

**From:** <DoNotReply@michigan.gov>  
**To:** <moorean@michigan.gov>  
**Date:** Fri, Apr 4, 2008 2:08 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

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5. Standards: MRT
6. Testimony: March 27, 2008

Testimony to the Certificate of Need Commission  
Presented by Tewfik J. Bichay, Ph.D., A.B.M.P., Director, Medical Physics,  
Saint Mary's Health Care  
On the Proposed Standards for Proton Beam Therapy

Dear Commissioners,

Trinity Health Michigan continues to be a proponent for a strong CON program. We know that Michigan hospital costs rank lowest among the six Great Lakes states while the quality of care at Michigan hospitals is equal to, or superior to that of hospitals nationwide. This is due, in part, to the CON program.

With 25,000 employees, 12 hospitals and 40 continuing care, home health, and senior housing facilities, and a \$1-billion payroll, Trinity Health is one of the state's largest employers. Michigan's Certificate of Need program has been a crucial tool that allows us to provide affordable quality health care while maintaining our commitment to serve the poor and underserved. We have hospitals in markets without Certificate of Need, like California, Idaho, Indiana, and Ohio, and have seen the medical arms race at a much higher level than in Michigan. It is leading to very high cost, more fragmentation, and a decreased ability for hospitals to support their charitable mission.

Trinity Health Michigan strongly supports the proposed language that would require the establishment of a statewide collaborative to initiate proton beam therapy. We commend the Commission for recommending this collaborative requirement and believe it is consistent with the Commission's objective to regulate the health care industry in Michigan by balancing cost, quality, and access issues and ensuring that only needed health care services are developed as identified in Public Act 256 of 1972. In this challenging economy where increasing health care costs put access to quality services out of reach for more and more people, the most judicious course of action is to grow programs and services through partnerships. If left unregulated, the potential for excess Proton Beam Therapy programs across this state is a real and expensive concern.

As a medical physicist, I closely monitor emerging technology for its clinical benefit and spend a good portion of my time applying this technology in the clinic. In my professional opinion, even after decades of experience, proton beam therapy has yet to demonstrate a definitive clinical benefit that significantly exceeds that of mature radiation therapy programs such as Intensity Modulated Radiation Therapy (IMRT) combined with Image Guided Radiation Therapy (IGRT), for example with Novalis, CyberKnife, or TomoTherapy, however the cost of the proposed proton therapy program is 20-30 times greater.

The only way I can conceive of such a program making any sense in Michigan is through a collaborative effort. Radiation collaborations do work. In Grand Rapids, Spectrum and Saint Mary's Health Care created a consortium to acquire, and offer, PET-CT services that has been very successful for years with the result being a cost savings to the communities served.

If this new and very expensive technology is going to be offered in Michigan, it should be: A made available to all residents, B provided in a clinically appropriate manner which include strict treatment protocols, and C housed in a geographically appropriate location so that it truly can benefit the majority of Michigan residents.

Thank you for your work on this important healthcare issue.

**From:** <DoNotReply@michigan.gov>  
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**Date:** Tue, Apr 1, 2008 3:15 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

1. Name: Carol Christner
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3. Phone: 313-576-8123
4. Email: [christne@karmanos.org](mailto:christne@karmanos.org)
5. Standards: MRT
6. Testimony: The Barbara Ann Karmanos Cancer Institute supports the unanimous vote of the CON Commission taken at the March 11, 2008 commission meeting regarding MRT standards. We encourage the commission to uphold their vote at the April 30, 2008 meeting.

We believe that a collaborative approach to Proton Beam Therapy (PBT), which was carefully designed in the MRT standards, is in the best interest of cancer patients in Michigan. While there are no existing examples of a PBT collaboration, we are confident that the many successful joint ventures, affiliate agreements and other legally binding collaborations among hospitals in our state, can serve as the model that other states aspire to.

We support the Departments efforts to require participation from the majority of MRT providers with ETV's greater than 30,000. We are confident that the number of required participants the department determines to be appropriate will be in the best interest of the state.

**From:** "Frances Fu" <Frances.Fu@procurecenters.com>  
**To:** <MooreAn@michigan.gov>  
**Date:** Mon, Mar 31, 2008 11:04 AM  
**Subject:** CON Written Comments for MRT

Andrea,

I called your office and spoke to Taleitha regarding a question I had on the written comment submissions. She and I could not find a way to submit an attachment via the online submission form (she says there normally is a way) so she suggested that I email you the written testimony being submitted by ProCure Treatment Centers regarding the proposed MRT standards.

Please confirm receipt and acceptance of this written testimony. If there is a way to attach files online, I would be happy to submit the comments via website as well.

Thank you for your help.

Kind regards,  
Frances

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**Frances Fu**  
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March 31, 2008

Dear Certificate of Need Commissioners:

Proton therapy is the most advanced form of radiation therapy available. Protons increase the probability of controlling cancer growth, and they spare patients many of the debilitating side-effects of radiation, such as damage to healthy tissue and secondary tumors. The technology is FDA-approved, and the therapy is lauded by the country's leading radiation oncologists. While much has been written about the "high costs" of deploying the technology, the per patient costs are much lower than are commonly believed, once reduced spending on complications and recurrences are taken into account, and once the long useful life of the facility is factored into the equation.

As you are aware, proton therapy has generated much interest in Michigan, and for good reason. There are five centers operating nationally with the capacity to provide proton therapy to approximately 7,000 patients annually; this is a fraction of the estimated 250,000 cancer patients who can benefit from this therapy. As a result, there is a wonderful opportunity to make Michigan a leader in the field of proton beam therapy. Having a proton center in Michigan means the citizens of Michigan can be treated without having to travel hundreds or even thousands of miles, and the community will benefit from a substantive economic development project.

In developing a proton project, planning and experience is as essential as the facility itself. Building a proton center is a highly complex, time intensive and capital intensive undertaking. Many institutions have started down the road but only a handful have succeeded. The heavily engineered building takes 12 months to construct. The sophisticated equipment takes 12 -18 months to install and commission. However, even more time intensive than the building and equipment installation is the planning process, which must be completed before construction begins. For example, University of Pennsylvania took 11 years to plan their center, and the University of Florida took 7 years. ProCure, the only multi-center developer in the world, has standardized these processes to reduce the aggregate planning and construction time to 26 months; if the State authorizes work to begin this summer, patients can be treated by the end of 2010.

ProCure chose to partner with Beaumont Hospital because they have one of the nation's leading radiation oncology departments. Beaumont diagnoses more cancer patients than any other hospital in the state and enjoys worldwide recognition as an innovator in the research of radiation oncology applications and solutions. ProCure is the only firm that can be reliably entrusted with this important project. Our management team, in previous capacities, has led the development of 3 of the 5 existing centers and has a proven track record of delivering projects on time and on budget. Because ProCure has done this before, we have shortened the process and eliminated delays. ProCure delivers on its projects. By way of illustration, last year in Oklahoma City, both ProCure, working with the largest hospital system in the state, and Oklahoma University ("OU") each announced, at the same time, plans to build a proton center. ProCure broke ground in April 2007 and just began installing the proton

equipment into our completed building. Our Oklahoma facility will be treating patients next summer. OU still has not broken ground on a facility to house the proton equipment.

Together, Beaumont and ProCure are ready to begin construction as soon as the Department of Community Health approves the Beaumont application, assuming the current rules apply. Patients will begin receiving treatment in 2010 and Michigan will take a leadership position nationally in this cutting edge technology.

Beaumont and ProCure both recognize the need to ensure that this life-altering technology is made available to all patients who need access to it. We understand the need to share this resource with other hospitals in Michigan, and the decision for who gets treated should be a decision of need, not of referral or ownership. In our plan, patients may be referred to the proton center regardless of the referring hospital or physician group, and any radiation oncologist who qualifies may obtain credentialing to treat his or her patients at the center. We envision having the proton center as a community resource, open to all patients who need it.

We also recognize the desire to have the major hospitals collaborate in developing and running a proton center. Unfortunately, consortiums and collaboration without a clearly defined leader increase the chance of a proton project never coming to fruition. To ensure timely development of a center and seamless patient care beyond proton therapy, there must be one hospital to lead the process and integrate other hospitals into the project. That hospital should possess an expertise and leadership position in radiation oncology. With a defined leader, the project will be completed expeditiously, and the integration of ancillary services will be ensured. ProCure and Beaumont will offer all Michigan cancer centers the opportunity to collaborate with us in the proton center.

I believe this project is a vital opportunity for the State of Michigan, and we hope the Commission will support our endeavors to bring a proton facility to the cancer patients of this region as soon as possible. Please recognize the complexities in developing a proton facility. I urge the commission to not create unrealistic and cost-prohibitive complications for an already complex process and keep the current MRT standards for obtaining a CON.

Sincerely,

A handwritten signature in black ink, appearing to read 'Hadley Ford', with a long horizontal flourish extending to the right.

Hadley Ford  
CEO, ProCure Treatment Centers, Inc.

**From:** <DoNotReply@michigan.gov>  
**To:** <moorean@michigan.gov>  
**Date:** Thu, Apr 3, 2008 2:24 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

1. Name: Sean Gehle
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5. Standards: MRT
6. Testimony: These comments are to supplement those made verbally on behalf of the Michigan Health Ministries of Ascension Health at the March 27th Public Hearing.

Once again, I would like to reiterate our support for a statewide collaborative of providers which would be eligible to apply to initiate an MRT service providing Proton Beam Therapy.

At the time of our verbal testimony I indicated that we may have some specific language changes that we felt would clarify the existing language. These suggested modifications are as follows:

1. Amend Sec. 10, Subsection (1)(B)(1) after "services" by inserting "who have expressed an interest in Proton Beam Therapy and" and continuing existing language to end.
2. Amend Sec. 10, Subsection (1)(B)(II) by inserting "Independent of Section 10(1)(B)(I) and continuing existing language to end.
3. Amend Sec. 10, Subsection (1)(D) after "Documentation" by striking "of" and inserting "Approved by its Governing Body and Satisfactory to the Department as to its ownership structure and" continue with existing language "its process, policy and procedures" strike "that will allow" and insert "For" continue with "Any other" and strike "interested entities" and insert "entity that has a CON-approved MRT Service or can demonstrate PBT ownership in another state to obtain an ownership interest and" and continue to end of sentence.
4. Amend Sec. 10, Subsection (1)(E) after "plan" by inserting "approved by its governing body satisfactory to the Department" and continue to end of section

Thank you for the opportunity to provide further comments on changes to the MRT standards.

Please do not hesitate to contact me if you have questions.

Sean Gehle on behalf of the Michigan Health Ministries of Ascension Health.

**From:** <DoNotReply@michigan.gov>  
**To:** <moorean@michigan.gov>  
**Date:** Tue, Apr 1, 2008 12:29 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

1. Name: Paul S Harkaway, M.D.
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5. Standards: MRT
6. Testimony: As I witness the profound impact that our current economic struggles are having on our communities and my patients, the seemingly profligate spending going on in the health care community befuddles me. A recent summary of major building projects in Southeastern Michigan published in a business periodical showed that many of the projects and some of the largest were in the healthcare systems. It gives the appearance of a matrix-like parallel reality going on in health care. Our citizens are loosing their jobs and homes. Many patients lack access to basic care. Many patients seem to be dropping healthcare coverage outright, and those who still have it have an increasing financial burden that they struggle to meet. I am seeing more and more patients who cant seem to afford needed medications including seniors covered by part D (many of whom have fallen into the dreaded donut hole.) There is an increasing disparity in health care between the haves and have nots. In the midst of all of this, the large health care systems seem to have ready access to capital for large projects. I realize that funding for these comes through a different pathway but ultimately the patients, the rest of our citizens, and all of the employers in Michigan have to foot the bill. When will that burden crush them? Has it already?

I do not know why the Health Care System (or non system as it were) has not collapsed yet, but most of us feel that this cannot go on forever and yearn for meaningful reform. For insights into why the system is still able to function, I would refer you to a recent publication in the New England Journal of Medicine: The Amazing Noncollapsing U.S. Health Care System ü Is Reform Really at Hand? <http://content.nejm.org/cgi/reprint/358/4/325.pdf>

I assure you that the System's perseverance is not because of clever design or exceptional performance. If its longevity were based on those factors alone, it would have vanished long ago.

I am not an expert on proton beam therapy, and I am not pretending to be one, but as you ponder this decision, I would suggest the following for your consideration:

- What is the strength of the evidence supporting this modality over others or over no treatment?
- How will those who propose to provide the treatment assure that it is available to all citizens who might benefit?
- How will those who propose to provide the treatment prevent indication creep, such that it does not end up being used where it has marginal or no proven benefit and only adds cost? If it is true that a half of the health care dollars spent on an individual are spent in the last 6 months of life, how will we protect against this being yet another modality to add in to that equation?  
[http://www.ahc.umh.edu/img/assets/25857/end\\_of\\_life.pdf](http://www.ahc.umh.edu/img/assets/25857/end_of_life.pdf)
- How will those who propose to provide the treatment avoid offering it under the guise of hope? How will they control the hype and avoid creating demand based on false hope? (As a parenthetical, I would offer to you that most health care advertising seems to fall squarely in the category of hype.) How will we keep this modality from becoming another example of what Ian Morrison characterizes as expensive technology excessively and aggressively applied to the affluent and well insured.
- How many of these machines are needed in this country? How many do other industrialized countries have? As a side note, how does our country compare to those other countries when we compare the performance of the respective health care systems?
- If the indications are limited and circumscribed, would it make more sense for patients to travel to other states who have already installed the modality rather than duplicating it in Michigan? Is Bloomington Indiana, Chicago Illinois, or Pittsburg Pennsylvania too far to ask patients to travel for such specialized treatment? These areas either have or will soon have this capability.
- Who are the investors in this initiative? How do they intend to re-coup their investment? How much usage beyond areas of clearly defined benefit would it require for them to do so?
- Is it not true that this effort by definition will have to compete for resources against other pressing healthcare system needs such as electronic communication and care tools oriented towards chronic disease, or preventative health tools and efforts? See Woolf SH, Johnson RE. The Break-Even Point: When Medical Advances Are Less Important Than Improving the Fidelity With Which They Are Delivered Ann Fam Med 2005;3:545-552.  
[http://www.hvpa.com/Physician/education/woolfandjohnson\\_article\\_break\\_even.pdf](http://www.hvpa.com/Physician/education/woolfandjohnson_article_break_even.pdf)

Good luck with your deliberations and decision.

Respectfully,  
Paul S Harkaway M.D.  
Pulmonary and Critical Care Medicine

**From:** <DoNotReply@michigan.gov>  
**To:** <moorean@michigan.gov>  
**Date:** Fri, Mar 28, 2008 2:39 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

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5. Standards: MRT
6. Testimony: Oakwood Healthcare, Inc. (OHI) would like to thank the Certificate of Need Commission and the Megavoltage Radiation Therapy work group for its work on this important subject.

OHI supports the Commission's efforts to balance access, quality and cost. We have a strong commitment to deliver comprehensive cancer services with a focus on these important principles.

It is essential that the proposed standards allow maximum flexibility in access to emerging technologies. As such, thresholds, while certainly relevant, should be regularly reviewed to assure that they do not create "artificial" impediments to quality service. The MRT Standards must recognize developmental factors in complex service areas including cancer treatment.

OHI's strategic goals may incorporate participation in the use of Proton Beam Therapy as well as other modalities.

OHI remains an active participant in the process and will work with the Department and CON Commission as a major provider of cancer treatment services.

**From:** <DoNotReply@michigan.gov>  
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**Date:** Thu, Apr 3, 2008 3:43 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

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  5. Standards: MRT
  6. Testimony: Beaumont Hospitals
- Written Comments Pertaining to Proposed MRT C.O.N. Standards  
April 3, 2008

The following is adapted from the Other Voices editorial column by Kenneth J. Matzick, President and CEO of Beaumont Hospitals, in the March 24, 2008 edition of Crain's Detroit Business (p. 9):

Cancer patients in Michigan don't have access to the most precise, effective radiation treatment in the world — proton beam therapy. This therapy uses protons instead of photons to target cancer tumors without harming adjacent, healthy tissue— resulting in fewer side effects and potential reduction in risk for secondary malignancies due to radiation exposure. Beaumont Hospitals is working to bring this technology to Michigan through an effort involving other major cancer programs, physicians across the state and a national firm with expertise in developing, financing and managing proton beam centers.

The Commission recently endorsed the idea that, because of high cost, proton beam projects should be collaborative. We agree, and are collaborating with others to bring protons to Michigan. This includes collaboration in teaching and research, and opportunities for equity ownership. And our CON application indicated we would credential any qualified physician in the state to use proton technology for his/her patients, as we have with lithotripsy for kidney stones and with gamma knife for cancer.

But the Commission is considering standards that would require creation of a single, mandated consortium involving the highest-volume cancer centers in the State.

Such a collaboration — requiring competing hospitals to form a single, statewide consortium with no designated leader — is unrealistic and unprecedented anywhere in the country. Even if the consortium was formed, disagreement among hospitals on location, leadership, equipment, research priorities or financial investment would derail the process and result in delay (such delay has occurred in New York due to inability to get agreement among interested parties).

Effective business relationships are built between willing partners, not through government mandates. As justification for a mandated and prescribed collaborative approach, some have cited examples of collaborative ventures to jointly offer clinical services among multiple hospitals. However all of these examples were voluntary collaborations and none of them were for services as complex as proton beam therapy.

ProCure Treatment Centers Inc. approached Beaumont as a partner because of the reputation of our physician specialists as world leaders in radiation oncology innovation. Together, and with other cancer centers and physicians, we could ensure a proton beam center is developed, constructed and treating patients within the next 2-1/2 years — by 2010. Beaumont is the only hospital prepared to bring proton therapy to Michigan now. The proposed standards would have the effect of delaying this technology, and its benefits, from coming to Michigan for many years beyond 2010.

In addition to providing timely access to proton treatment for Michigan's cancer patients, this project would bring \$159 million in new investment to Michigan's economy, generating 400 construction jobs and more than 100 positions for physicists and other highly educated personnel. This aligns with efforts to promote our region's life sciences sector and transition to a knowledge-based economy, a goal of groups such as Detroit Renaissance, the Detroit Regional Chamber, Automation Alley and the Michigan Economic Development Corporation. Along with jobs, it's estimated that people traveling here for proton treatment would generate another \$22 - \$32 million in revenue for area businesses.

We support the CON Commission's responsibility to regulate health care quality, access and cost. But the proposed standards will deny Michigan cancer patients access to proton therapy.

We believe that mandatory, regulated collaboration — as specified in the CON standards being considered by the Commission — is the wrong approach. We all have a responsibility to bring proton cancer treatment to Michigan as soon as possible for the sake of Michigan's cancer patients.

Beaumont has filed a C.O.N. application for proton therapy and meets the current C.O.N. standards. We ask that the Commission not act to change the standards at its newly scheduled Special C.O.N. Commission meeting on April 30 so that this application can be approved, thus allowing this project to proceed without delay. Because of the complexity, cost, financial risk, and required expertise to establish a proton treatment center, Beaumont does not believe there will be a "medical arms race" that would result in proliferation of proton treatment centers in our State. However, as we have to date, Beaumont would be pleased to participate in re-focused efforts to develop appropriate and realistic C.O.N. standards for proton treatment that do not mandate leaderless consortiums and business relationships between unwilling partners. The proposed standards can only result in significant delay in access to the most advanced form of radiation treatment for Michigan's patients.

**From:** <DoNotReply@michigan.gov>  
**To:** <moorean@michigan.gov>  
**Date:** Wed, Mar 26, 2008 3:08 PM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

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2. Organization: Baraga County Memorial Hospital
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5. Standards: NH
6. Testimony:

This letter responds to the posting for public comment on section 7(1)(a) of CON Review Standards for Nursing Home and HLTCU Beds, specifically, the change that was proposed by the CON Commission at its March 11, 2008 meeting.

I thank the Commission for recommending the change, and urge it to make that modification final when it next has an opportunity to address these standards.

Whatever rationale may support limiting the relocation of nursing home beds to half of a facility's complement of licensed beds, those policies do not equally inform the relocation of HLTCU beds.

HLTCU beds are found, for the most part, in rural hospitals, which of necessity bear great responsibility for the entire health care system in their service areas. They should be afforded maximum flexibility in generating and preserving the resources that their rural populations need.

Second, unrestricted relocation should be allowed because the federal Critical Access Hospital reimbursement system, which is designed to promote the health of rural hospitals through cost-based reimbursement, often works against a CAH that has a portion of its physical plant and service days in SNF use. Despite Medicare's high per diem rates (relative to Medicaid), a CAH is always in danger of being swallowed by the costs that it must allocate to its HLTCU.

Third, Michigan's own Medicaid program pays an enhanced per diem rate to an HLTCU, compared to the rate paid to a freestanding nursing home. That enhanced rate does not cover the costs of the typical HLTCU, however. A great deal of money would be saved by both CAHs and Medicaid by empowering hospitals with such units to place them into freestanding nursing home structures.

I note that at the March 11, 2008 Commission meeting, advocates for nursing home residents spoke favorably of this proposal. Although preservation of the financial health of nursing homes is typically not their concern, they are aware that, if only because of the age of those units, HLTCU physical plants are much colder and clinical in their feel than are most nursing homes. In the case of my own client, Baraga County Memorial Hospital, the nursing home to which these beds would be moved is a modern one, built with contemporary notions of home-like environment and program initiatives in mind.

Thank you for your attention to this matter. I look forward to the Commission's favorable action on this amendment to Section 7(1)(a) of the Nursing Home/HLTCU standards.

Very truly yours,

BRIAN KASER, PLC

Brian A. Kaser

**From:** <DoNotReply@michigan.gov>  
**To:** <moorean@michigan.gov>  
**Date:** Thu, Apr 3, 2008 10:29 AM  
**Subject:** March 27, 2008 Written Testimony (ContentID - 147062)

1. Name: John Tembreull
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3. Phone: 906-524-3321
4. Email: [jtembreull@bcmh.org](mailto:jtembreull@bcmh.org)
5. Standards: NH
6. Testimony: These comments are related to the CON Commission's proposed review standards for Nursing Home and HLTCU beds. I would like to thank the Commission for its proposed amendment to Sec. 7(1)(A) which would allow unrestricted relocation of HLTCU beds to a nursing home.

Baraga County Memorial Hospital is the owner and operator of a 28 bed attached HLTCU and a 59 bed freestanding nursing home. The proposed standard would give the hospital the opportunity to restructure its long term care services. The proposed standard would allow the hospital to relocate a portion of its 28 HLTCU beds to the nursing home. This would give us the opportunity to build new beds with a much improved physical environment for the residents. It would also give us the opportunity to consolidate long term care services for a more cost effective organization.

In addition, it would help secure the hospital financially. Currently, the hospital's status as a Critical Access Hospital results in lost Medicare reimbursement due to allocated costs from the hospital to the HLTCU. This lost reimbursement is in excess of any per diem rate advantage that may exist between a HLTCU and a freestanding unit. The relocation of the beds also presents a significant Medicaid cost savings opportunity for the State of Michigan due to the rate differentials in the bed classification.

The removal of the restriction on the number of beds that may be relocated gives this community the opportunity to restructure its services while allowing for the decision process to determine what best meets the community need in a financially sound manner.

Thank you for your consideration.

John P. Tembreull  
Administrator  
Baraga County Memorial Hospital