients across a wide array of healthcare services.

We continue to oppose the creation of a different and lower threshold for for-profit entities vis-α-vis non-profit providers that would be necessary in order to convert a mobile MRI to Fixed and believe that this establishes a dangerous precedent in the broader CON Standard context. We further question what legal basis may exist around the creation of standards that differentiate providers based on tax status within CON standards.

Finally, we are supportive of the comments that we expect will be submitted on behalf of the MHA and its members before the comment period closes.

Thank you for the opportunity to comment on this important issue.

7. Testimony:

1. Name: Yahya M. Basha, M.D.
2. Organization: Basha Diagnostics, PC
3. Phone: 248-288-1600
4. Email: bashadiagnostics@aol.com
5. Standards: MRI
6. Testimony:

Content-Length: 279875

Basha Diagnostics, P.C.
specializing in medical imaging

February 15, 2010

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

Re: CON Standards for MRI Services

Dear Chairman Goldman,

I would like to take this opportunity to thank you and all of your colleagues on the Certificate of Need Commission for all of the care and attention you have given to the issues we have raised over the past year regarding access to MRI services for the underserved patient populations in our state. We especially would like to thank Dr. Sandler for all of the time he spent as the chair of the MRI workgroup and the extra effort he made in explaining this issue to the Commission at the many meetings during which this issue has been discussed. In addition, we would also like to specifically thank those CON Commissioners who took extra time out of their busy schedules to talk with us directly about this important issue and review the information and data we have provided to all of you over the past year, and especially those who felt strongly enough to speak up in support. We feel this issue has received a great deal of consideration and support from the Commission and we are truly grateful.

I am writing today to respectfully withdraw our request to the Commission to modify the CON Standards for MRI Services to allow the conversion of a mobile MRI host site to a fixed MRI unit upon maintaining a volume of 2,000 available adjusted procedures with a payer mix of at least 25% Medicaid and/or No Charge, more commonly referred to as the MRI Charity Care Proposal. Although our mission and belief in providing access to the underserved has not waivered, we recognize that the timing for these proposed changes may not yet be ideal. Everyone is struggling in this economy - patients, providers, and payers - putting a great deal of strain on all. Rather than moving forward with our proposal in an environment of increasing conflict and opposition, we would rather focus our attentions on working in the spirit of cooperation with our colleagues and the Department.

The support of the Commission in our efforts has been refreshing. Through your efforts on this issue you have shown that patient care and good public policy comes first in Certificate of Need. Rest assured that we will continue to reach out to those in need and continue to provide diagnostic services to the underserved populations in southeast

Michigan and beyond, and look forward to working with others to continue improving access for our most vulnerable citizens. Again, we thank you for your time and attention to this issue and look forward to working with you in the future on such important policy matters.

Respectfully,

Yahya M. Basha, M.D., President
BASHA DIAGNOSTICS, P.C.

DiagnosticImaging.com

November 4, 2009
Diagnostic Imaging

ACR predicts 'access catastrophe' from 16% Medicare rate cuts

By James Brice

The American College of Radiology is predicting that imaging access will plunge and patient waiting times will soar from new Medicare Physician Fee Schedule rules that will cut Medicare payments for outpatient imaging by an estimated 16% next year.

Pressure from the Obama administration to restrain Medicare spending to offset the expected costs of expanded access through healthcare reforms was evident in rules that generally chipped away at high-cost services or well-paid physician specialists.

ACR officials expressed dismay at the new fee schedule rules, to be implemented Jan. 1.

"These shortsighted, unfounded, and misguided cuts will imperil community-based imaging, restrict access to cutting-edge imaging scans, and delay diagnosis of cancers and other critical conditions, which may ultimately cost lives," said Dr. James Thrall, chair of the ACR board of chancellors, in a written statement. "Many hospitals are not equipped to handle the substantial influx of patients that could result from the inevitable closure of rural and suburban imaging facilities caused by these cuts."

Thrall's concern stems from new fee schedule rules that will raise the assumed utilization rate from 50% to 90% for a typical 45-hour work week for imaging equipment with an initial purchase price of more than $1 million. The increased utilization rate translates into lower reimbursement rates for outpatient imaging services.

To back up its opposition the 90% assumed utilization rate, the ACR referred to a recent Radiology Business Management Association survey finding that rural providers use scanners only 48% of office hours and that the national average is only 54%. The survey was conducted after a high utilization rate was proposed, however, a factor that may have biased how the imaging center managers responded to the questionnaire.

For the 2010 rules, CMS used practice expense data from the AMA's Physician Practice Information Survey, a move that led to payment cuts for CT and MRI. The ACR criticized the AMA survey for not questioning enough radiologists to assure accurate results. The costs of office-based radiology practices were significantly underrepresented, it said.

In combination, the higher utilization assumption and practice expense reimbursement adjustments produced an across-the-board average 16% cut to imaging providers. Reimbursement for some procedures, such as lung CT or spinal MRI, could fall more than 40%, according to the ACR.

According to the Access to Medical Imaging Coalition, which represents proimaging interests, the 2010 fee schedule will cut payments for nonhospital outpatient imaging by 48% for pelvic CT, 46% for MRI of the chest and spine, and 27% for selected cardiovascular imaging services. Cuts to cardiology services could affect up to two-thirds of cardiovascular

patients as some practices are forced to close, AMIC said in a release.

"These are catastrophic cuts when you talk about the combination of the practice expense and presumed utilization rate changes," said AMIC executive director Tim Trysla. "I know there is a lot of money being shifted to primary care physicians, but our biggest concern is these decisions are based on very limited information, largely from hospitals, to make these cuts."

BAD NEWS FOR CARDIOGISTS

Cardiologists were also displeased with CMS's use of the AMA practice survey. The American College of Cardiology blamed it for cuts from 10% to more than 40% for individual services. The reductions will be phased in over four years. Imaging-related cuts include a 36% cut for SPECT myocardial perfusion imaging, a 10% cut for transthoracic echocardiography with spectral and color flow Doppler, a 4% cut for coronary artery stenting, and a 5% cut for EKG.

The myocardial perfusion imaging rate cut will be implemented in January. CMS has also reduced payments for myocardial perfusion/SPECT studies by including wall motion and ejection fraction under a single billing code. The deep reimbursement cuts stem from a reduced physician work value and practice expense value, according to the ACC.

The 2010 fee schedule rules would be set in stone if this were an ordinary year, but with Congress fixated on reform, anything could happen in the next few weeks.

PENDING SGR CUTS

The imaging community will count on Congress to stave off the 21.2% across-the-board physician payment cut announced by CMS to adjust payments for its mandated sustainable growth rate requirement. Congress has intervened in each of the past seven years to delay proposed reductions. The accumulated effect of those individual decisions is reflected in the magnitude of the pending cut.

How Congress will respond this year is not easy to determine, according to Tom Greeson, a healthcare attorney with the law firm of Reed Smith. There have been attempts to deal with the so-called physician fix of the SGR mandate in reform legislation and in separate bills in the House and Senate.

The House reform bill would create two SGR update categories, Greeson said. The SGR increase in 2010 would be based on the Medicare Economic Index, a measure of inflation. It would be governed by two separate formulas in 2011, with primary and preventive services set at 2% above the index, and all other services, including diagnostic imaging, nuclear medicine, and radiation oncology, adjusted to 1% above the index, Greeson said.

Congress will also probably weigh in on the assumed utilization rate controversy. The Senate Finance Committee reform bill would increase the presumed utilization for advanced imaging technologies from the current 50% to 65%. The higher rates would be adopted incrementally between 2010 and 2013, according to Greeson. A required study of the higher rates will assess the reform's impact on Medicare costs and access to imaging services and in rural and underserved communities. It would have to be completed by 2013. Without follow-up congressional action, the presumed rate will increase to 75% in 2014.

The House bill would cut the presumed rate for MR, CT, PET, and nuclear medicine to 75%. That cut would be implemented in 2011.

ACCREDITATION TALK

Though still in the discussion stage, CMS invited comments on the 2010 final rules about the possibility of linking the 2012 accreditation requirement for high-tech medical imaging covered by Medicare and the antimarkup rule for

independent diagnostic testing facilities, including self-referred in-office imaging services.

CMS raised the possibility of requiring physicians who provide general supervision for imaging to also serve as the physician who bills Medicare for those services, Greeson said. The new accreditation rule will apply professional competency standards to the supervising physician.

"It is generally assumed that the accrediting organization will require physicians to demonstrate that they are qualified to perform the service," Greeson said. "CMS will not dictate what those qualifications are, but it expects the accrediting organizations to have credentialing requirements for the physicians who perform and provide general supervision for imaging services."

This article is part of a series

2010 Medicare fee schedule boosts equipment utilization rate

Medicare cuts threaten small imaging facilities

2010 rate cuts could be worse than DRA, analysis finds

- ACR predicts 'access catastrophe' from 16% Medicare rate cuts

1. Name: Eric Fischer
2. Organization: Detroit Medical Center
3. Phone: (313) 966-8283
4. Email: efischer@dmc.org
5. Standards: MRI
6. Testimony:

The Detroit Medical Center opposes the language to amend the Magnetic Resonance Imaging Standards that define the process through which host sites initiate fixed services. If approved, the change would benefit a select group of host sites in a manner that increases costs, fails to enhance access and does not improve quality. Further, the compliance terms linked to the change would be difficult to monitor and impossible to enforce in any reasonable manner.

The following proposed language in Section 3 of the Standards would dramatically alter the CON process:

(IV) AT LEAST 2,000 MRI ADJUSTED PROCEDURES AND THE APPLICANT MEETS ALL OF THE FOLLOWING:
(A)AT LEAST 25% OF THE MRI VISITS HAVE A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE.
(B) THE APPLICANT IS A FOR-PROFIT, FREESTANDING FACILITY.

Lowering the threshold to specifically accommodate for-profit imaging centers essentially removes them from the thoroughly researched and calculated need justification process. The proposed change would create an unbalanced field of competition between for profit and nonprofit MRI services.

As the MRI standards now read, any host site may become a fixed service once it reaches the 6,000 AP threshold. This language is consistent with the MRI fixed service initiation process. The current methodology upholds the stated goals of the MDCH with regards to cost, access and quality. By holding a host site to the current stipulations, the MDCH assures the public that expenditures for new units will only be made where proven need truly exists.

The proposed language will increase medical service cost by adding more fixed MRI's in already well served areas. Per the Novemenber 1, 2009 MRI Utilization List, at least twelve for profit host sites meet the proposed criteria for initiating fixed units and three more are within 500 AP's. So, in the very near future, if approved, this new language could put fifteen new MRI units in Michigan. Using an average price of $1,500,000 per unit, amending the standards would create $22,500,000 in for profit health care expenditures. If the language were more equitably amended to include nonprofits, at least another eighteen services would immediately qualify. Combined, Michigan health providers woud be free to spend roughly $49,500,000 on new equipment without inproving access or quality.

Many of these for profit centers exist within five miles of nonprofit hospitals who have already invested in the appropriate fixed technology. The attached maps show ten mile radiuses around two host sites owned by Basha Diagnosics in Royal Oak and Sterling Heights that would qualify under the proposed language. In Royal Oak, the surrounding ten mile area already contains twenty seven fixed MRI units. Fourteen of these are within five miles. Beaunmont's Royal Oak Hospital operates six MRI's within a half mile of the Basha Diagnostics host site.

Similarly, in Sterling Heights, Basha Diagnostics is less than a mile from another fixed provider, Macomb MRI. Ten services, operating fourteen fixed units, serve patients within this ten mile radius. From these maps, which do not even include the other

mobile host sites in the areas, one clearly understands that neither cost nor access is a reason to approve the proposed language.

According to Kaiser Family Foundation research, in 2006 18% of Michigan's population participated in Medicaid. Therefore, achieving the 25% proposed Medicaid and self pay threshold would not be difficult. Since Michigan's CON standards already require that CON licensed facilities accept Medicaid, adding more fixed units would not improve access based on one's ability to pay.

In medicine, clinical quality is synonymous with repetition. One of the reasons the MDCH insists upon minimum volumes is the health care industry standard that providers improve when they deliver high volumes of similar care. Lowering the initiation threshold by two-thirds means that host site clinical and support staff will not be as experienced as if they had done 6,000 AP's the previousl twelve months. This could negatively affect the delivery of patient care.

One way to improve staff skills as the patient base grows is to utilize mobile MRI services. Many existing mobile units have the capacity to meet the needs of busy host sites. Once a site reaches the already appropriately defined threshold of 6,000 AP's, it may then initiate a fixed unit. Until then, host sites should work collaboratively with existing mobile units to cultivate staff.

The compliance language in Section 12 (3) associated with this proposed change presents another set of challenges:

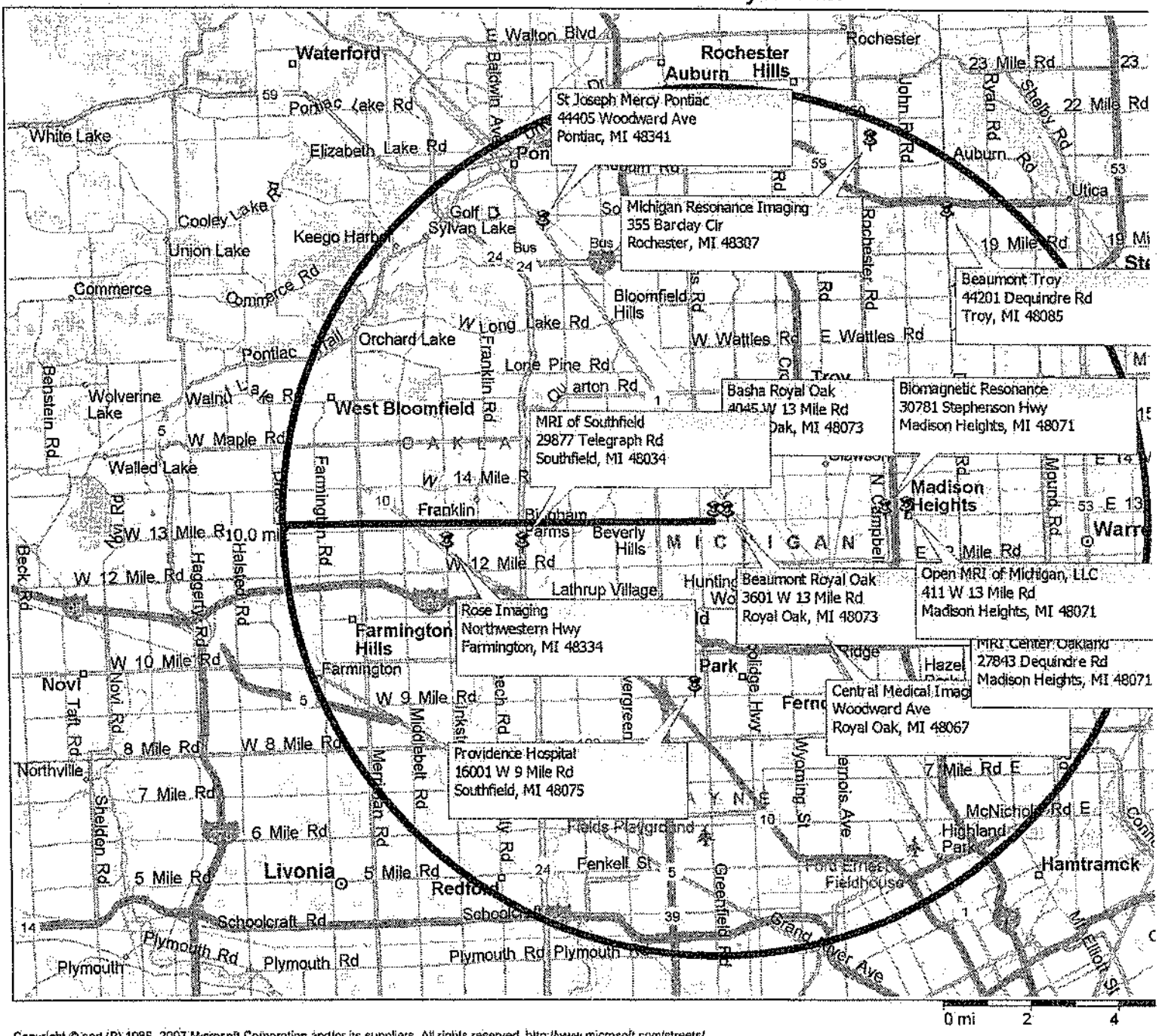
(3) AN APPLICANT FOR AN MRI UNIT APPROVED UNDER SECTION 3(2)(B)(IV) SHALL AGREE TO CONTINUE TO PROVIDE AT LEAST 25% OF THE MRI VISITS WITH A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE DURING THE FIRST 12 MONTHS OF OPERATION AND ANNUALLY THEREAFTER FOR AT LEAST 10 YEARS.

Who will cover the cost to monitor this? What will happen if the service payer mix improves? Since treating fewer Medicaid and self pay generally means that one receives higher average reimbursement, will the MDCH shut down a fixed MRI service because it is more profitable than before? How does the MDCH plan to enforce this standard and what will the penalties be for failing to meet it? The DMC thinks that these questions should be answered and appropriate enforcement language included in the standards before any vote is taken on the proposed language.

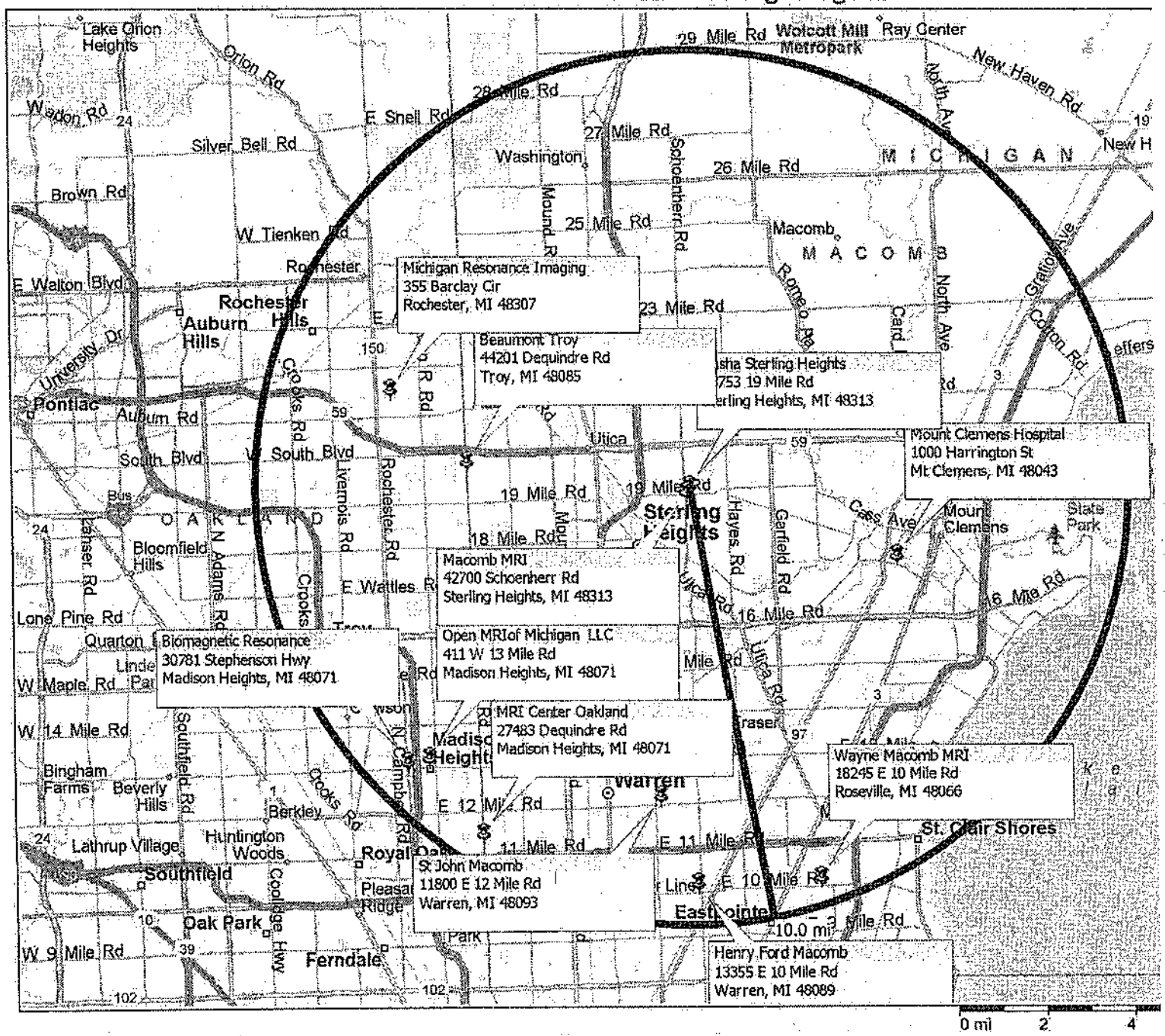
In conclusion, the Detroit Medical Center strongly opposes the proposed language as written. altering or adding language to create separate rules in favor of for profit centers undermines the CON process, to which the nonprofits would still be held, and establishes a competitive advantage at the expense of the hospitals. The language does not meaningfully address cost, access, or quality. further, it poses complicated, and thus far, unanswered questions as to monitoring and compliance. The DMC sincerely hopes that the Commission will reject this proposed language.

7. Testimony:

Basha Royal Oak



Basha Sterling Heights



Basha Diagnostics Sterling Heights Ten Mile Radius

Service	Clinical Units	Service ID
Bio-Magnetic Resonance, Inc	2	850137
Macomb MRI Center	1	920090
Mich Resonance Imaging/MCGH	1	060213
Michigan Resonance Imaging	2	880211
MRI Center/Oakland	1	870430
Open MRI of Michigan LLC	1	000175
St John Macomb Hospital	1	990133
William Beaumont Troy	3	960174
Henry Ford macomb	1	650161
Wayne Macomb MRI	1	870029
	14	TOTAL UNITS

1. Name: Dennis McCafferty
2. Organization: The Economic Alliance for Michigan
3. Phone: 248 596 1006
4. Email: dennismccafferty@EAMonline.org
5. Standards: MRI
6. Testimony:

Magnetic Resonance Imaging (MRI) Services:
EAM Board does not support the proposed changes in the MRI Standards that would allow replacing a mobile MRI with fixed MRI units for freestanding, for-profit imaging centers that provide at least 25% of their services to Medicaid and ôno chargeö patients. This change would allow for-profit, freestanding MRI programs that are providing MRI services using a mobile unit, to replace the mobile unit with a fixed unit when their annual volume of adjusted scans has exceeded just 33% (2000 adjusted scans) of the CON standardÆs required annual minimum of 6000 adjusted scans.

This proposed change in the CON standards is most likely to affect only the BASHA Diagnostic MRI programs in Royal Oak and Sterling Heights. The non-profit hospitals in or near these two communities that have a CON for MRI unit are already obligated, as are all other holders of CONs for MRI services, to provide this service to patients regardless of what insurance coverage they may have or if they have any insurance.

There is clearly a difference in how to assess the data on the provision of MRI services to Medicaid patients, but also to the medically indigent and the non-English speaking populations. BASHA Diagnostic, as the one for-profit arguing for this special provision to allow it a much easier requirement for securing a fixed MRI, has had a special analysis prepared by its lobbying firm saying that the nearby hospitals are significantly lacking in serving these populations. More recently, the Michigan Health and Hospital Association has done a different analysis indicating that there is no statistically significant difference in the providing of MRI services for these populations. Hopefully the data dispute will be soon resolved by the analysis of the data on this question that was requested of the MDCH staff by the Commission at the December meeting.

For the Economic Alliance for Michigan, the remedy for some programs not living up to their CON obligations to provide MRI services regardless of ôsource or amount of paymentö is for MDCH to promptly enforce this long-standing CON requirement. All MRI CON programs should collectively and individually be held to providing MRI services to Medicaid recipients and the indigent in reasonable proportion to those numbers in their service areas.

The wrong response is to allow a specific exemption to the MRI CON standardÆs annual minimum volume requirements, when community need has not been demonstrated. That would seriously undermine the CON programÆs obligation to serve the communityÆs needs for access to high quality, low cost health care services.

There is no obvious logic to saying that this special lower volume requirement would apply to for-profit but not to non-profits who have a State and Federal tax obligations to serve these special populations. If the Commission adopts this provision, you will soon be faced with a series of other requests for special exemptions to the minimum CON requirements from others who say theyÆre fulfilling the socially and medically desirable objective that are CON requirements for all holders of CON for a particular service.

7. Testimony:

1. Name: Amy Barkholz
2. Organization: Michigan Health & Hospital Association
3. Phone: 517-886-8224
4. Email: abarkholz@mha.org
5. Standards: MRI
6. Testimony:

Content-Length: 150300

TO: Certificate of Need Commission

FROM: Amy Barkholz, General Counsel

DATE: February 10, 2010

SUBJECT: **Public Comment – Proposed MRI Language**
MHA Position: OPPOSED

The Michigan Health & Hospital Association opposes proposed language amending the Certificate of Need standards for magnetic resonance imaging (MRI) services that would allow a for-profit, freestanding facility to obtain a fixed unit if it performed 2,000 annual adjusted procedures and provided at least 25 percent of its total MRI services to Medicaid and 'no charge' patients for a specified period of time. **The MHA believes this exception is unwarranted because data does not support the access concern and it will create an arbitrary financial incentive for excess utilization.**

The current MRI standards generally require applicants for a fixed unit to perform 6,000 annual adjusted procedures. In addition there are two current exceptions in the MRI standards to ensure adequate patient access to services. The first exception allows an applicant located in a county without any fixed MRI services and located more than 15 miles from another fixed MRI machine to qualify for a fixed unit if it performs 4,000 annual adjusted procedures. The second exception allows a licensed hospital with a high volume 24-hour emergency department (ED) to qualify for a fixed MRI if the ED has at least 20,000 annual visits and the applicant performs at least 3,000 annual adjusted procedures. Both of these exceptions address a specific concern related to access to care.

Basha Diagnostics, the MRI service provider that initiated the proposed exception, has a facility in Oakland County and another in Macomb County. According to data provided to the CON Commission by Basha Diagnostics at the December 2009 CON Commission Meeting using Michigan Department of Community Health figures, 4.7 percent of patients in Macomb/Oakland/Wayne counties that sought MRIs from July 1, 2008 through June 30, 2009 had Medicaid insurance and 1.2 percent sought services at 'no charge.' During that same period of time, according to the MDCH data, 4.3 percent of the MRI's hospitals in Macomb/Oakland/Wayne counties provided were to patients with Medicaid insurance and 1.1 percent were provided to patients at 'no charge.' The Macomb/Oakland/Wayne hospitals' MRI payer mix very closely mirrors the payer mix of the tri-county residents seeking MRI's, which indicates appropriate access for Medicaid and 'no-pay' patients. Non-hospital MRI providers, other than Basha Diagnostics, were not included in the MDCH data but existing CON law requires all applicants to accept Medicaid patients. Given the similarity between the percentages of Medicaid and 'no-charge' patients seeking MRI services and the percentages of these patients receiving MRI's (at least at non-profit hospitals) there does not appear to be justification for this proposed 'for-profit charity exception' based on a lack of access for Medicaid and 'no charge' patients. Furthermore, no quality or cost justification for this proposed language has been suggested.

In addition to demonstrating no cost, quality or access problem with the MRI standards as currently written, the proposed language would cause excess capacity if approved. By reducing the current fixed unit volume threshold of 6,000 annual adjusted procedures by two-thirds to only 2,000 annual adjusted procedures, at least twelve for-profit host sites would be eligible to convert to fixed MRI units according to the MDCH November 1, 2009 MRI Utilization List. As it stands now, there are currently 27 fixed MRI units within a 10 mile radius surrounding the Basha Diagnostics facility in Royal Oak and 14 fixed MRI units within a 10 mile radius of the Basha Diagnostics facility in Sterling Heights. Given the prevalence of fixed MRI units already servicing this area, the current volume requirement should not be reduced by two-thirds.

This proposed 'for-profit charity' exception to the MRI standards highlights legitimate concerns about the need to ensure that all patients have appropriate access to health care, regardless of the type of insurance they have or whether they can pay for their care. Specific instances of lack of access for certain groups of patients should be investigated. For profit entities should fully participate in Medicaid and are encouraged to take charity patients as well. Traditionally, and appropriately, it has fallen mainly to nonprofit community hospitals to serve as the 'safety net' for all patients regardless of their ability to pay for health care. Increasingly this role has become more and more difficult in light of growing numbers of uninsured patients, inadequate Medicaid rates, and a reduced willingness of other payers to absorb these shortfalls. In 2008, Michigan's nonprofit hospitals provided more than $240 million in charity care, more than $557 million in uncollectable costs for treatment ("bad debt"), and more than $706 million in care to Medicaid patients.

This proposed MRI language, which is intended to improve access to care for Medicaid and uninsured patients, actually puts further strain on the health care safety net and weakens full-service, nonprofit providers. This is unprecedented in CON policy and fails to recognize that nonprofit community hospitals and for-profit freestanding facilities do not compete on a level playing field. Unlike for-profit freestanding entities, nonprofit community hospitals must provide care across a full range of services. The CON program has traditionally recognized this additional burden when setting its standards. In contrast, this proposal specifically grants a very significant exception (a two-thirds reduction in the adjusted volume level) to freestanding, for-profit entities. The proposal sets an artificial Medicaid and charity care threshold for one category of providers (for-profit freestanding facilities) that is not based on a factual determination of need. MDCH data provided to the CON Commission shows that the payer mix of southeast Michigan patients seeking MRI's closely matches the Medicaid and 'no charge' payer mix of patients receiving MRI's. **The MHA is concerned that the unintended effect of approving this language will be the creation of a financial incentive for inappropriate utilization in order to meet an artificial threshold and thus gain an unfair carve-out in the CON standards to qualify for an unnecessary fixed MRI that will primarily service privately insured patients.**

Michigan's effective CON program has allowed it to escape some of the problematic excesses of unregulated states. In other states, for profit specialty services have crowded out nonprofit community hospitals and this has resulted in higher health care costs, uneven access, and less quality care for all patients. Proposed carve-outs to the existing standards, such as this one, create a bad precedent that will further erode and weaken the effectiveness of the CON program. For these reasons, the MHA strongly opposes the proposed MRI carve-out for for-profit entities and urges the CON Commission to vote 'no' on this amendment during final action at the March CON Commission meeting. Please contact Amy Barkholz at (517) 886-8224 or abarkholz@mha.org with any questions.

1. Name: Janelle R. Spann
2. Organization: Michigan Resonance Imaging
3. Phone: 248-299-8000
4. Email: mrirochesterhills@ameritech.net
5. Standards: MRI
6. Testimony:

Content-Length: 50827

TO: Certificate of Need Commission

FROM: Janelle Spann, Executive Director

DATE: February 16, 2010

SUBJECT: **Public Comment – Proposed MRI Language**
Michigan Resonance Imaging Position: OPPOSED

Michigan Resonance Imaging is a 501 C-3 not-for- profit Michigan Corporation, performing only MRI services in Southeastern Michigan. We are a joint venture for 3 community hospitals, Crittenton Hospital Medical Center, Mt Clemens Regional Medical Center and POH Regional Medical Center. Michigan Resonance Imaging opposes proposed language amending the Certificate of Need standards for magnetic resonance imaging (MRI) services that would allow a for-profit, mobile host site service provider to convert to a fixed unit if it performed 2,000 annual adjusted procedures and provided at least 25 percent of its total MRI services to Medicaid and 'no charge' patients for a specified period of time. **Michigan Resonance Imaging believes this exception is not justified because data does not support the access concern and it will create an arbitrary financial incentive for excess utilization with 25% Medicaid, the remaining 75% revenue would be generated potentially from private insurers.**

The current MRI standards generally require applicants for a fixed unit to perform 6,000 annual adjusted procedures. In addition there are two current exceptions in the MRI standards to ensure adequate patient access to services. The first exception allows an applicant located in a county without any fixed MRI services and located more than 15 miles from another fixed MRI machine to qualify for a fixed unit if it performs 4,000 annual adjusted procedures. The second exception allows a licensed hospital with a high volume 24-hour emergency department (ED) to qualify for a fixed MRI if the ED has at least 20,000 annual visits and the applicant performs at least 3,000 annual adjusted procedures. Both of these exceptions address a specific concern related to access to care. **These existing exceptions are based on population density and patient focused standards of care requiring emergent access.**

Basha Diagnostics, the MRI service provider that initiated the proposed exception, has a facility in Oakland County and another in Macomb County. According to data provided to the CON Commission by Basha Diagnostics at the December 2009 CON Commission Meeting using Michigan Department of Community Health figures, 4.7 percent of patients in Macomb/Oakland/Wayne counties that sought MRIs from July 1, 2008 through June 30, 2009 had Medicaid insurance and 1.2 percent sought services at 'no charge.' During that same period of time, according to the MDCH data, 4.3 percent of the MRI's hospitals in Macomb/Oakland/Wayne counties provided were to patients with Medicaid insurance and 1.1 percent were provided to patients at 'no charge.' The Macomb/Oakland/Wayne hospitals' MRI payer mix very closely mirrors the payer mix of the tri-county residents seeking MRI's, which indicates appropriate access for Medicaid and 'no-pay' patients. Non-hospital MRI providers, other than Basha Diagnostics, were not included in the MDCH data **but existing CON law requires all approved CON applicants to accept Medicaid patients**. Given the similarity between the percentages of Medicaid and 'no-charge' patients seeking MRI services and the percentages of these patients receiving MRI's (at least at non-profit hospitals) there does not appear to be justification for this proposed 'for-profit charity exception' based on a lack of access for Medicaid and 'no charge' patients. Furthermore, **no quality or cost justification for this proposed language has been suggested.**

In addition to demonstrating no cost, quality or access problem with the MRI standards as currently written, the proposed language would cause **excess capacity** if approved. By reducing the current fixed unit volume threshold of 6,000 annual adjusted procedures by 66% to only 2,000 annual adjusted procedures, at least twelve for-profit host sites would be eligible to convert to fixed MRI units according to the MDCH November 1, 2009 MRI Utilization List. These potential additional fixed sites would create a **"compliance issue"** for existing providers **and the MDCH** with the existing MDCH MRI standards in areas that are currently market saturated. Subsequently, should this language be approved, existing providers may not be compliant or able to replace out-dated equipment, **causing a potential quality of care issue**. As it stands now, there are currently 27 fixed MRI units within a 10 mile radius surrounding the Basha Diagnostics facility in Royal Oak (Beaumont has 6 fixed MRIs less than ¼ of a mile from this site) and 14 fixed MRI units within a 10 mile radius of the Basha Diagnostics facility in Sterling Heights (Macomb MRI is less than ½ mile from the Basha Diagnostics Sterling Heights location). Given the prevalence of fixed MRI units already servicing this area, the current volume requirement should not be reduced by two-thirds.

A **'for-profit charity'** exception to the MRI standards highlights legitimate concerns experienced by all providers, about the need to ensure that all patients have appropriate access to health care, regardless of the type of insurance they have or whether they can pay for their care. For profit entities should fully participate in Medicaid and should take charity patients as well. Traditionally, and appropriately, it has fallen mainly to nonprofit community hospitals to serve as the 'safety net' for all patients regardless of their ability to pay for health care. Michigan Resonance Imaging has a charity policy and does perform charity MRIs, in addition to participating with all Medicaid programs. Increasingly this role has become more and more difficult in light of growing numbers of uninsured patients and inadequate Medicaid rates, but will continue to be part of our mission.

This proposed MRI language, which is intended to improve access to care for Medicaid and uninsured patients, actually puts further strain on the health care safety net and further weakens, nonprofit providers, in an already nationwide stressed environment. This is unprecedented in CON policy. The CON program has traditionally recognized this additional burden when setting its standards. In contrast, this proposal specifically grants a very significant exception (a two-thirds reduction in the adjusted volume level) to freestanding, **for-profit** entities. The proposal sets an arbitrary Medicaid and charity care threshold for **one category of providers** (for-profit freestanding facilities) that is not based on a factual determination of need. Historically, MDCH data provided to the CON Commission shows that the payer mix of southeast Michigan patients seeking MRI's closely matches the Medicaid and 'no charge' payer mix of patients receiving MRI's. **Approving this language will foster financial incentive for inappropriate utilization. This biased, unnecessary carve-out in the CON standards to convert mobile host sites to unneeded additional fixed MRIs will primarily service privately insured patients creating further hardship on existing "not for profit" providers.**

To date the Michigan CON commission has worked at applying a uniform rigorous application process proving need. The commission has judiciously avoided some of the problematic excesses

of unregulated states by maintaining these standards. In other states, for profit specialty services have created inequities for nonprofit entities, resulting in higher health care costs, uneven access, and less quality care for all patients. Approval of this language will erode and weaken the effectiveness and opposes the "mission" of the CON program. For these reasons, Michigan Resonance Imaging strongly opposes the proposed MRI "for-profit" exception and would ask the CON Commission to vote 'no' on this amendment during final action at the March CON Commission meeting. Questions, please contact Janelle Spann at mrirochesterhills@ameritech.net or call to 248-299-8000.

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: (616) 391-2779
4. Email: robert.meeker@spectrum-health.org
5. Standards: MRI
6. Testimony:

The proposed changes allow a for-profit imaging center to convert from mobile to fixed MRI with a reduced volume requirement, if at least 25% of the patients served are indigent (defined as Medicaid or no charge). Spectrum Health has concerns about this proposal. While it is admirable for an imaging center to accept indigent patients, we do not agree that this behavior counterbalances the risk of introducing excess MRI capacity into the system and of reducing the utilization of existing MRI units. The requirement of 6,000 adjusted MR procedures achieved on mobile MRI units is the standard for conversion to fixed MRI. While there are exceptions written in the Standards for instances of demonstrated access concerns, no such access deficit has been demonstrated in this instance. While 6,000 is a high standard, it is achievable through extended hours and use of multiple mobile MRIs. These Standards have been successful in keeping Michigan from experiencing th
e over-capacity (and potential over-utilization) of MRI services that has occurred in other states. Therefore, Spectrum Health recommends that the CON Commission reject these proposed revisions.

Spectrum Health appreciates the opportunity to comment on the revised CON Review Standards for MRI. We urge the CON Commission not to approve the proposed Standards at the March meeting, since the exception included in these proposed revisions is not necessary to assure access to MRI services for the Michigan populace.

7. Testimony:

1. Name: David Williams
2. Organization: Williams Consulting Services, LLC
3. Phone: 248-895-6856
4. Email: david@williamscs.com
5. Standards: MRI
6. Testimony:

Content-Length: 4871587

Williams Consulting Services, which works with both hospital systems and physician owned imaging, opposes the language proposed to amend the Magnetic Resonance Imaging Standards that define the process through which host sites initiate fixed services. If approved, the change would benefit a select group of host sites in a manner that increases costs, fails to enhance access and does not improve quality. Further, the compliance terms linked to the change would be difficult to monitor and impossible to enforce in any reasonable manner.

The proposed changes in Section 3 of the Standards dramatically alter the CON process. Lowering the threshold to specifically accommodate for-profit imaging centers essentially removes them from the thoroughly researched and calculated need justification process. The proposed change would create an unbalanced field of competition between for profit and nonprofit MRI services.

As the MRI standards now read, host sites may initiate fixed units once they reach a threshold of 6,000 AP's. This language is consistent with the MRI fixed service initiation process. The current methodology upholds the stated goals of the MDCH with regards to cost, access and quality. Forcing a host site to adhere to the current stipulations assures the public that expenditures for new units will only be made where proven need truly exists.

The proposed language will increase medical service cost by adding more fixed MRI's in already crowded market places. Per the November 1, 2009 MRI Utilization List, at least twelve for profit host sites meet the proposed volume criteria for initiating fixed units and three more are within 500 AP's. So, in the very near future, if approved, this new language could put fifteen new MRI units in Michigan. Using an average price of $1,500,000 per unit, amending the standards would create $22,500,000 in for profit health care expenditures. If the language were more equitably amended to include nonprofits, at least another eighteen services would immediately qualify. Combined, Michigan health providers would be enabled to spend roughly $49,500,000 on new equipment without improving access or quality.

Many of these for profit centers exist within five miles of nonprofit hospitals who have already invested in the appropriate fixed technology. The attached maps show ten mile radiuses around two example host sites owned by Basha Diagnostics in Royal Oak and Sterling Heights. In Royal Oak, the surrounding ten mile area already contains twenty seven fixed MRI units. Fourteen of these are within five miles. Beaumont's Royal Oak hospital operates six MRI's within a half mile of the Basha Diagnostics host site.

Similarly, in Sterling Heights, Basha Diagnostics' site is less than a mile from another fixed service, Macomb MRI. Ten services operating fourteen fixed units serve patients within a ten mile radius of this site. From these maps, which do not even include the other mobile host sites in the areas, one clearly understands that neither cost nor access is a reason to approve the proposed language. Further, all Michigan CON standards require that CON licensed facilities accept Medicaid. Therefore, adding more fixed units would not improve access based on geography or ability to pay.

In medicine, clinical quality is synonymous with repetition. One of the reasons the MDCH insists upon minimum volumes is the health care industry standard that providers improve when they deliver high volumes of similar care. Lowering the initiation threshold by two-thirds means that host site clinical and

support staff will not be as experienced as if they had done 6,000 AP's the previous twelve months. This could negatively affect the delivery of patient care.

One way to improve staff skills as the patient base grows is to utilize mobile MRI services. Many existing mobile units have the capacity to meet the needs of busy host sites. Once a site reaches the already appropriately defined threshold of 6,000 AP's, it may initiate a fixed unit. Until then, host sites should work collaboratively with existing mobile units.

Many of my clients have already invested heavily in the mobile MRI industry. These companies followed the prescribed rules and made long term plans based upon them. As written, the proposed language has the capability to completely undermine the value of those CON's and their related equipment. A good deal of capital and many jobs could be lost if the new language is approved.

In addition to the increasing upfront costs and failing to enhance access, the compliance language in Section 12 (3) associated with this proposed change presents another set of challenges:

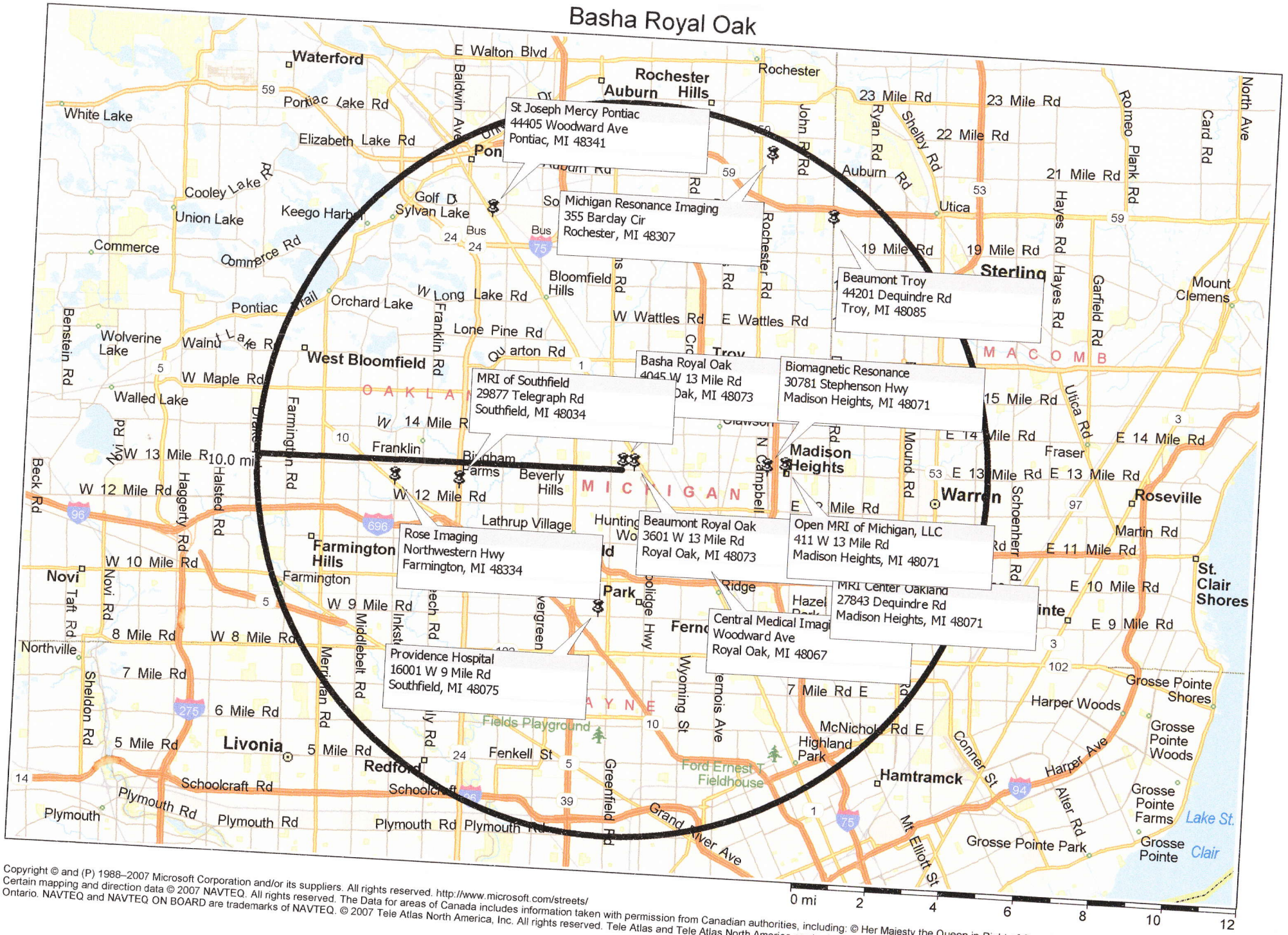
(3) AN APPLICANT FOR AN MRI UNIT APPROVED UNDER SECTION 3(2)(B)(IV) SHALL AGREE TO CONTINUE TO PROVIDE AT LEAST 25% OF THE MRI VISITS WITH A PAYER SOURCE OF MEDICAID AND/OR NO CHARGE DURING THE FIRST 12 MONTHS OF OPERATION AND ANNUALLY THEREAFTER FOR AT LEAST 10 YEARS.

Who will monitor this? What will happen if the service's payer mix improves? Will the MDCH shut down a fixed MRI service because it is more profitable than before? How does the MDCH plan to enforce this standard and what will the penalties be for failing to meet it? WCS thinks that these questions should be answered and appropriate enforcement language included in the standards before any vote is taken on the proposed language.

I think a better approach would be to enhance the Medicaid participation language for all CON holders. I would suggest that a minimum percentage of payer mix each year should be mandatory for CON stakeholders. An automatic fine, payable to the Medicaid fund, could be assessed to non-compliant entities

In conclusion, the Williams Consulting Services strongly opposes the proposed language as written. The language undermines the established and researched measure of need in the current fixed MRI CON process and the existing capital intensive mobile MRI industry. It benefits a select group of for profit stakeholders at the direct expense of the nonprofit hospitals and outpatient centers. Further, it poses complicated, and thus far, unanswered questions as to monitoring and compliance. WCS sincerely hopes that the Commission will reject this proposed language.

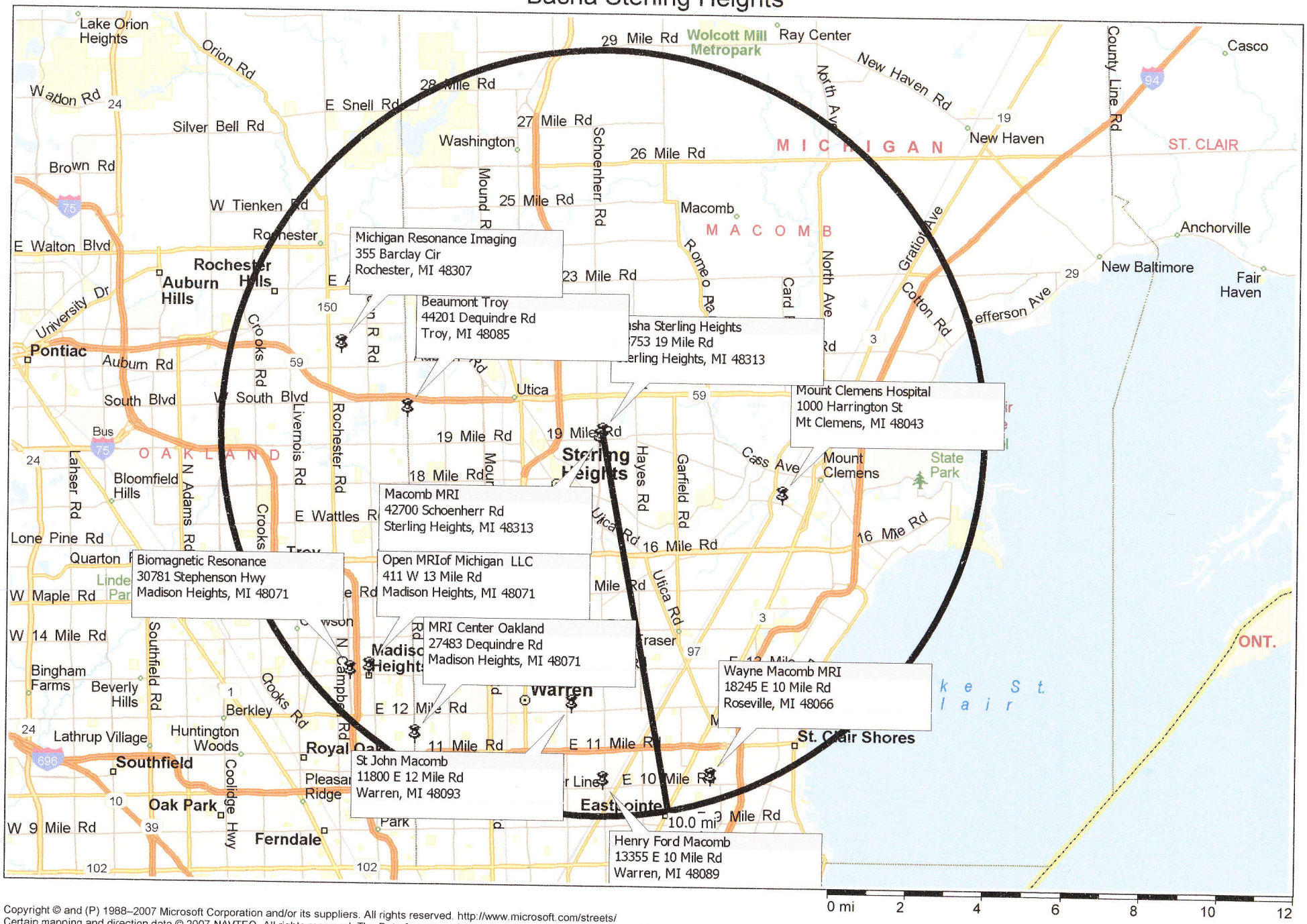
Basha Royal Oak



Basha Diagnostics Royal Oak Ten Mile Radius

Service	Clinical Units	Service ID
Bio-Magnetic Resonance, Inc	2	850137
Central Medical Imaging	1	301186
Mich Institute of Neuro Disorders	2	930123
Michigan Resonance Imaging	2	880211
Millennium MRI Center	1	010445
MRI Center/Oakland	1	870430
MRI of Southfield	2	850131
Open MRI of Michigan LLC	1	000175
Providence Hospital	2	910234
Rose Imaging	1	650157
St Joseph Mercy Oakland	2	940181
William Beaumont Royal Oak	6	650163
William Beaumont Troy	3	960174
	26	TOTAL UNITS

Basha Sterling Heights



Basha Diagnostics Sterling Heights Ten Mile Radius

Service	Clinical Units	Service ID
Bio-Magnetic Resonance, Inc	2	850137
Macomb MRI Center	1	920090
Mich Resonance Imaging/MCGH	1	060213
Michigan Resonance Imaging	2	880211
MRI Center/Oakland	1	870430
Open MRI of Michigan LLC	1	000175
St John Macomb Hospital	1	990133
William Beaumont Troy	3	960174
Henry Ford macomb	1	650161
Wayne Macomb MRI	1	870029
	14	TOTAL UNITS

1. Name: Patrick O'Donovan
2. Organization: Beaumont Hospitals
3. Phone: 248-551-6406
4. Email: podonovan@beaumonthospitals.com
5. Standards: BMT
6. Testimony:

Dear Commissioners:
Beaumont appreciates the opportunity to comment on the proposed BMT standards. We ask that you read and carefully consider the case for expanding BMT access that was made in Frank Vicini's letter to the Commission dated December 8, 2009 (attached). Dr. Vicini is Chief of Oncology for the Beaumont Cancer Institute.

In addition, two comments made by Commissioners in conjunction with the December 9 C.O.N. Commission meeting are worth noting- one relating to patients and one relating to the C.O.N. process:

One Commissioner indicated that he voted against the proposed standards because he felt that a hospital of Beaumont's size with a full service cancer program ought to have BMT services. Another Commissioner stated that he could tell the outcome of the SAC just by looking at the membership composition.

There has never been a methodology behind the BMT C.O.N. standards, and the SAC did not establish one. This goes against a basic tenet of C.O.N., that standards be based on an objective, need-based methodology.

Accordingly, in order to improve access to BMT for cancer patients, we ask the Commission to consider removing BMT from C.O.N. altogether, or quickly consider an institution specific methodology for BMT services.

Sincerely,

Patrick O'Donovan
Director, Planning
Beaumont Hospitals

Content-Length: 280415

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:

Proposed Bone Marrow Transplant Standards:

The EAM Board does not support increasing the number of BMT programs in Michigan. We strongly endorse the proposed standard that would keep the current limit of BMT programs in east Michigan at 3. We feel that the three current programs in east Michigan (Henry Ford, Karmanos and U of M) meet the access and quality needs of the community and that additional programs will result in increasing the cost while harming quality.

However, most Commissioners, while supporting the limit of 3 programs in eastern Michigan, voted to allow one additional program in western Michigan. Given that change, EAM would argue even more strongly in favor of certain other changes included in the proposed BMT standards.

ò Increase the annual volume (from 10 to 30) for all new adult .programs

ò All new adult programs should provide a minimum of 10 allogeneic transplants annually to insure that the level of quality being provided by any new program is of the highest standards. Every patient should be given the option of the most appropriate BMT treatment alternative (allogeneic or autologous). Every BMT program should be able to provide patients the highest level of staff experience/expertise and treatment resources. Autologous only transplant programs do not have the same level of resources and staff experience/ expertise as BMT programs that are able to provide allogeneic transplants.

ò For these reasons, we also support the elimination from the standardÆs all provisions related to autologous only transplant programs.

The three existing programs already meet the above requirements. WhatÆs important is that these requirements would apply to the following possibilities for new programs:

1. The one additional program in west Michigan authorized in the proposed standards,
2. Any other new programs should a CON become available under the current limit of 3 or
3. Any other new programs subsequently allowed in a future Commission process.

BMT SAC Process:

The SAC members were appointed by then Vice-Chair Norma Hagenow from the recommendations made by the MDCH staff, from the candidates who volunteered to participate on this SAC. The MDCH staff reviewed the resumes and selected those who best represented a broad cross-section of BMT ôexpertsö and non-experts from different perspectives, from across the state. All members of the SAC were given a fair opportunity to present their case and that the SACÆs recommendations are a valid consensus of the community at large.

The reason why there was no SAC members from the northern half of the state is that no one from the northern half of the state had express an interest to participate on this SAC. For future SACs, we would urge MDCH to revert to a prior Departmental practice of actively recruiting people during the application period where they see that there is a lack of appropriate candidates. This would apply to assuring geographic representation but also representation of different perspectives.

7. Testimony:

1. Name: Carol Christner
2. Organization: Barbara Ann Karmanos Cancer Institute
3. Phone: 313-578-4436
4. Email: christne@karmanos.org
5. Standards: BMT
6. Testimony:

Content-Length: 9009557

BARBARA ANN
KARMANOS
CANCER INSTITUTE
Wayne State University

Certificate of Need Commission Public Testimony
February 10, 2010

Comments Regarding: BMT SAC Recommendations
Comments Provided by: Carol Christner
Director, Government Relations
Barbara Ann Karmanos Cancer Institute

Karmanos agrees with the SACs recommendation to continue regulation of BMT Services

Karmanos agrees with the SACs recommendation to establish a second planning area, mirroring the pediatric BMT planning area and allow one new program in that area.

Karmanos agrees with the SACs recommendation that no further expansion is needed within southeast Michigan.

On this particular issue, the SAC determined that the only reasons to change the current CON criteria would be if:

1. **Patient needs were not being met;**
2. **Quality of the current programs was poor; or**
3. **Needed treatments were not available.**

There are currently three nationally recognized adult transplant programs in southeast Michigan, all with Foundation for the Accreditation of Cellular Therapy (FACT) accreditation, all with well established quality, and who all report their data to the CIBMTR where outcomes are monitored on an annual basis.

Needs Based Methodology

The SAC reviewed a needs based methodology presented by representatives from Beaumont and St. John's. 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 relies on an accurate assessment and estimation of the number of patients requiring a transplant. The presentation and discussion indicated how difficult this estimation would be. First the number of cancer cases seen at any individual center may have no correlation to how many patients would ultimately require transplant. Transplant is often used in patients who have either advanced disease, relapsed disease or have failed several therapies. These data are 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 152 to one per year over the course of a few years. These changing practice patterns make long term predictions difficult.

4100 John R
Detroit, Michigan 48201
1-800-KARMANOS (1-800-527-6266)
info@karmanos.org | www.karmanos.org

As an indication of how difficult and erroneous this may be, various groups presented the potential number of patients who may be transplanted and volume projections However when these numbers were compared to national standards they were extremely inflated and far higher than what is seen at the national level.

Access

Throughout the SAC process, no member was able to demonstrate that bed shortages exist nor were they able to show that they couldn't get patients to transplant centers.

Data was cited by those wishing to open new programs indicating there is an underutilization of transplantation, however it was not demonstrated that any alleged underutilization was due to a lack of beds 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.

Those wishing to open new programs also suggested that there be a separation of autologous (auto) and allogeneic (allo) transplants because auto transplants are less taxing on families than allo or unrelated transplants. Because auto transplants come from the patients own stem cells, they do not need to stay close to the hospital for as long of time period and are, in many cases, sent home right after the transplant is completed

The major proponents of opening new centers in southeast Michigan operate hospitals that are within a 15-20 minute drive from the existing centers. Adding more programs in this vicinity of the state does not alleviate any burden from the family or social systems that are already intact in the area. Patients who are referred from these close centers are part of the existing transplant center community.

There is no doubt that early and appropriate treatment and referral of cancer patients would improve survival. However, there is no data to indicate that opening up new transplant centers in areas where there are already existing transplant centers would improve earlier treatment of cancer.

We have already seen what has happened when auto only programs open, they failed. Both, an auto-only program in Grand Rapids, as well as the Oakwood program, closed, at least in part due to the fact that they were built on the assumption that transplantation for breast cancer would be a standard of care. This did not materialize and the programs were unable to sustain themselves and were creating an additional burden on the health care system. We do not believe this

mistake should be repeated. Building programs with the idea that transplants will exceed the current capacity is a significant waste of time and resources.

Quality

Five studies were cited that looked at the relationship between quality and quantity of transplants conducted at BMT centers, all of which indicate there is a correlation between quality and volume. The only study that did not show a correlation between small and large centers defined a small transplant center as serving 70 patients per year with a median of eight years experience. Small centers can be started but the learning curve may be steep and no study has shown centers performing less than 70 transplants per year do as well as larger centers. Community programs can have good outcomes but these are primarily at hospitals with large staff and experience

Quality in BMT is essential because of the risks associated with the procedure. Mortality rates have measured as high as15% in autologous transplants, the safest form of transplant, within the first 100 days.

Michigan currently has three existing adult programs in the State which provide outstanding quality. To maintain this quality you need experienced staff and currently there is a shortage of trained personnel at all levels in transplant. There is a shortage of physicians, physician assistants, nurse practitioners, nurses and the support personnel who are needed to take care of transplant patients. These things are possible to overcome but spending the resources and going through the learning curve associated with BMT when there are quality centers already available in our community is not necessary. Adding more programs will simply result in the cannibalization of existing programs, effectively decreasing their quality.

The learning curve for taking care of bone marrow transplant patients is high even with nurses and support personnel who are comfortable in taking care of leukemia patients. One of the existing transplant centers in Michigan recently moved some of their auto patients to the leukemia floor of their hospital which required a large educational effort by the nurses, physicians and pharmacists. In fact, FACT, the national accrediting organization required that they had to verify training competency and coverage issues with these nurses who were used to high dose chemotherapy that is normally given to leukemia patients.

COST

There is no doubt that the cost of a bone marrow transplant is often less than standard chemotherapy. There is also no doubt that to set up and maintain an autologous program is less than an allogeneic program. However, we should not recommend or justify a transplant or need to build more transplant programs because it is cheaper than standard chemotherapy. There are very few diseases where transplant and standard chemotherapy are used as equivalent options.

Transplant centers do not recommend transplantation because it is cheaper than standard chemotherapy and yet we have heard this used as a justification for more transplantation programs. Ethical transplant specialists would never recommend or embrace transplantation for someone simply because it is cheaper than standard therapy; we only do so if it is better than standard chemotherapy, especially when taking into consideration the high risks associated with transplant.

Transplantation is still an expensive procedure, sometimes requiring a 30 day hospitalization for many of our autologous patients. While some of these transplants may be started as an outpatient procedure, they are often accompanied by prolonged hospitalizations.

CONCLUSION

The Barbara Ann Karmanos Cancer Institute believes the Commission should approve the SAC recommendations regarding continued regulation of BMT; the need for one additional program in western Michigan based on the planning zones for pediatric BMT services; and maintaining the cap of three adult BMT programs in southeast Michigan.

Following is a copy of Dr. Uberti's presentation to the SAC, which answers many questions raised by the Commission at the December 10, 2009 meeting, **including whether a population based methodology was discussed and considered by the SAC.**
In some locations throughout the presentation there are statements made by the SAC members representing Beaumont and St. John. These statements can be identified by quotation marks and blue font color. Letters from patients and/or family members who have received a bone marrow transplant at KCI also follow.

BONE MARROW TRANSPLANT CON STANDARDS

July 29, 2009

BARBARA ANN
KARMANOS
CANCER INSTITUTE
Wayne State University

BARBARA ANN KARMANOS CANCER INSTITUTE
Wayne State University

Joseph Uberti, M.D., Ph.D.

Service Chief
Division of Hematology and Oncology

Co-Director
Blood & Marrow Stem Cell Transplant Program

Karmanos Cancer Center

CON Standards

BARBARA ANN KARMANOS CANCER INSTITUTE

- BMT is NOT the only standard with a cap in the number of programs.
  - Heart Transplant – 3
  - Liver Transplant – 3
  - Lung Transplant – 3
- BMT standards were determined by a panel of experts, much like the composition of the current SAC.
- Why regulate hematopoietic stem transplantation?

FDA Requires Regulations-
Based on 5 public health and regulatory concerns of HSCT

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1. Prevention of the transmission of communicable diseases.
2. Assurance that necessary processing controls exist to prevent the contamination of cells and tissues and to preserve their integrity and function.
3. Assurance of clinical safety and effectiveness.
4. Assurance of necessary product labeling including permissible promotion of or proper product use.
5. Establishment for a mechanism for FDA to communicate with the cell and tissue industry.

Stem cell transplant = Organ transplant
Regulation Now Part of Federal Register

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Wayne State University

- Federal Register, FDA 21 CFR 1271--Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments -requires FDA registration yearly.

- Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing through CLIA- Clinical Laboratory Improvement Amendments, Requires registration for certificate of accreditation every 2 years.

- National Marrow Donor Program (NMDP), accreditation to receive unrelated products every year.

Current regulatory agencies

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Wayne State University

- Government regulation federal state level.
- FDA regulates human cells tissues and cellular and tissue based product/Facilities registered with the FDA.
- CBER-Center for Biological Evaluation and Research.

Do we need more state regulation/limits?

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Wayne State University

- "Government regulation of HC therapy at the state level is fragmented, often voluntary and, in the opinion of the FDA inadequate to prevent transmission of disease. Many states have little specific regulation."

- In order to overcome this

  "Some states have adopted mechanisms of qualifying HCT programs and facilities such as the Certificate of Need Process."

Hematopoietic Cell Procurement, Processing and Transplantation:Regulation and Accreditation Warkentin et al in Hematopoietic Stem Cell Transplantation--2003

Why regulate/limit stem cell transplant?

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Wayne State University

- Prevent indiscriminate, unsafe use of stem cells
- High mortality
- Limited stem cell availability
- High risk of infectious disease transmission
- Expense

Transplant Mortality Remains High

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Wayne State University

- 100 day mortality is taken as a marker for toxicity of transplantation
- Stem cell transplantation mortality and outcome is worse than solid organ transplantation
- Reduced Intensity Transplants have high mortality

Limited Stem Cell Availability

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Wayne State University

"Opportunity for life saving treatment with BMT is not limited by a finite number of available organs as with other transplants"

- Currently over 25 patients at Karmanos are searching for donors for stem cell transplantation—No donors are found
- Numbers are not higher because patients die due to lack of donors
- GAO estimated that over 10,000 patients each year in the United States should receive an unrelated hematopoietic cell transplant but do not due to lack of donor availability.
- Increasing donor registry above current level of 11,000,000 not cost effective way to increase the number of patients who could be transplanted.
- To increase the number of transplants by 1% we would need to add 7,000,000 more donors to the registry.*

Use of a needs based methodology to increase transplant units

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- Depends on accurate estimation of patients who require transplant.
- Needs to take into account the age of patient performance status of the patient as well as underlying disease characteristic.
- Beaumont/St. John estimated based on a consultant what percentage of patients with a new diagnosis of cancer would require a transplant. They estimated that

  "Beaumont Patients alone should generate Over 100 BMTs"

- However, number of new cancer cases may not be accurate as most patients do not undergo transplant until they relapse or fail several therapies.

  "This methodology could serve as a basis for institutional based methodology."

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Primary Site	MI Actual 2005*		Est. Total Transplants/disease /2005**	Beaumont Volume projection
Acute Myeloid Leukemia	455		103	227 (50%)
Myelodysplastic Syndrome	296		31	98 (33%)
Non-Hodgkin Lymphoma	2277		125	523 (23%)
Multiple Myeloma	642		113	321 (50%)
Total	3670		372	1169

*Source : Michigan Resident Cancer Incidence File. Includes cases diagnosed in 2004 - 2006 and processed by the Michigan Department of Community Health, Division for Vital Records and Health Statistics by December 29, 2008.

**Estimated total transplants based on KCI performance of 35% of total 438 Adult Transplants in MI in 2005 per the Annual Hospital Statistical Survey

Using Beaumont Methodology how many patients would require a transplant in US

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Myeloma	20,000 new cases x 50%	=	10,000
ALL	5,760 new cases x 50%	=	2,800
NHL	65,000 new cases x 23%	=	15,000
Hodgkins	8,510 new cases x 9%	=	765
AML	12,810 new cases x 50%	=	6,400
CML	5,050 new cases x 10%	=	500

TOTAL TRANSPLANT in USA (Beaumont Method)	35,464
TOTAL TRANSPLANT in USA (2005)	15,000

Needs Based Methodology

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Wayne State University

- Changes in practice patterns affect needs for transplant
- Numbers fluctuate dramatically
- Examples Transplants/year Karmanos

			2009
Breast Cancer	152	to	1
CML	15	to	1
Myeloma	15	to	80

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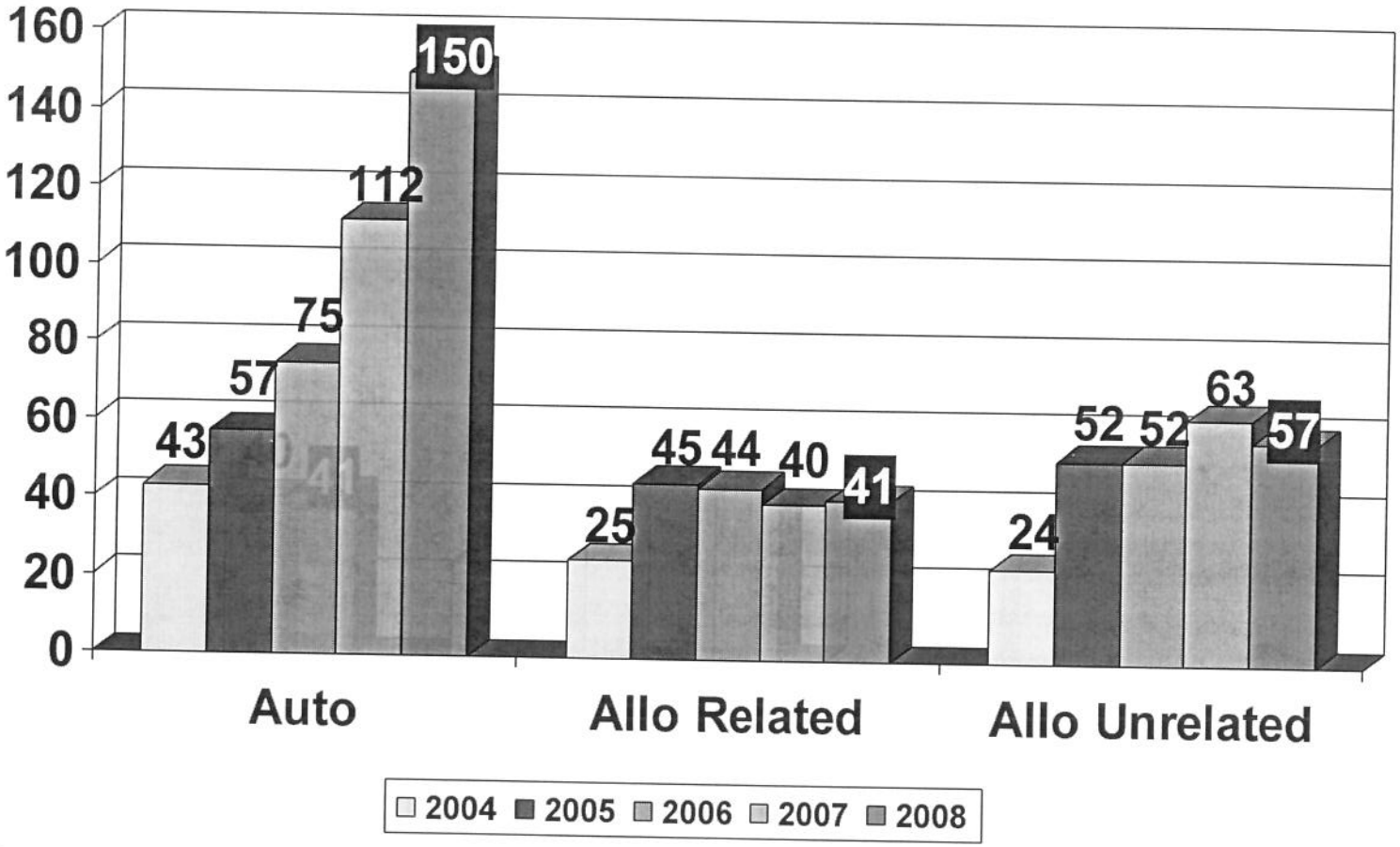
2008 is thru 12/31/08



Transplants by Disease (KCI & CHM) **2004-2008**

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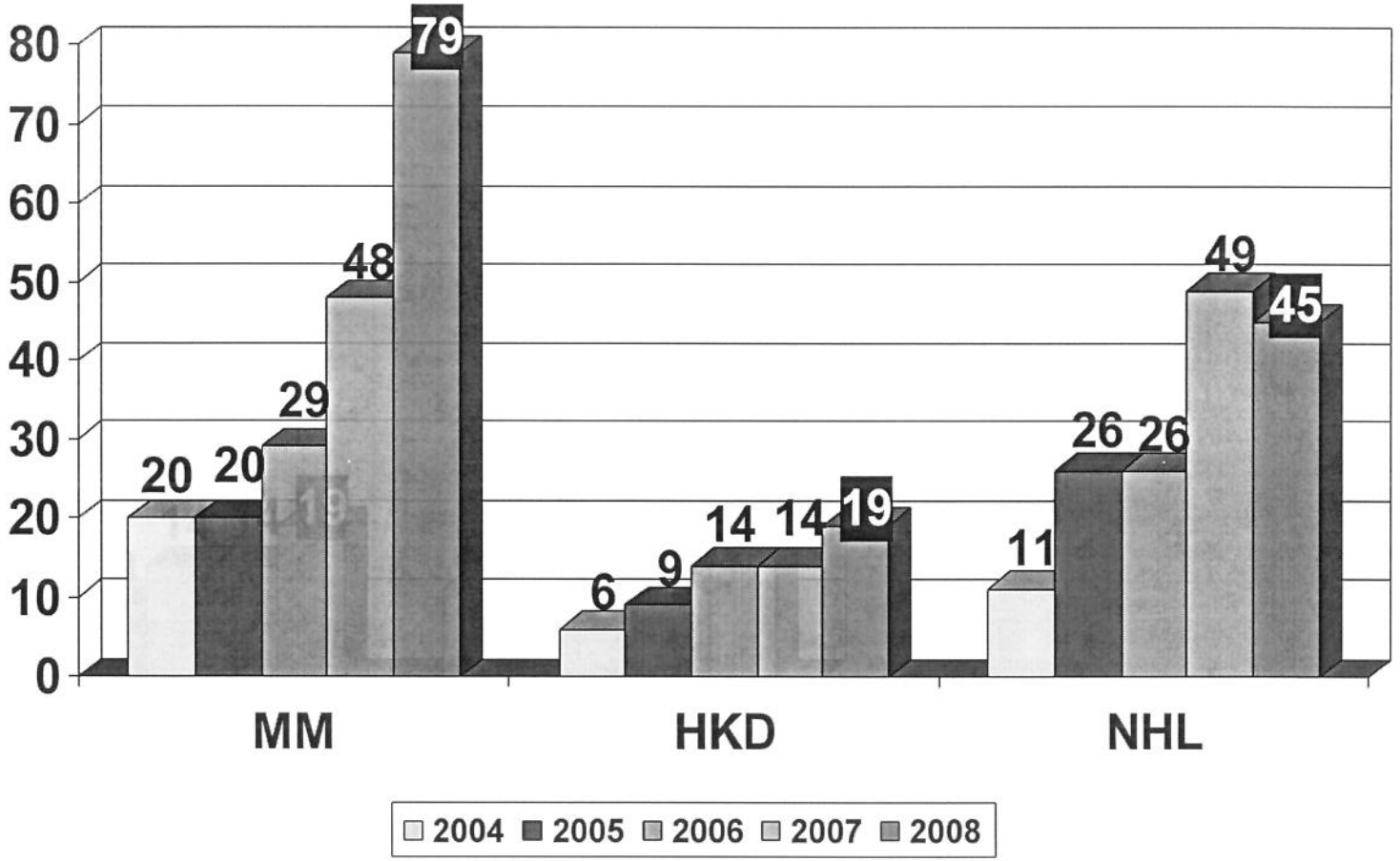

Guidelines for the Treatment of Multiple Myeloma

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Wayne State University

- Some believe the availability of newer agents with unique mechanisms of action may change the treatment algorithms for all patients with multiple myeloma.

- "To date, stem cell transplantation provides the best long term survival benefit. However, novel agents such as the IMiD's, bortezomib and pegylated doxorubicin have raised speculation that HDT for myeloma may become obsolete. "

[1] Siddiqui et al : The role of high dose chemotherapy followed by peripheral blood stem cell transplantation for the treatment of multiple myeloma. Leukemia & Lymphoma August 2008

Quality

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Wayne State University

- Needs based methodology has to ensure quality and patient safety

  "No Correlation Between 1 Year Survival and Annual BMTs/Program"

5 Studies have shown Correlation between Outcome Size/Experience of Programs

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• Horowitz, et al Blood 1992	Procedure Volume	Significantly affected TRM and DFS
• Hows, et al BMT 1993	Procedure Volume	Significantly affected survival
• Frassoni, et al Lancet 2000	Procedure Volume	Significantly affected survival and transplant related mortality
• Matsuo, et al BMT 2000	Procedure Volume	Affected 100 day survival Disease free survival and survival
• Apperly, et al Blood 2000	Procedure Volume Center Experience	Correlated with overall Survival TRM

Review: Transplant Center Characteristics and Clinical Outcomes After Hematopoietic Stem Cell Transplantation: What Do We Know, Loberiza, et al, Bone Marrow Transplantation 2003

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- Studies on Center Experience and Volume on Outcome Suggest the Following:

1. Although a threshold for what is considered "high procedure volume' has not been consistently defined, the relation between high volume and superior clinical outcomes is replicable.
2. Outcomes associated with center effect (mainly procedure volume) include TRM, treatment failure and survival but not relapse.

Association of Transplant Center and Physician Factors on Mortality

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- Studies in experienced well established transplant centers have not shown an effect on volume and survival.

- Defined by median of 70 transplants/year and a median of 11 years of center experience.

- "Appears that the greater involvement of properly trained physicians is associated with better early outcomes, particularly in the allogeneic HSCT and autologous HSCT for high-risk patients, and should be encouraged.

Lobrezia et al Blood 2005

Quality

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- "Arbitrary" BMT standards have produced outstanding programs in Michigan
  - Highly skilled professionals with extensive training in BMT.
  - All programs have FACT Accreditation- x 3 cycles
  - Karmanos rated "Outstanding"
  - Insurance companies use our programs as Centers of Excellence:

    AETNA Blue Distinction Centers for Transplant, Cigna/Lifesource, Humana/HTN

Years of Experience among Karmanos BMT Team

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Name	Role	Experience
Joseph Uberti, MD, PhD	Co-Director	22 years
Voravit Ratanatharathorn, MD	Co-Director	25 years
Lois Ayash, MD	Physician	20 years
Muneer Abidi, MD	Physician	8 years
Lawrence Lum, MD	Physician	27 years
Zaid AL-Kadhimi, MD	Physician	7 years
Anne Marie Campbell, BSN, RN, OCN	Coordinator	13 years
Stacey Prieur, BSN, RN	Coordinator	8 years
Amy Beck MSW	Clinical Social Worker	17 years
Cheryl Grey-Gilliard, MSW	Clinical Social Worker	2 years
Ann Zdilla-Dejonckheere	Patient Finance Mgr	18 years
Stephanie Bower, RN, CCRP	Manager	12 years
Alanna Kurosky R.N. ANP-BC	Nurse practitioner	20 years
Stephanie Mellon-Reppen RN MSN ACNP	Nurse practitioner	12 years
LaDonna Hinch, RD	Clinical Dietitian	6 years
TOTAL YEARS EXPERIENCE		**217 years**

Cost

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- Average Sized BMT Unit $1,300,000 start up and maintenance- Advisory Board March 10, 2009
- Equipment
  - Controlled rate cryopreservation systems
  - Liquid nitrogen freezers
  - HEPA filtered inpatient care areas
- Does not take into account training and experience of staff
  - Annual nursing/patient care expense of:
    - Allogeneic Patient Unit - $3,046,000
    - Autologous Patient Unit - $1,554,000
    - BMT Coordinators and NPP's - $2,580,000

Access

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- Are transplants increasing in MI?
- 2001 498 transplants
- 2008 533 transplant
- 2007 536 transplants
- Over 8 years transplant numbers have gone up by 35 patients < 1% increase/year

Access

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- No center has reported a bed shortage
- No referring center has reported lack of access to a transplant center
- No potential BMT candidate was denied service because of lack of capacity.
- No potential BMT candidate should have died because they weren't referred to an existing program.

Conclusions

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- Adding more BMT programs in Southeast Michigan would be like REARRANGING THE DECK CHAIRS:
  - Diluting the patient base among more hospitals, thereby increasing cost.
  - Diluting highly skilled personnel throughout the region, thereby harming quality.
  - Creating no appreciable improvements in access.

Conclusions

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Wayne State University

- No Capacity issues
- Increase in transplant numbers due to myeloma but changes in treatment strategies may lesson the need for transplantation for this disease.

Conclusions

BARBARA ANN KARMANOS CANCER INSTITUTE
Wayne State University

- Level of experience of current transplantation programs makes it impossible to duplicate the quality of care now provided to patients in new programs.
- There is no duplication of expensive tests (despite claims to the contrary).
- Requirement for new services, equipment, and personnel will increase cost.
- The current BMT CON Standards meet the needs of patients in Southeast Michigan.

316 County Road KCG
Marquette, MI 49855-9771

January 16, 2010

To whom it may concern:

Our lives were dramatically altered, literally with three small words ~ acute myelocytic leukemia. Discovering a problem in early January of 2008, our family physician referred my dear husband, Richard Parmenter to the local Hematology/Oncology office for further assessment. Rick's oncologist, Dr. Frank, was adamant about Rick traveling immediately to the Karmanos Cancer Institute for evaluation, testing and treatment. I must admit our naive ness in not knowing of the existence of this top-notch national cancer center within the state of Michigan.

Scared and alone the coordination between all the physicians and support staff was incredible. The professionals at Karmanos stepped up and took care of all the logistics and gave us hope for a future during our darkest hour. We were physically uprooted from our rural home in the Upper Peninsula, family and friends and relocated five hundred miles south to Detroit, Michigan. Talk about shock and awe!

These caring and compassionate individuals embraced us and helped us fight an extraordinary battle. There are no adequate words to convey our gratitude to the following members of the Blood and Marrow Stem Cell Transplant Program; Dr. Joseph Uberti, Stacey Prieur, Rick's transplant coordinator and Karen Birt, Rick's clinic nurse practitioner. The communication and passage of medical information between our team at Karmanos and the physicians in Marquette was exemplary. I could write a list of the names of the many wonderful doctors, nurses and support staff from the BMT Clinic, (5) now 8 and 10 Webber North who made us comfortable, answered questions and explained procedures. All went above and beyond the call of duty and truly became our family.

Once we were finally allowed to return to our beloved home in the U. P. after day + 100, we traveled biweekly and then monthly for follow-up appointments. This one thousand mile round trip was never questioned. It became routine, our "new normal" and to quote Rick, "Anything for science." Even our winter habit of throwing a wrench into the BMT Clinic's well prepared daily schedule by showing up unexpectedly didn't dissuade these individuals from sharing their knowledge, concern, energetic smiles and spirit lifting laughter while expediting our visits knowing the distance we traveled. They dotted all the "i"s, crossed all the "t"s and made sure we understood the treatment plan.

In closing, I would be remiss if I didn't mention Laura Zubeck, Director of Volunteer Administration/ Guest Housing Services. When Rick's leukemia returned more aggressive than ever he was admitted to Karmanos in late March of 2009 and transitioned to Karmanos Hospice in mid April. This cardinal friend was at my side and became my sister in sorrow as I let go of Rick's hand and he took the next.

Rick died nine months ago today in room 8207. We had so hoped for a different outcome. At present, I am in survival mode. Without the program at Karmanos and the dedicated professionals we wouldn't have had an extra fifteen months together. We were so blessed to have all of these special people fighting for us and with us. I am thankful and indebted to all. To this day many still call to check on my well-being. Now how cool is that? May God bless them and all the work they do.

Most sincerely,

Shelby M. Parmenter

To whom it may concern:

I am currently a Karmanos patient. In November 2007, at the age of 44, I was diagnosed with a very aggressive AML leukemia. From August 2001 up until that time, I had been treating with hematologists from Beaumont Hospital for polycythemia rubra vera, a blood disorder. I also saw specialists at the University of Michigan for this condition. Upon receiving the AML diagnosis from my Beaumont physician, aside from being devastated, my first thought was where do I go for second opinions and treatment. My treating doctor, at this point, was out of the picture as far as I was concerned, since I knew I would need to start treating with highly trained and educated medical specialists for leukemia. Locally, the only thought was Karmanos and the U of M, both nationally recognized cancer centers affiliated with research universities. Even though other local hospitals have cancer centers, they were not even considered. Nationally, based on my research, it was MD Anderson Cancer Center in Houston, Texas. My only concern at the time was to secure the best possible course of treatment with renowned specialists, no matter where located. My life was in serious danger, convenience or familiarity with treating and/or referral physicians and geographic proximity were not of concern. I was fortunate, however, to have these institutions in the area. I sought second opinions from MD Anderson and Karmanos, respectively, but never made it to Karmanos since I was immediately admitted and received my initial introduction chemotherapy at MD Anderson. After 40 days there, and many complications, I left (against doctor's orders) and began treatment with the transplant and infectious disease doctors from Karmanos, truly, some of the most brilliant, respected and compassionate doctors I have ever met and/or treated with. I received my bone marrow/stem cell transplant in January 2008, and have been receiving follow up treatment and monitoring with Karmanos since. Karmanos is a short drive from the suburbs and southeast metro area. The last thing this area needs is a new transplant center that will take patients and resources away from Karmanos. The focus should be on Karmanos, and ways to improve it's resources and funding in order to allow them to continue their cutting edge research and finding ways to beat and cure this horrendous disease. Even though other hospitals have a transplant center, or may be approved for one, in my opinion, unless they are well known for doing transplants and have superstar transplant doctors, it is a waste of resources and detrimental to existing and well known transplant centers such as Karmanos. The transplant doctors at MD Anderson spoke very highly of Karmanos, knew the doctors, and even recommended that I have my transplant there. Although Karmanos may not be conveniently located for some suburban patients, it is easily accessible from the suburbs and the benefits it offers significantly outweigh any perceived inconvenience in having to drive there from the suburbs or having to leave your referring physician. These are non-issues when your life is at stake. Thank you.

Thomas Kalas, Esq.
Kalas Kadian, PLC
43928 Mound Rd., Ste 100
Sterling Hts., MI 48314
Ph: 586-726-0760 Fax: 586-726-0766
tom@kalkad.com

To To whom it may concern,

We would like to take this opportunity to express our gratitude to the Karmanos Cancer Center for helping to make a very awful situation so much easier to endure and get through. In May of 2009 my husband, Chris, was diagnosed with A.L.L, with myeloid markers. He was immediately hospitalized and spent the next 3 months in and out of St John Hospital in Detroit for chemotherapy treatment. Fortunately for us we had been referred to a wonderful, truly gifted doctor, M. Schurafa.

Dr. Schurafa focused on Chris' long-term quality of life, thus focusing on a 'cure' was very prevalent. He consulted with numerous doctors about Chris, but always came back to where he felt Chris would have the BEST care and treatment: The Karmanos Cancer center with Dr. Schiffer and Dr. Voravit at the helm.

It is very daunting to be in a situation like Chris faced, yet the transition from St. John's to Karmanos was seamless. The Karmanos Bone Marrow Transplant Unit provided a haven of sorts and the staff there is clearly at the top, which is why Dr. Shurafa referred us there. He stressed that we wanted the best-and Karmanos was Chris' best option (we DID investigate other options, yet the communication between our hematologist and Karmanos doctors could not be compared and was a HUGE factor in our decision).

Chris received his stem cell transplant on Sept 1, 2009 and is doing very well today. Although being at 'the doctors' is never a fun thing, we truly look forward to Chris' continued visits at the Bone Marrow Clinic as ALL the doctors, nurses, practitioners, etc work together, each and every day, to ensure that Chris gets the best care and treatment possible. I recommend the Karmanos Cancer Center and BMT to anyone who needs specialized treatment, especially if they are already under the care of a doctor who they trust, because we know how well Karmanos communicates with other professionals and extends that trust to new patients.

Chris and Deanna Slezak

January 18, 2010

Barbara Ann Karmanos Cancer Center
Bone Marrow Transplant Clinic, Main Floor
4100 John R
Detroit, MI 48201

To Whom It May Concern,

I am writing this letter to express our deepest gratitude and appreciation for the care and concern shown us by the doctors and staff of Karmanos Hospital. The skill and knowledge present in every one who came into contact with us during my 5 month hospitalization and the months of treatment afterward at the BMT Clinic since then have made my stem cell transplant the success and miracle we had hoped it would be.
The fact that my local oncologist recommended Karmanos above all other hospitals in the state gave us the confidence in their stem cell program. The availability of the hospital – only 35 minutes from our home in Pontiac and easily accessed from Woodward Ave. or Interstate 75- was another reason we chose Karmanos.

The staff at Karmanos worked with us to set up financing with our insurance, helped us with the testing of my siblings to find a donor, scheduled all the preadmission testing, and accommodated our whole family on the day of the transplant. During my stay there, I witnessed their efficient and empathetic care over and over for all the patients on the floor. They were patient in explaining all the drugs I was taking and what to expect, encouraging me to walk my 'laps', and always ready to lend a hand when I was too weak to manage my basic necessities. Any procedure I needed was conveniently able to be performed within the connected hospitals of the Detroit Medical Complex. They were never too busy to find someone who could help me with my learning to cross stitch, and one aid even stayed after his shift to help me set up and learn about a new laptop, enabling me to share my thoughts and progress on Caring Bridge with family and friends. No small feat for him to have to teach someone as computer challenged as I am!

In the ensuing months as we have traveled down to the Karmanos BMT Clinic, we have always been greeted warmly, and during the winter months when weather, roads or (once) an accident, caused us to be late for an appointment, they were always able to work us in without any complaints or sense of imposition from them.
We feel very fortunate to have Barbara Ann Karmanos Cancer Center so close to us, and we have told many friends about the extraordinary quality of care that we received there. My sister's nephew in Traverse City was diagnosed with lymphoma, and was referred by his doctor to Karmanos. My sister assured him he would be in excellent hands because of her experience with me.

In closing, we would like to thank the many people who made our journey through the highs and lows of my leukemia treatment as uncomplicated and pain free as they possibly could. We look forward to each visit now, not only to check my progress, but to see the friends we have made there as well. We are very grateful to Karmanos for the gift of a new life.

Sincerely,

Sallie Ann Bishop

Sallie and Joe Bishop

January 18, 2010

To Whom It May Concern:

This past summer, I was diagnosed with acute mylogenous leukemia and needed a bone marrow transplant. We feared my husband would have to find lodging and essentially relocate to a transplant center out of our area for a prolonged length of time. Fortunately we were referred to the Barbara Ann Karmanos Cancer Center, a state of the art transplant center, only 40 miles from our home. Karmanos is located right off a major expressway, which made it easy for my husband, friends and family to be with me on a daily basis. Even now that I am out of the hospital, our weekly trips to the outpatient clinic at Karmanos are convenient and parking is always available with great valet service.

From our first visit to our most recent, we found the doctors, nurses, pharmacists, case workers, practitioners, social workers and financial specialists to be experts, sharing information and providing exceptional care, both as inpatient and outpatient. We especially appreciated the great continuity of care and always knew who to contact with a question or a problem.

We are continually provided with the latest information regarding my progress and feel that we are included in the decision making process. Not only are we kept up to date, but my oncologist and primary care physician receive regular update notices regarding my status. This is very important to me as I will be seen less frequently at Karmanos and return to the care of my regular doctors.

I could go on and on singing the praises of the transplant team and the completeness of the bone marrow transplant program, which is completely patient centered. As a patient, it feels like every aspect of my care has been thoroughly planned out. Most of my questions are answered before I even ask. I cannot imagine a better experience.

Sincerely,

Carole G. Robertson

Carole G. Robertson

Dear Staff,

I wanted to write to let you know how grateful I am to the entire staff at Karmanos and the BMT Clinic. I was diagnosed with AML at Beaumont Hospital by my primary oncologist. I was told that I'd need a bone marrow/stem cell transplant and an appointment was made for me to see the doctors at BMT. After meeting the doctors, my family and I felt that I was in good hands. I needed many tests done and it was very convenient that I was able to get all of them done there.

After my transplant and I was stable, the doctors set up my infusions with my primary oncologist at Beaumont since it is around the corner from where I live. The staff is very willing to work with my primary oncologist and make appointments as convenient for me as they can. Most of my appointments however, are at Karmanos, which is very easy to get too. There is plenty of parking and it's not a far walk from the parking deck to the clinic.

I am so grateful for your support during my illness and recovery. You all gave me courage, when I was down. You gave me support, when I was in despair. You gave me smiles when I was sad and was lonely. Most of all, you always gave me hope!

It was the continuous thoughtfulness of your staff that truly made a difference in my recovery. I sincerely want to thank every single one of you at Karmanos for my outlook on life and continued improvement. I wish all of you well, and know; your thoughtfulness and actions will never be forgotten.

Sincerely,

Janice Kingrey

Janice Kingrey

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/Lung and Liver Transplant:

The Heart/Lung and Liver Transplant (HLLT) proposed standards will maintain the current limit of 3 Heart/Lung Transplant programs in Michigan. Our Board feels that, given the fixed supply of organs available for transplant, this limit of 3 Heart/Lung Transplant programs in the state meets the access, cost and quality needs of the community. We strongly recommend that this limit of three HLLT programs be maintained.

We would also support the findings of the MDCH staff that there have been only two of the three CONs available for Heart/Lung Transplant programs active. As provided in section 4 (5) of the HLLT standards, that the Henry Ford and ChildrenÆs Hospital heart transplant programs are part of a ôjoint sharing arrangementö and not two separate CONs.

The CON application submitted in October by Spectrum Health to open a third Heart/Lung Transplant program in west Michigan should help address any perceived geographic access issues.

7. Testimony:

1. Name: Robert Meeker
2. Organization: Spectrum Health
3. Phone: (616) 391-2779
4. Email: robert.meeker@spectrum-health.org
5. Standards: HLL
6. Testimony:

In testimony a year ago, Spectrum Health raised concerns about accessibility to heart & lung transplant services in Michigan. The current Standards limit the number of organ transplantation services to three (3) transplant programs in Michigan. All the existing transplant programs are located in southeastern Michigan. This concentration of all programs in the same region of the state does not promote access to transplant services for the remainder of the stateÆs population. We strongly believe that there needs to be better access to organ transplant services in western Michigan. This area constitutes more than a third of MichiganÆs population and is growing at a faster rate than the rest of the State. From Grand Rapids, the nearest heart & lung transplant program is in Ann Arbor, 125 miles away. Other northern and western Michigan communities are even farther away. In the last year, Spectrum Health cardiologists referred 19 patients for heart transplant
. Only half of those patients (10) stayed in Michigan. Other patients went without needed organ transplants due to lack of access or lack of understanding of the applicability of this vital service. Spectrum Health is grateful to the Commission for responding to our concerns and establishing a SAC to investigate the issue of statewide access to heart & lung transplant services.

At the time the SAC was established, it was generally believed that three (3) heart & lung transplant programs already existed in Michigan: University of Michigan Medical Center, Henry Ford Health System, and ChildrenÆs Hospital of Michigan. However, during the SAC process, it was revealed that the ChildrenÆs û Henry Ford program was approved as a single transplant program under a joint sharing agreement, and that there are actually only two (2) heart transplant programs operating in Michigan. Therefore, an additional heart transplant program can be approved for CON under the current statewide cap of three (3) programs. While this was not the result that Spectrum Health desired, because it does not explicitly acknowledge the need for outstate access, it does provide an avenue for establishing a heart & lung transplant program in western Michigan.

In the revisions to the Standards, proposed by the SAC and endorsed for public hearing by the Commission, the statewide limit of three (3) heart & lung transplant programs is retained. The proposed Standards also include streamlined project delivery requirements which defer to the requirements of the organ procurement and transplant network. Spectrum Health endorses these changes.

Spectrum Health would like to suggest one change to the proposed Standards. The current definition of the term ôinitiate,ö as applied to transplant services, specifies that a new program must perform the first transplant procedure within 18 months of approval. This is an extremely short time frame. Currently, the 92 Michigan heart transplant patients on waiting lists have been listed for an average of 16 months. The waiting time for lung transplant is comparable. A new transplant program cannot begin listing patients for transplant until all the UNOS requirements have been met, including all specialized personnel (transplant surgeon, transplant cardiologist, transplant coordinator, trained nursing staff, etc.) available at the center. Recruitment of these specialists can take a year or more. Added to the average patient wait on the transplant list of greater than one year, it is nearly impossible for a new program to meet an 18 month time frame. We respectfully reques
t that the implementation period for a new heart & lung transplant program be extended to 24 months in the Standards. Alternatively, ôinitiationö could be defined as performing the first transplant procedure within 18 months of UNOS certification.

Spectrum Health appreciates the efforts of the SAC and the Commission in revising the CON Review Standards for Heart/Lung and Liver Transplant Services. While the SAC did not endorse our recommendation for a western Michigan planning area for transplant services, we are pleased for the opportunity to address access to this service for residents of the outstate area afforded by the recent ruling by the Attorney General that there are only (2) heart transplant programs operating in Michigan. We urge the CON Commission to extend the initiation date for transplant services to 24 months and to approve the proposed Standards, with that change, at the March meeting.

7. Testimony: