MICHIGAN DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED (CON) COMMISION MEETING

Wednesday, April 30, 2008

Capitol View Building
201 Townsend Street
MDCH Conference Center
Lansing, Michigan 48913

APPROVED MINUTES

I. Call To Order

Chairperson Goldman called the meeting to order at 10:10 a.m.

A. Members Present:

Edward B. Goldman, Chairperson
Norma Hagenow, Vice-Chairperson
Peter Ajluni, DO (via teleconference from 10:00 a.m. to 11:38 a.m.)
Bradley N. Cory
Dorothy E. Deremo (via teleconference from 11:00 a.m. to 11:38 a.m.)
Marc Keshishian, MD
Adam Miller (via teleconference 10:00 a.m. to 11:38 a.m.)
Michael A. Sandler, MD
Vicky L. Schroeder
Thomas M. Smith
Michael W. Young, DO

B. Members Absent:

None.

C. Department of Attorney General Staff:

Ronald J. Styka

D. Michigan Department of Community Health Staff Present:

William Hart
John Hubinger
Joette Laseur
Irma Lopez
Nick Lyon
James McCurtis
Andrea Moore
Janet Olszewski
Taleitha Pytlowanyj
Brenda Rogers

II. Review of Agenda

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Cory, to accept the agenda as presented. Motion Carried.

III. Declaration of Conflicts of Interest

Chairperson Goldman stated that the University of Michigan had a Letter Of Intent (LOI) for Proton Beam Therapy (PBT), but has withdrawn its LOI and therefore, he no longer has a conflict of interest.

Commission Sandler stated Henry Ford has submitted a LOI for Megavoltage Radiation Therapy (MRT) – PBT and therefore, has a conflict of interest.

IV. Review of Minutes – March 11, 2008

Motion by Commissioner Smith, seconded by Commissioner Young, to approve the minutes as presented. Motion Carried.

V. Michigan Department of Community Health (MDCH) Comments on MRT Services/Units

Ms. Olszewski spoke on behalf of the Department. She summarized the MDCH amendments to Section 10 of the MRT Standards (Attachment A). She also summarized the Proposed CON Commission Resolution on Proton Beam Therapy (Attachment B). Discussion followed.

VI. MRT Services/Units – Public Hearing Comments

Ms. Rogers provided a brief summary of the public hearing comments (Attachment C).

A. Public Comments

Jim Potchen, Michigan State University
Tina Grant, Trinity Health
Benjamin Movsas, MD, Henry Ford Health System (Attachment D)
Patrick O'Donovan, William Beaumont
Jon Slater, Optivos
Bob Meeker, Spectrum Health
Joan Ebner, General Motors
Carol Christner, Karmanos Cancer Institute (Written Testimony Only, Attachment E)
Dennis McCafferty, Economic Alliance for Michigan (Attachment F and G)

B. Commission Discussion

Commissioner Keshishian stated that he was the Commission liaison for the MRT PBT Workgroup. He read the Commission Findings from the Proposed CON Commission Resolution on Proton Beam Therapy Document (Attachment B). Discussion followed.

C. Commission Final Action

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Smith, to accept the Commission Findings. Motion Carried, 10-0, Commissioner Sandler abstained.

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Cory, to approve the MRT Standards with the proposed amendments and move forward to the Joint

Legislative Committee (JLC) and Governor to begin the 45-day review period. Motion Carried, 10-0, Commission Sandler abstained.

Motion by Commissioner Keshishian, seconded by Commissioner Young, to adopt the "Commission Expectations for Prompt Development of a PBT Collaborative" (Attachment B). Motion Carried, 10-0, Commission Sandler abstained.

VII. Computed Tomography (CT) Scanner Services – Public Hearing Comments – Non-Diagnostic Intra-Operative Guidance Tomographic Units

Ms. Rogers provided a brief summary of the public hearing comments (Attachment H).

A. Public Comment

Amy Barkholz, MHA, Supports CT Language

B. Commission Final Action

Motion by Commissioner Keshishian, seconded by Commission Sandler, to accept the Standards and move forward to the JLC and Governor to begin the 45-day review period. Motion Carried, 11-0.

VIII. Nursing Home and Hospital Long-term Care Unit (NH/HLTCU) Beds – Public Hearing Comments – 50% Limitation for Relocation of Beds for HLTCUs

Ms. Rogers provided a brief summary of the public hearing comments (Attachment I).

A. Public Comment

Pat Anderson, HCAM, Supports NH/HLTCU Language
Amy Barkholz, MHA, Supports NH/HLTCU Language

B. Commission Final Action

Motion by Commissioner Cory, seconded by Commissioner Young, to approve the NH/HLTCU Standards and move forward to the JLC and Governor to begin the 45-day review period. Motion Carried, 11-0.

IX. Surgical Services (SS) – Public Hearing Comments

Ms. Rogers provided a brief summary of the public hearing comments (Attachment J).

A. Public Comment

None.

B. Commission Final Action

Motion by Commissioner Smith, seconded by Vice-Chairperson Hagenow, to accept the SS Standards and move forward to the JLC and Governor to begin the 45-day review period. Motion Carried, 11-0.

X. Public Comment

Lody Zwarensteyn, Alliance for Health

XI. Review of Commission Work Plan

A. Commission Discussion

Ms. Rogers provided a brief overview of the draft work plan (Attachment K) and stated there were no changes.

Commissioner Sandler raised the question as to where CT stood. Ms. Rogers stated there is a discussion meeting scheduled regarding Mini-CT Scanners on May 13.

B. Commission Action

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Smith, to accept the work plan. Motion Carried, 11-0.

XII. Future Meeting Dates

June 11, 2008
September 16, 2008
December 9, 2008

XIII. Adjournment

Motion by Vice-Chairperson Hagenow, seconded by Commissioner Smith, to adjourn the meeting at 11:38 a.m. Motion Carried, 11-0.

MDCH PROPOSED AMENDMENTS TO SECTION 10

MDCH has proposed amendments to Section 10 of the MRT Standards. Section 10 addressed Proton Beam Therapy Services.

Summary: The suggested modifications of the PBT language in the MRT Standards were developed in response to the Commission's March 11, 2008 particular request for comment on the minimum requirements for participation in the PBT collaborative.

Requiring participation from hospitals with both high volume MRT ETV volumes and not just from one planning area would assure a reasonable achievement of those goals, without requirements being so complex that they might interfere with the prompt establishment of a PBT program in Michigan.

Establishing a standard of 30,000 MRT ETV's (Equivalent Treatment Visits) ensures that sufficient volume exists within the programs forming a collaborative to provide the best chance for high quality care for patients. This volume will also allow this type of cancer radiation to be evaluated at the highest possible volume, thus ensuring greater statistical validity for the outcome analyses. This would meet the CON goals of high quality, cost-effective health patient care.

Comments on Specific Proposed Modifications:

1. **Why "Majority" Instead of "All" High Volume Hospital MRT Programs Required to be in the Collaborative and at a minimum?** This would assure greater likelihood of a PBT program being promptly established in Michigan to provide this advance in cancer radiation treatment to Michigan residents with:
   - High quality of PBT treatments for patients due to high and concentrated volume, and thus high proficiency of practitioners and the overall service
   - High validity of research and outcome findings due to the involvement of a significant number of established hospital MRT programs and experienced practitioners and researchers regarding cancer radiation treatment services.
2. **Why Involvement of hospital MRT programs from "more than one" health planning area instead of "four"?** There could be a conflict among the goals of assuring (a) PBT services are promptly made available in Michigan, (b) participation in the collaborative by high volume hospital MRT programs, and (c) that the participating hospitals would not be from just one area of the state.
3. **Why use the list published by the Department on April 30th, 2008?** The April 30th, 2008 list is based upon the most recent data available to the Department and has been finalized as of this date. This is the data that the CON Commission will have to make its final decision on the PBT standard at its April 30, 2008 meeting.

PROPOSED CON COMMISSION RESOLUTION ON PROTON BEAM THERAPY

(To be considered by Commission at its meeting on April 30, 2008)

Commission Findings:

Proton Beam Therapy (PBT) is the most expensive medical equipment yet developed. Physician cancer radiation experts at most of Michigan's major hospital cancer programs, and at all four medical schools, testified to the Commission that PBT is an unproven technology. The predominant medical judgment of nearly all these cancer experts was that PBT would be of significant benefit for only a small number of patients (mostly pediatric brain tumors and certain neck tumors in patients of all ages). Beyond that, the predominant medical judgment of cancer medical experts was that they were not yet convinced of the long-term net value to the great bulk of cancer patients with other tumors.

However, there was general agreement among medical experts that Michigan should be involved in the research and evaluation of the benefits for patients that PBT may have for other cancer cases. Having a PBT center in Michigan also could have economic benefits. Constructing a PBT center would take about two years and would require extensive technological leadership to operate. Having one program, jointly sponsored by most major hospital cancer programs, is the best approach for assuring that needed expertise and to best pursue the goals of both patient value and economic benefit. Most importantly, a statewide collaborative provides the best chance for the possible patient and economic benefits of this new type of cancer radiation to be evaluated at the highest possible volume facility, allowing greater statistical validity for the outcomes. Requiring the participation in the collaboration of a majority of hospital-owned MRT centers with equivalent treatment visits above 30,000 would maximize the chances of meeting these goals of high quality in patient treatment and the validity of outcome analyses.

Absent final approval of the MRT Standards (proposed by the Commission on March 11, 2008), there could be multiple PBT centers in Michigan. That would divide the initially expected limited volume of appropriate cases among multiple facilities, resulting in less than desirable validity of outcome analysis. Also the costs of multiple centers, each having the most expensive medical equipment yet developed, would be tremendous. Four hospitals have already requested approval of more than $500 million in initial project costs with more than $100 million in annual operating costs.

A collaborative will require multiple high volume cancer centers to agree on many issues such as the location, size, funding and operation of one PBT center. This collaborative approach, however, should not result in an unacceptable delay in bringing PBT to Michigan. To assure that the members of this

collaborative are expeditiously moving towards accomplishing the goal of bringing PBT to Michigan, the Commission hereby establishes the following criteria for its careful monitoring of this process:

Commission Expectations for Prompt Development of a PBT Collaborative:

1. Commission commits to repeal/modify PBT language in the MRT Standard IF it reaches the conclusion that substantial and timely progress (per expectations described below as number 3, 4, and 5) is not being made to assure Michigan will promptly have a collaborative PBT program.

2. Commission will reach the conclusion about the adequacy of substantial and timely progress being made towards a successful collaborative no later than three months from the effective date of the PBT Standard (thus at its September 16, 2008 meeting).

3. Each of the high volume hospital-owned MRT programs (those eligible to be among the minimally required participants in the collaborative because they are above 30,000 MRT ETVs statewide or are among the highest volume programs in at least two health planning areas) are asked to report in writing to the Commission within 10 days before each scheduled Commission meetings with their assessment of progress in developing a collaborative.

4. By June 5, 2008, the CEOs of those of the high volume hospital-owned programs identified in Section 10 (1) (b) of the CON MRT Standards who have committed to be in the collaborative shall submit a letter to MDCH for review and analysis to be provided to the Commission. This letter will indicate that the respective governing bodies for the participating hospitals have agreed to (a) participate in the collaborative, and (b) contribute their appropriate share of at least $13 million to be the minimum sponsoring hospitals' share of the program.

5. By September 6, 2008, the collaborative is to submit a business plan. That business plan shall include: a proposed financial plan outlining the projected costs and sources of funds for the PBT Collaborative, a proposed governance plan, a proposed time-line for completing the PBT facility, the process and timeline for selecting the PBT equipment manufacturer, and a timely process for identification and purchase/lease of the site.

Summary of March 27, 2008 Public Hearing Comments: Megavoltage Radiation Therapy (MRT)

Megavoltage Radiation Therapy (MRT)

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
Carol Christner	Barbara Ann Karmanos Cancer Institute	Support: 1. 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. 2. 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.		*As one of only two NCI-designated comprehensive cancer centers in the State of MI, we strongly believe that a collaborative approach to Proton Beam Therapy (PBT)… 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.*
Hadley Ford	CEO, ProCure Treatment Centers, Inc.		Does not support: 1. 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.	*Together, Beaumont and ProCure are ready to begin construction [of a proton therapy center] as soon as the Dept. of Comm. Health approves the Beaumont application, assuming the current rules apply. Patients will begin receiving treatment in 2010 and MI 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. 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.
Sean Gehle	The Michigan Health Ministries of Ascension Health	Support: 1. For the concept of a statewide collaborative of providers who would be eligible to apply to initiate an MRT Service providing Proton Beam Therapy envisioned by the language given preliminary approval by the CON Commission at its March 11th meeting.	Does not support: We have some specific language changes that we felt would clarify the existing language. The suggested modifications are as follows: 1. Amend Sec. 10, Subsection (1)(B)(1) after "services" by inserting "who have expressed an interest in PBT 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	*We believe that PBT should be made available to MI residents who could benefit from this form of radiation treatment. However, given this technology's current limited applicability to pediatric cancer cases and some rare tumors in the brain, neck and spine, and likewise limited theoretical applications, we believe it is appropriate to limit this technology within the state and that a statewide collaborative of providers is the most appropriate method by which to ensure that eligible patients have access, while also constraining the proliferation of numerous centers that would result in multiple lower-volume centers and significantly increased health care costs. We believe that the proposed language provides for a deliberative and open structure by which all interested entities with clinical expertise in this arena and who want to participate in making this technology accessible and available to the residents of Michigan can perform a*

			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.	*valuable role. A statewide collaborative of health systems who operate significant radiation oncology programs will result in ensuring that the needs of the patient remain the focus of any initiative to bring PBT to Michigan.*
Paul S. Harkaway, M.D.	Self			*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. 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 [several question - see testimony] for your consideration.*
Monica Harrison	Oakwood Healthcare, Inc.	Support: 1. Oakwood Healthcare, Inc. (OHI) would like to thank the CON Commission and the MRT workgroup for its work on this important topic. 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. 2. OHI remains an active participant in the process and will work with the Dept. and CON Commission as a major provider of cancer treatment services.		*It is essential that the proposed standards allow maximum flexibility in access to emerging technologies. As such, threshold, while certainly relevant, should be regularly reviewed to assure that they do not create "artificial" impediments to quality service. OHI's strategic goals may incorporate participation in the use of PBT, as well as other modalities.*
Patrick O'Donovan	Beaumont Hospitals		Does not support: 1. We believe that mandatory, regulated collaboration as specified in	*We all have a responsibility to bring proton cancer treatment to MI as*

			the CON standards being considered by the Commission is the wrong approach. Beaumont has filed a CON application for proton therapy and meets the current CON standards. We ask that the Commission not act to change the standards at its newly scheduled Special CON Commission meeting on April 30 so that this application can be approved, thus allowing this project to proceed without delay. Beaumont would be pleased to participate in re-focused efforts to develop appropriate and realistic CON 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.	*soon as possible for the sake of Michigan's cancer patients. 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 MI now. The proposed standards would have the effect of delaying this technology, and its benefits, from coming to MI for many years beyond 2010.*
Ms. Deborah Riddick	BCBSM/BCN	Support: We endorse the position put forth by the MRT Workgroup encouraging health systems to work together in drafting regulations and jointly filing a certificate of need for a proton beam accelerator in SE Michigan. The formation of a statewide consortium of providers is strongly recommended. The Blues support the reasons summarized by the Workgroup and the CON Commission, including: 1. PBT is new technology and there is lack of sufficient medical data and research supporting its cost-effectiveness and impact on clinical outcomes and quality of care. 2. PBT has limited application and is established in a small number of cancers. 3. There is a lack of		

		consensus among the medical community, especially among radiation oncologists, regarding its efficacy in treating cancers outside of certain types of malignancies. 4. The Blues are concerned that a proliferation of proton beam accelerators would encourage hospitals to place pressure on physicians to direct patients toward proton therapy, when in fact; less costly alternatives utilizing photon therapy are just as effective. Overutilization will unnecessarily drive health care costs. 5. There is <u>not</u> enough demand (or number of cancer cases that fit the inclusionary criteria) to justify the need to invest in more than one facility in SE Michigan. 6. It is recommended that cancer centers participating in the consortium submit an application demonstrating their qualifications before acceptance is granted. 7. Members of the consortium should submit authorized signatures declaring their commitment to collaborate and display their willingness to provide periodic updates to the workgroup.		
Bret Jackson, Legislative Director	The Economic Alliance for Michigan	Support: 1. The CON Commission's proposal to require a truly collaborative approach among the highest volume hospital MRT programs, with other groups also able to participate, to establish a PBT program in Michigan.		*EAM is going through its internal process to consider the Commission's question whether the collaborative must involve "all" the highest volume hospital MRT programs, or just "most." Some of our members already indicate that they share the concern that requiring agreement among*

				"all' would mean just one program could block the effort. EAM will have a response to the Commission's inquiry by the April 30th meeting. We agree with the Commission's balanced judgment to bring this new anti-cancer technology to MI in a careful and deliberative manner. Having one program, jointly sponsored by major hospital cancer programs and other interested parties, is the best approach.
Cassandra Saunders, Legislative Program Manager	Chrysler	Support: 1. The actions of the Commission taken on March 11th and the standards that were adopted. Chrysler applauds the Commission's swift and decisive action to create a CON standards that addresses the needs of the entire state.		*We do not see a need for multiple proton beam centers in this state. There is no compelling evidence that PBT is better at treating most cancers than established practice. Where there is compelling evidence that PBT is superior for certain cancers, there seems to be adequate capacity for treatment of these cancers, especially if a center is built in MI. Without any further demonstration of quality, or a problem of access, we are left with cost. At $70 million, or $159 million, based on the applications submitted, PBT is the single most expensive piece of medical equipment ever to be invented. For MI to allow unrestricted proliferation of this technology into this state would be irresponsible.*
Liz Palazzolo	Henry Ford Health System	Support: 1. HFHS strongly supports the proposed revisions to the MRT Standards, particularly with		*Although PBT has been available for many years at a few centers across the*

		respect to the proposed rules for PBT. We believe the approach described in the proposed standards, whereby a consortium of Michigan hospitals would work together to bring this technology to Michigan is the right approach. Together the consortium would develop patient selection criteria, treatment protocols, collect data and contribute to the body of medical knowledge about PBT. The consortium would be a truly collaborative model with shared decision making, as opposed to a model where collaboration means that a facility is developed by one organization and the collaborators simply function as a source of patients.		*country, its use has not spread quickly. There are a number of reasons, most importantly there is not a consensus amongst clinical experts in radiation oncology that this therapy offers substantial incremental benefit for the vast majority of patients who need radiation therapy. Most clinicians agree that some rare pediatric tumor cases can be treated more successfully with this modality, but the number of cases is small. PBT has been used in prostate cancer for some time… it has not been clearly proven that it is superior to other available treatments. Finally, a most important consideration in the dissemination of this technology has been the enormous cost associated with developing a center. Current estimates of cost for a proton center range in the vicinity of 150 million dollars.*
Dr. Howard Sandler	University of Michigan Medical Center	Support: 1. The University of Michigan strongly supports the current language and a collaborative approach. Implementing PBT in Michigan is an important step. It is important for us to take the time and make sure that as a state we get this right. True collaboration gets all interested parties involved and is a sound decision for the people of the State of Michigan. Our Department of Radiation Oncology has extensive positive experience collaborating with other hospitals to deliver radiation oncology services, and this experience has been beneficial for patients throughout MI. Our		*Although proton technology has been used to treat many patients, often patients with prostate cancer, definitive studies comparing radiation given with proton beam vs. radiation given with state-of-the-art non-proton methods have not been performed. So proton beam carries the label "unproven" by conventional measures of technology*

		collaborations with Foote Hospital, Alpena General Hospital, Providence Hospital, Ingham Regional Medical Center, Central Michigan Community Hospital, and the Ann Arbor VA Hospital have led to improvements in research, teaching and patient care. Our experience with these collaborations indicates to us that it is feasible for proton beam therapy to move forward using a joint approach.		*assessment. A recent structured review by BRADA of all proton clinical studies was published by the Journal of Clinical Oncology in 2007. That study noted that there was probably modest efficacy with proton beam for some unusual tumor situations. Given that the tumors most likely to benefit from proton beam treatment are quite rare, a collaborative venture that pools the state's resources seems like an efficient and sound way to proceed.*
Dr. Tewfik Bichay	Trinity Health of Michigan	Support: 1. Trinity Health strongly supports the language that would require the establishment of a statewide consortium or collaborative program that brings PBT to Michigan. We commend the Commission for recommending this collaborative requirement and believe that it is consistent with the commission's objective to regulate the health care industry in MI by providing quality health care at a reduced cost.		*In this particularly challenging economy that we are in at the moment, increasing health care costs puts access to quality services out of reach for more and more residents of MI. The most sensible course of action is really to grow programs as a collaborative venture and not in isolation. If left unregulated, the potential for excessive PBT programs within the state and resulting increased cost is certainly a concern.*
Bob Meeker	Spectrum Health	Support: 1. Spectrum Health supports the collaborative approach to PBT and supports the recommendations of the commission in the proposed standards.		*I think that the collaborative approach makes sense for any number of reasons. It maximizes the use of expertise from across the state. It maximizes the availability of patients from across the state. And it also maximizes the ability to do definitive – or contribute to definitive research*

				into the proper and most appropriate uses for this technology.
Amy Shaw	Michigan Manufacturers Association (MMA)	Support: 1. We strongly support the current position of the CON Commission requiring a collaborative approach to establish a PBT program in Michigan.		*MMA has been a staunch supporter of the CON process to balance cost, quality and access issues and to ensure that only needed services and facilities are developed in MI. We believe that the PBT issue is a prime example of why the CON process is necessary. At a cost of over $100 million per facility, it is essential that a deliberative approach be taken to determine the level of need in MI, which would in turn identify how many facilities would be necessary to meet that need. We simply cannot afford, as a state, to allow every hospital with the ability to raise the enormous funds that would be necessary to build their own facility with absolutely no evidence that PBT provides superior outcomes except in a few rare pediatric cancers. It would make no sense to allow an "if we build it, they will come" mentality to drive the proliferation of facilities across the state.*

Comments to the Certificate of Need Commission Regarding Proton Beam Therapy

April 30, 2008

Benjamin Movsas, MD

Good Afternoon. My name is Benjamin Movsas and I am Chairman of Radiation Oncology for Henry Ford Hospital and Health Network. Henry Ford Health System provides radiation oncology services at five locations in southeast Michigan, at which, during 2007, we provided nearly 90,000 Equivalent Treatment Visits to patients from across Michigan.

I would like to strongly support the CON standards that have been proposed today for proton beam therapy. As we stated in previous testimony to this Commission and further reinforced in public testimony on this service, we strongly believe that this service should be provided on a collaborative basis by a consortium of major cancer centers in Michigan. Given that this would be a new service in our state, we believe that it has a greater likelihood of success if it is developed by a group of providers rather than a single entity.

Multiple participants in a consortium would bring the expertise of cancer experts from Michigan's most prestigious cancer centers together to jointly develop patient selection criteria and treatment protocols. Furthermore, the ability to attract funding for research on proton therapy is enhanced by creating a group that includes the largest clinical research programs in the state. Finally, a coalition that includes multiple providers would create the opportunity to serve diverse patient populations across Michigan.

Michigan citizens deserve every opportunity to access proven treatments that are available elsewhere. We believe that the approach described in the proposed standards is doable and that it will provide Michigan patients with a very high quality service. An opportunity is at hand to demonstrate that a large-scale project such as this can be done properly -- in a manner that is reasonable, safe,

cost efficient, and that involves a fully collaborative approach based on a foundation of active clinical trials.

On behalf of the Henry Ford Health System I appreciate the opportunity to make these comments. Again, we strongly support the approach that has been described in the standards and urge the Commission to approve the standards as written.

I would be glad to respond to any questions you might have. Thank you.

The Barbara Ann Karmanos Cancer Institute supports the unanimous vote of the CON commission regarding MRT standards at the March 11, 2008 commission meeting. We encourage the commission to uphold that vote during final action today, with the amendments proposed by the department of community health.

Throughout our participation in the MRT workgroup and during testimony at previous meetings and hearings, we have consistently advocated for a collaborative approach to bringing Proton Beam Therapy to cancer patients in Michigan. During the past month, we have communicated our desire to collaborate on PBT with the Governor and all state Senators and Representatives. In a letter sent to the Governor on April 25, 2008, our President & CEO, Dr. John Ruckdeschel, assured her that Karmanos will work collaboratively with other health entities to bring PBT to Michigan by 2011.

At the initial organization meeting of the PBT collaborative held yesterday, April 29, 2008, Karmanos agreed to the following principles:

1. We agree to report in writing to the Commission within 10 days before each scheduled Commission meetings with our assessment of progress in developing a collaborative.

2. We agree that by June 5, 2008, Dr. Ruckdeschel will submit a letter to MDCH for review and analysis to be provided to the Commission. This letter will indicate that we have agreed to (a) participate in the collaborative, and (b) contribute our appropriate share of at least $13 million to be the minimum sponsoring hospitals' share of the program.

3. We agree that by September 6, 2008, the collaborative will submit a business plan. That business plan shall include: a proposed financial plan outlining the projected costs and sources of funds for the PBT Collaborative, a proposed governance plan a proposed time-line for completing the PBT facility, the process and timeline for selecting the PBT equipment manufacturer, and a timely process for identification and lease or purchase of the site.

We look forward to providing a status update to the Commission at the June 11, 2008 meeting that demonstrates the ability to deliver PBT in Michigan while ensuring the CON tenets of cost, quality and access.

Thank you.

General Motors Statement on CON Commission Action on
PROTON BEAM THERAPY

4/30/08

General Motors applauds the actions by the CON Commission to establish appropriate guidelines for a proton beam therapy center in Michigan. The introduction of this technology to treat cancer needs to be done properly to assure quality and affordability of patient care.

There is a lack of consensus among physician leaders from the state's major cancer centers and experts at our state's medical schools regarding the efficacy of this technology in other than a small number of cancer cases. This, in combination with the significant cost of up to $159 million to build a proton beam therapy center, is of great concern. It would not make sense for there to be multiple sites for this very expensive technology without evidence that there is a significant need based on medical evidence.

GM supports the standards calling for a collaborative process among the major hospital cancer centers in Michigan to sponsor a joint proton beam therapy program. We applaud the leaders of the cancer centers in Michigan who have confirmed their commitment to the approach and have started the dialogue to bring this collaborative to fruition. We urge the Commission and all parties to allow this sensible approach for providing Michigan access to this new technology, while assessing its value, to move forward. This is sound public policy and will permit an informed approach about if and how to establish other proton beam therapy programs in the future.

The Economic Alliance for Michigan Public Testimony at April 30, 2008 CON Commissioners Meeting

Dennis McCafferty, EAM Health Policy Director

Megavoltage Radiation Therapy (MRT) Proton Beam Therapy (PBT) Services:

The Economic Alliance for Michigan strongly supports the Proton Beam Therapy (PBT) Standard as approved March 11 by the Commission per Work Group recommendation. We also support MDCH fine-tuning amendments in response to Commission's focused inquiry on that language in sending the Standards to public hearing.

At the March 11th meeting, the Commission unanimously adopted proposed standards requiring applicants proposing to initiate an MRT service providing (PBT) to be a broad-based collaborative. This collaborative should include majority of the Michigan hospital owned MRT services with more than 30,000 ETVS to assure high volume of patients. That is important to assure high enough volume for the PBT center to be economically viable AND for its reports on treatment outcomes to have statistical validity.

To assure that the collaborative extends beyond just southeast Michigan, the collaborative should include representation from more than one of the eight Michigan Planning areas by any combination of hospitals among the highest volume hospital owned MRT services statewide or in any particular HSA

Proton Beam Therapy is by far the most expensive medical equipment (up to $159 million for each a facility). Physician cancer radiation experts in Michigan at most major hospital cancer programs, and at all four medical schools, testified this is an unproven technology with so far agreement on benefits for only a small number of patients. However, there was general agreement among medical experts that Michigan should be involved in the research and evaluation of the benefits for patients that may be shown for other cancer cases. Thus, one program jointly-sponsored makes sense.

Having one program, jointly sponsored by most major hospital cancer programs provides the best chance for the possible benefits of this new approach to be evaluated at the highest volume facility, allowing greater statistical validity for the outcomes.

We urge MDCH to act on all CON applications per its well established timeline and not disrupt the CON process by acting on any application before the usually timelines of Departmental action from which there has been no deviation for this type of major project of what is substantively a new service. Also we urge the Governor and all parts of her Administration to support the PBT Standards approved by the Commission.

Absent final enactment of the Commission's proposal, there could be multiple centers. That would mean dividing the potentially small volume of appropriate cases among multiple facilities, resulting in far less than desirable research results. Also the costs of multiple centers, each having the most expensive medical equipment yet developed, would be tremendous. So far five hospitals have filed with the CON program, requesting approval of a total of $689 million in initial project costs and projected to have more than $100 million in annual operating costs.

Michigan has been a national leader in CON standards for access, quality, and affordability of healthcare. Michigan should be a national leader in Proton Beam Therapy Collaboration.

Finally, we urge the Commission commits to repeal/modify PBT language in the MRT Standard IF it reaches the conclusion that substantial and timely progress has not been made to assure Michigan will have collaborative PBT program.

1. EAM urges the CON Commission to call on each participant in the collaborative or otherwise interested in this issue to report in writing 10-days prior to each scheduled Commission meetings with their assessment of progress in developing a PBT collaborative.
2. By June 5, 2008, the CEOs of those of the high volume MRT hospitals programs identified in Section 10 (1) (b) of the CON MRT Standards who have committed to be in the collaborative shall submit a letter to the Commission. This letter will indicate that the respective governing bodies for the participating hospitals have agreed to (a) participate in the collaborative, and (b) contribute their appropriate share of at least $13 million to be the minimum sponsoring hospitals' share of the program.

3. By September 6, 2008, a business plan will be submitted that includes; a proposed financial plan outlining the projected costs and potential sources of funds for the PBT Collaborative, a proposed governance plan and a proposed time-line for completing the PBT facility.

EAM has no objection to the amendments to the CT and OR Standards pending before the Commission, as recommended by Department.

Summary of March 27, 2008 Public Hearing Comments: Computed Tomography (CT) Scanners

Computed Tomography (CT) Scanners

Name	Organization	Supports proposed recommendations	Doesn't support proposed recommendations	Comments
Bret Jackson, Legislative Director	The Economic Alliance for Michigan	Support: 1. Strongly agree with the position recommended by the SAC and again approved by the Commission at its March 11, 2008 meeting that all CT scanners should continue to be subject to CON.		*We continue to be opposed to efforts by some to exempt Specialty Use CT units from CON regulations. The Michigan Dental Association's representative has told the Commission that MDA would like to see the paperwork associated with filing for a dental CT simplified. At its March 11th meeting, the Commission called for a workgroup to determine if the paperwork could be simplified. EAM supports this effort to simplify the paperwork associated with filing for a CON for a dental CT. In fact, we think that any unneeded paperwork should be eliminated for all CON applications. During the review of the CT standards in 2007, the SAC tried to determine if the ENT CT could be regulated with a more appropriate minimum annual volume and a defined authorized use, as was done for Dental CTs. The advocates for the ENT CT were unwilling to discuss any limited and appropriate CON regulations on these specialty CTs. EAM would support CON standards for specialty CT with appropriate annual minimum volumes. That would ensure the appropriate minimum level of proficiency and training for those operating the CT, usually staff, and the reading of the images, usually the physician. Finally, there should be some definition of the medical situations where the use of the specialty CT is appropriate.*
Amy Barkholz	MHA	Support: 1. MHA supports the amendment of the definition of a CT scanner to clarify that a CT is used for diagnostic purposes.		*This needed language allows the continued use of O-arm technology in surgical procedures and serves the patients of Michigan.*

Robert Meeker	Spectrum Health	Support: 1. Spectrum Health supports the exclusion from the definition of diagnostic CT scanner the type of non-diagnostic image guidance systems that are used in operating rooms.		*This is appropriate and certainly does not violate the intent of the CON to regulate the diagnostic use of CT scanners.*
The Department supports the proposed standards. No additional change is recommended based on the CT comments received during public hearing.				

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: April 8, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Review of Public Hearing Testimony on the Proposed Nursing Home and Hospital Long-Term-Care Unit Beds (NH-HLTCU) Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the NH-HLTCU Standards at its March 11, 2008 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed NH-HLTCU Standards on March 27, 2008. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. Testimony was received from three organizations and is summarized as follows:

1. Baraga County Memorial HLTCU
   - Supports the recommended modification to Section 7 (1)(a) within the Standards.

2. Health Care Association of Michigan
   - Supports the recommended modification to Section 7 (1)(a) within the Standards.

3. Michigan Health and Hospital Association
   - Supports the recommended modification to Section 7 (1)(a) within the Standards.

Staff Analysis and Recommendations

The public hearing testimony supports the modifications to Section 7 (1)(a) of the proposed NH-HLTCU Standards. Therefore, the proposed NH-HLTCU Standards are recommended for final action at the April 30, 2008 Commission meeting.

Michigan Department of Community Health
MEMORANDUM
Lansing, MI

DATE: April 8, 2008

TO: Irma Lopez

FROM: Andrea Moore

RE: Review of Public Hearing Testimony on the Proposed Surgical Services (SS) Standards

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Public Hearing Testimony

Pursuant to MCL 333.22215 (3), the Certificate of Need (CON) Commission "...shall conduct a public hearing on its proposed action." The Commission took proposed action on the SS Standards at its March 11, 2008 meeting. Accordingly, the Department held a Public Hearing to receive testimony on the proposed SS Standards on March 27, 2008. Written testimony was accepted for an additional 7 days after the hearing via an electronic link on the Commission's website. The Department received no testimony on the proposed SS Standards.

Staff Analysis and Recommendations

The lack of public testimony and the technical nature of the changes indicate that no additional modifications are necessary to the proposed Standards. Therefore, the proposed SS Standards are recommended for final action at the April 30, 2008 Commission meeting.

Note: New or revised standards may include the provision that make the standard applicable, as of its effective date, to all CON applications for which a final decision has not been issued.

DRAFT CERTIFICATE OF NEED (CON) COMMISSION WORK PLAN

	2007												2008											
	J	F	M*	A	M	J*	J	A	S*	O	N	D*	J*	F	M*	A*	M	J*	J	A	S*	O	N	D*
Air Ambulance Services	PH		D R	•	•	• —	P		▲									F						
Bone Marrow Transplantation (BMT) Services																						PH		
Computed Tomography (CT) Scanner Services	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —		P	▲ F P	• ▲ F	•	•						
Heart/Lung and Liver Transplantation Services																						PH		
Hospital Beds	•	•	•	•	•	• R				PH			D R	•	•	•	•	• —	• P	•	• ▲ F			
Magnetic Resonance Imaging (MRI) Services	P	•	▲F—		P				▲F				•	•	• R	•	•	• —	• P	•	• ▲ F	PH		
Megavoltage Radiation Therapy (MRT) Services/Units										PH		R	D R	•	• — P	• ▲ F								
Nursing Home and Hospital Long-term Care Unit Beds	PH		D R	S ▮	▮	▮	▮	▮	▮	▮	▮	▮ —	•	P •	▲ F • P	• ▲ F								
Pancreas Transplantation Services																						PH		
Psychiatric Beds and Services																						PH		
Surgical Services										PH			D R	•	• — P	• ▲ F								
New Medical Technology Standing Committee	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R A	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R	• M	• M	• M R
Commission & Department Responsibilities			M			M			M			M			M			M			M			M

KEY

— - Receipt of proposed standards/documents, proposed Commission action
* - Commission meeting
▮ - Staff work/Standard advisory committee meetings
▲ - Consider Public/Legislative comment
** - Current in-process standard advisory committee or Informal Workgroup
• Staff work/Informal Workgroup/Commission Liaison Work/Standing Committee Work

A - Commission Action
C - Consider proposed action to delete service from list of covered clinical services requiring CON approval
D - Discussion
F - Final Commission action, Transmittal to Governor/Legislature for 45-day review period
M - Monitor service or new technology for changes
P - Commission public hearing/Legislative comment period
PH - Public Hearing for initial comments on review standards
R - Receipt of report
S - Solicit nominations for standard advisory committee or standing committee membership

For Approval April 30, 2008

Updated April 17, 2008

The CON Commission may revise this work plan at each meeting. For information about the CON Commission work plan or how to be notified of CON Commission meetings, contact the Michigan Department of Community Health, Health Policy, Regulation & Professions Administration, CON Policy Section, 7th Floor Capitol View Bldg., 201 Townsend St., Lansing, MI 48913, 517-335-6708, www.michigan.gov/con.

SCHEDULE FOR UPDATING CERTIFICATE OF NEED (CON) STANDARDS EVERY THREE YEARS*

Standards	Effective Date	Next Scheduled Update**
Air Ambulance Services	June 4, 2004	2010
Bone Marrow Transplantation Services	March 8, 2007	2009
Cardiac Catheterization Services	February 25, 2008	2011
Computed Tomography (CT) Scanner Services	December 27, 2006	2010
Heart/Lung and Liver Transplantation Services	June 4, 2004	2009
Hospital Beds and Addendum for HIV Infected Individuals	March 8, 2007	2011
Magnetic Resonance Imaging (MRI) Services	November 13, 2007	2009
Megavoltage Radiation Therapy (MRT) Services/Units	January 30, 2006	2011
Neonatal Intensive Care Services/Beds (NICU)	November 13, 2007	2010
Nursing Home and Hospital Long-Term Care Unit Beds, Addendum for Special Population Groups, and Addendum for New Design Model Pilot Program	December 3, 2004	2010
Open Heart Surgery Services	February 25, 2008	2011
Pancreas Transplantation Services	June 4, 2004	2009
Positron Emission Tomography (PET) Scanner Services	March 8, 2007	2011
Psychiatric Beds and Services	February 25, 2008	2009
Surgical Services	June 5, 2006	2011
Urinary Extracorporeal Shock Wave Lithotripsy Services/Units	February 25, 2008	2010

*Pursuant to MCL 333.22215 (1)(m): "In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years."

**A Public Hearing will be held in October prior to the review year to determine what, if any, changes need to be made for each standard scheduled for review. If it is determined that changes are necessary, then the standards can be deferred to a standard advisory committee (SAC), workgroup, or the Department for further review and recommendation to the CON Commission. If no changes are determined, then the standards are scheduled for review in another three years.