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**Date:** Tue, Aug 12, 2008 2:11 PM  
**Subject:** August 5, 2008 MRT Public Hearing Written Testimony (ContentID - 196938)

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5. Testimony: Megavoltage Radiation Therapy (MRT) Standards Proposal  
University of Michigan Health System Written Testimony  
August, 2008

The University of Michigan Health System (UMHS) would like to thank the MDCH and the CON Commission for this opportunity to provide written testimony regarding proposed changes to the MRT standards. We realize this is a complex issue, and believe all constituents have the same objective of doing what is best for the citizens of the State of Michigan.

The Michigan Certificate of Need Commission took proposed action on July 23, 2008 to amend standards for MRT services to allow for a collaborative of providers to initiate a new heavy particle accelerator service. The University of Michigan Health System's position is that any adopted regulatory language should maximize the opportunity for success of a collaborative approach consistent with CON cost, quality and access objectives. UMHS believes that a successful collaborative will set a national benchmark for introducing cutting edge medical technology to the State of Michigan. Consequently, any final action taken by the Commission must include flexibility at the onset, and a strong foundation for ongoing success.

A collaborative approach has to be given the greatest opportunity for success to meet the public policy objectives of accessible, evidence-based medical technology at an appropriate cost for the citizens of the State of Michigan. The state is poised to be a national leader in addressing the appropriate adoption of very expensive medical technology. To ensure the greatest opportunity for success, UMHS believes any adopted regulations must:

- ò Contain reasonable oversight and project delivery requirements that do not burden the collaborative approach;
- ò Promote access to emerging technologies by supporting participation among all interested parties, and allowing sufficient flexibility while developing a successful enterprise; Effectively address concerns raised by the Governor in the veto of the previous proposed regulations

UMHS supports the volume-based ETV methodology proposed by the collaborative consisting of UMHS, Henry Ford Health System, Karmanos and St John/Ascension as the best approach to address the principles outlined above. UMHS is committed to the collaborative approach and will continue to work with the Department as well as its partners to refine language that will provide for these key principles.

Again, we thank MDCH and CON Commission for the opportunity to provide this testimony.

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Thank you for the opportunity to provide comment regarding MRT Standards for High MRT Units (HMRT). Karmanos Cancer Institute provided public testimony on July 23, 2008 to support an alternate methodology defining the development of an HMRT collaborative defined in Section 10(1)(B) of the Standards. We encouraged the commission and the department to consider this methodology in addition to the language which was suggested by the Department. We recognize that there are issues with the alternative methodology and we will continue to work with the Department and Commission to come to common agreement prior to the Commission meeting in September. We believe the oversight language in Section 16(3)(C) must be altered to ensure it is not overly burdensome for either providers or the Department and we will work with the Department and Commission to reach common agreement on this issue also.

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PUBLIC TESTIMONY IN REGARD TO PROPOSED CHANGES TO THE MEGAVOLTAGE RADIATION THERAPY STANDARDS

August 5, 2008

Oakwood Healthcare, Inc. would like to thank the Commission and the Department for their work in the revision of the Megavoltage Radiation Therapy Standards.

With the many advances in technology and cancer treatment, we feel it is important to revise these standards to more adequately address these components.

Oakwood Healthcare, Inc.'s cancer program includes three linear accelerators - two housed at the main campus, Oakwood Hospital and Medical Center, and one at Oakwood Healthcare Center-Southgate. We have a strong commitment to deliver comprehensive cancer services with a focus on efforts to balance access, quality and cost.

It is essential that the proposed standards permit access to emerging technologies. Additionally, it is important that an interested entity be allowed the opportunity to participate in a collaborative utilizing an HMRT unit. OHI's future goals could possibly include participation with other facilities in the provision of Proton Beam Therapy as well as other innovative modalities. For these reasons, we support a methodology that facilitates a successful collaborative while maintaining access to the service among all interested parties.

Oakwood Healthcare, Inc. remains an active participant in the CON process and will work with the Department and CON Commission as a major provider of high quality cancer treatment services.

Thank you for the opportunity to provide testimony regarding this subject

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5. Testimony: Testimony  
Blue Cross Blue Shield of Michigan  
/Blue Care Network  
Public Hearing  
August 11, 2008

On behalf of Blue Cross Blue Shield of Michigan and Blue Care Network, I would like to thank you for this opportunity to testify about the Megavoltage Radiation Therapy (MRT) standards that address Proton Beam Therapy (PBT). As stated previously, BCBSM and BCN strongly support this proposed language with its collaborative approach for the delivery of any type of heavy particle accelerator cancer radiation treatment program. We urge the Commission to move this language forward as a final action at its September 16th meeting, in order to expedite the process as quickly as possible.

BCBSM/BCN feels strongly that there is no current evidence of a need for multiple heavy particle radiation therapy programs (HMRT) programs. At a minimum, we support the at least 40% criterion participation of high volume cancer treatment centers (as opposed to the prior majority requirement). However, we want to articulate our support for ANY additive measures to prevent the initiation of multiple HMRT programs. Although we believe that this criterion addresses the Governor's concerns and is consistent with the Commissioner's approach to minimize proliferation of heavy particle radiation therapy programs (HMRT) programs: we feel that allowing for the deliberate and methodical growth of PBT or any HMRT program in the state is a preferred public policy for the following reasons:

- o Treatment quality: Concentrating volume at fewer programs usually generates better treatment quality. Many clinical studies suggest that higher volume per service site correlates with better patient outcomes.

- o Research: Other testimony provided to the Commission and the MRT work group strongly upheld the view that one program would significantly increase the validity of research outcomes.

- o Costs: High costs to develop and operate these HMRT program will result in higher payments per patient treatment episode (for professional and hospital services) than current cancer treatment programs without evidence of improved outcomes except for a small number of pediatric cases. Also, as we have indicated in prior testimony, the availability of PBT may increase demand for this higher cost treatment for cases that have not been shown to have improved results over standard photon therapy.

Limiting the number of HMRT programs will allow the state to continue to provide the latest technology to those who need it while helping to control overall health care costs

Additionally we support the need for clear supervisory/oversight language related to the operation of these programs. We have some concerns regarding the vagueness of the language added to the standard just prior to the Commission meeting. We believe that it is important to have clear language in place allowing MDCH oversight for defensibility as well as cost, quality and access purposes.

In conclusion, we remain concerned that a proliferation of HMRT programs will ultimately increase the cost of health care delivery despite indications that less costly alternatives utilizing photon therapy are just as effective treatment modalities. BCBSM/BCN feels that this proposed language addresses many concerns raised by the Governor and others. This language also provides an equitable across the board approach to assure high quality, valid research, and appropriate utilization while preventing unnecessary costs for all of our stakeholders.

BCBSM/BCN retains its commitment to facilitating access to cost-effective, high quality health care. We continue to support the Certificate of Need program to ensure the effective expenditure of health care dollars in Michigan.

Thank you very much for the opportunity to share our perspective to this issue.

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5. Testimony:

Spectrum Health supports the activities of the CON Commission and, in particular, the proposed revisions to the CON Review Standards for Megavoltage Radiation Therapy (MRT). We agree with the Commission that a single High MRT service is sufficient to meet the needs of the state's populace. Therefore the requirement that a consortium of major cancer centers must operate the HMRT service represents good policy. By requiring the consortium to include at least 40% of the highest volume (>30,000 ETVs) MRT providers in Michigan, the proposed Standards assure that the most experienced cancer centers in the state will be involved in the HMRT service. This approach is preferable to the alternative methodology proposed, which would require members of the consortium collectively to account for >200,000 ETVs annually. Such a requirement would not insure that the major cancer centers participate in the consortium, since a large group of smaller MRT providers could collectively achieve 200,000 ETVs. Furthermore, this alternative approach could conceivably permit three (3) or more HMRT centers to be established in Michigan, a result that would exceed the needs of the state's residents and would substantially increase healthcare costs in Michigan. For these reasons, Spectrum Health supports the proposed revisions to the MRT standards as approved by the Commission at the meeting on July 23, 2008.

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Beaumont Hospitals opposed the recently vetoed standards for proton beam therapy (PBT) because they did not address consumer/patient need.

The Department has now proposed revised (HMRT) standards, which again do not include any evaluation of patient, the basis for the entire C.O.N. program. We believe a better approach would be to establish a SAC made up of experts and other constituents to carefully consider cost, quality and access need issues related to HMRT.

Legal problems remain as well. First, there is nothing in the certificate of need law that gives the C.O.N. Commission the authority to dictate how providers, and which providers, must organize in order to qualify for C.O.N.

Second, the active state supervision standard referred to in the DOJ letter is met only if there is ongoing monitoring and regulation of the activities of the collaborative. It is not enough that a state agency supervises the initial application process or requires an annual report. The C.O.N. Commission has no statutory authority to engage in the type of ongoing supervision that is required.

Any hospital considering participation in a collaboration that has the ability to restrict competition will be at risk in light of previously expressed DOJ concerns. For this reason, before proceeding, the Commission should request that the DOJ review and comment on the revised proposed standards.

At the July 23 Commission meeting, an alternative methodology was introduced that excludes ownership interest in a new HMRT project if an entity provides or has a C.O.N. to provide HMRT services. This too could be interpreted as anti-competitive and should be reviewed by the DOJ before being adopted.

There is no rational basis for this exclusion, and in fact it may preclude participation of MRT centers that have the most HMRT knowledge and experience, to the detriment of patients.

Beaumont remains a strong proponent of the C.O.N. program. We believe that proposed standards such as these, which do not address need criteria and expose participants to potential legal and anti-trust issues, compromise the integrity of C.O.N. and put the program at risk.