STATE OF MICHIGAN

DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED

PUBLIC HEARING

MRT SERVICES/UNITS

BEFORE ANDREA MOORE, DEPARTMENT TECHNICIAN TO CON COMMISSION

201 Townsend Street, Lansing, Michigan

Tuesday, August 5, 2008, at 10:30 a.m.

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Lansing, Michigan

Tuesday, August 5, 2008 - 10:35 a.m.

MS. MOORE: Good morning, I am Andrea Moore, Department Technician to the Certificate of Need Commission from the Health Policy Section of the Department of Community Health. Chairperson Ed Goldman has directed the department to conduct today's hearing on the Megavoltage Radiation Therapy Services/Units Standards.

Copies of the standards, comment cards, and the sign-in log are located on the back table. A comment card needs to be completed and provided to me if you wish to give testimony.

The proposed CON Review Standards for MRT Services/Units are being reviewed and modified to include, but not limited to, the following:

1. Modification of the definition of "heavy particle accelerator" to specifically include carbon ions.
2. Added definitions for "high MRT (HMRT) units" and "hospital MRT service" for purposes of Section 10.
3. Modification of the definition for "non-special MRT unit" and "special purpose MRT unit."
4. Removed references to heavy particle accelerators under sections 5 and 6 since they would no longer be considered special purpose MRT units.
5. Added a new Section 10, "Requirements for approval for

applicants proposing to initiate an MRT service utilizing an HMRT unit." This section includes the following provisions:

- The applicant shall be a single legal entity authorized to do business in Michigan.
- The applicant shall be a collaborative consisting of, at a minimum, at least 40% of all Michigan hospital MRT services with more than 30,000 equivalent treatment visits performed in the most recent 12-month period of data available to the department.
- The collaborative shall include hospital MRT services from more than one planning area from either or both of the following: I) the participating services under subsection (b) (those above 30,000 ETVs); ii) hospital MRT services with the highest number of ETVs in a planning area based on the most recent 12-month period of data available to the department.
- The MRT services that are already part of a collaborative application under the section for an MRT service utilizing an HMRT unit or part of an existing collaborative using an HMRT unit approved under the new section shall not be included in a new application.

- The applicant shall provide documentation of its process, policy, and procedures, acceptable to the department, that allow any other interested entities to participate in the collaborative utilizing an HMRT unit.
- The applicant shall provide an implementation plan, acceptable to the department, for financing and operating the proposed MRT service utilizing an MRT unit which includes how physician staff privileges, patient review, patient selection, and patient care management shall be determined.
- MRT services utilizing an HMRT unit shall be provided to adult and pediatric patients.
- The MRT service utilizing an HMRT shall have simulation capabilities available for use in treatment planning.
- MRT services utilizing an HMRT unit shall demonstrate compliance with the requirements of Section 4(3).
- Additional project delivery requirements for MRT services utilizing an HMRT unit have been added to include: 1) All patients treated shall be evaluated for potential enrollment in research studies focusing on the applicability and efficacy of utilizing an HMRT unit to treat site-specific

cancer tumors. A summary of the information shall be provided to the department. 2) The MRT service utilizing an HMRT unit will provide, on an annual basis, the department with reports designed to assess the affordability, quality, and accessibility of the MRT service utilizing an HMRT unit. The report shall include annual updates to the information provided in subsections 10(e), (f), and (g). 3) As a condition of approval, the MRT service utilizing an HMRT unit shall agree that upon review of the report submitted under subsection (b), the department may order changes in regard to the provisions of the service.

6. Replaced reference to heavy particle accelerator with HMRT units where applicable in the project delivery requirements and Table 1 in Section 13.

7. Updated the following project delivery requirement that: "All MRT treatments shall be performed under the supervision of a radiation oncologist and at least one radiation oncologist will be IMMEDIATELY AVAILABLE -- the words on ~~site at the geographic location of the unit~~ have been stricken -- during the operation of the unit(s)." Immediately available is already defined in the standards as "continuous availability of direct communication with the MRT unit in person, by radio,

telephone or telecommunications."

8. And additional technical changes.

In addition to the comments on the draft language, the department and the CON Commission are soliciting public comment on an alternative methodology using ETVs. You can refer to the "Alternative Methodology" document for potential language. This language would utilize a percentage versus utilizing a percentage of participation in an application to initiate an MRT service.

If you wish to speak today on the proposed standards, please turn in a comment card to me. Additionally, if you have written testimony, if you could please provide a copy of that. Just as a reminder, all cell phones and pagers need to be turned off or set to vibrate during the hearing today.

As indicated on the Notice of Public Hearing, written testimony will be accepted by the department via our Web site at www.michigan.gov/con through Tuesday, August 12th, 2008 at 5:00 p.m.

Today is Tuesday, August 5th, 2008, and we will begin taking testimony. First we will hear from Sean Gehle from Michigan Ministries of Ascension Health.

MR. GEHLE: Good morning. My name is Sean Gehle. I'm here on behalf of the Michigan Health Ministries of Ascension Health. We continue to support a collaborative

approach to the acquisition of HMRT and specifically support an ETV methodology. We are confident that the requisite data will be available shortly in order to suggest an appropriate volume-based threshold.

We intend to provide more specific comments prior to the deadline for submission of written remarks on August 12th. Thank you very much.

MS. MOORE: Thank you. Liz Palazzolo from Henry Ford Health System.

MS. PALAZZOLO: Good morning. My name is Liz Palazzolo, Director of Planning and Research at Henry Ford Health System. Henry Ford Health System supports the proposed changes to the MRT Standards whereby heavy particle therapy services are provided by a group of hospital-based services. We also believe that the best approach to determining qualification for applicants is by using a volume-based methodology that allows for a group of providers to pool their volume to demonstrate that they collectively have sufficient experience and patients to justify this very costly technology. We are confident the data that will allow us to suggest an appropriate volume threshold will be available shortly, and we intend to provide more specific written comments addressing these standards on or before August 12th.

MS. MOORE: Thank you. Carol Christner from

Karmanos.

MS. CHRISTNER: Good morning. Carol Christner, Director of Government Relations for Karmanos Cancer Institute. Ditto to Sean and Liz. Karmanos supports the action taken by the commission at the July 23rd meeting, allowing both the department language and the alternate language to move forward for public hearing. We believe the ETV volume-based methodology would result in the best collaborative outcome, and we'll provide greater detail in written testimony on or before August 12th. Thank you.

MS. MOORE: Thank you. Is there anyone else that would like to provide public testimony today? Okay. Larry Horwitz from Economic Alliance.

MR. HORWITZ: I'm Larry Horwitz. I'm President of the Economic Alliance for Michigan. We are here, as are the others, in favor of having a collaborative standard. I think everybody is in agreement with that and is supportive of the department, of the commission, having proceeded expeditiously at its last meeting in taking expeditious action in September.

I am pleased that there is that consensus of views among, so far, the witnesses. I think the only item of difference is the one that the three prior people mentioned, which is the question of, How do you decide if the collaborative is big enough? Who is going to be -- how do

you measure who has to be in the collaborative? As we indicated in our prior testimony, we think the department's approach, which is very similar to that which the commission had previously approved unanimously, is the better way to go. It provides the change of going from a majority to 40 percent, in response to the governor's concern that she didn't think there was a majority of the current nine there. We continue to feel strongly about this.

We've also been looking at the data, and I think it's going to be a very hard challenge for the department to have that data available today, tomorrow or somewhere to be really validated from 60, 70 different points. At no time in the history of the program has the department ever needed to not only accumulate the data but validate it, and that's a lot of work to do. The last time they had such a report was 2003, and I don't believe there was much effort, because there was no need to put such effort, into validation of it. We think that the 40 -- that this is a much easier way to do it, and the theoretical premise is different. Our view of why you wanted to have it was to have the big hospitals do it, those who were presumed to be -- have the high-scale competence and knowledge and had the auxiliary competencies and additions. If you just add up individual data points, you could have a collage of a lot of the small-to-medium-size hospitals. You wouldn't necessarily need the largest

ones with the competencies. So it's unclear to me why, then -- what's the public policy rationale of having the small -- of this approach, nor what would then be the public policy rationale for limiting it to hospitals only. Before it made sense, it seemed to us, because you wanted people that had all that inpatient services. If you now -- I don't know why you would then justify excluding the non-hospital connected entities, of which we have a few.

We also think that the data number that is probably going to be relevant to this application won't be the approximate million that the U of M came up with, but it's probably going to be more like 1.3, 1.5 million. Just by the time the application is actually submitted, which we don't think it's going to be for another two, three years, the volume of the total ETV count will rise. If you look back at the history, the number of simple procedures has gone to nearly zero. Everyone seems to count. There's only a small number of intermediate rates, most of them are complex rates. It's unclear whether that's the nature of the process or we're just upcoding -- upgrading codes. But the ETV volumes will be much higher. But the 40-percent figure, if you look at the data, is not going to ever -- is not going to, even in the next three or four years, get beyond ten. The only hospital that's anywhere close to the 30,000 number is just one. And 40 percent of ten is still

four. So we think that makes sense.

The one issue we would like to raise that has been mentioned to us by others, I do think that there needs to be -- this is not just from an Economic Alliance staff perspective -- there needs to be greater clarity about that supervisory language that was crafted at the last minute, just to have it more clarity and precision as to exactly what it is the department would have control over and in what way. The language -- this is no critique whatsoever of the department. They got this legal counsel from their attorney just a few -- a short time before, so they didn't have time to craft it. But I do think that there needs to be some greater precision as to what that means and that the -- there are other issues of the ETV, which is how do you count halvesies? How do you decide to count part of something? I think that's going to be a tremendous burden for the department to not only look at that data, but to validate that your claim is really 50 percent and over here it's one-third and over here it's something else. I'm not sure whether the department keeps track of that or not on an ongoing basis. I don't think it knows automatically what the ownership percentages are of an entity that got a CON "X" years ago. They'd have to go back and dig up the data.

So for all of those reasons, we think it accomplishes the objective. We are hoping that there can

become agreement between all of us who are interested in this project, to have a consensus agreement on the different details of this question, and that we'll have a consensus agreement by the time of the 16th.

Thank you very much, and we'll see if we do provide further comments or not. Thank you so much.

MS. MOORE: Thank you; thank you. Is there anybody else that wishes to provide testimony today? Seeing none, we will go ahead and adjourn for the day. And just a reminder, any additional comments can be posted via the department's link at www.Michigan.gov/con. Thank you.

(Hearing concluded at 10:52 a.m.)

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