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STATE OF MICHIGAN
DEPARTMENT OF COMMUNITY HEALTH
CERTIFICATE OF NEED

PUBLIC HEARING
REVIEW STANDARDS FOR
BONE MARROW TRANSPLANTATION SERVICES
MAGNETIC RESONANCE IMAGING SERVICES
POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES
HOSPITAL BEDS

BEFORE ANDREA MOORE, SPECIAL ASSISTANT TO C.O.N. COMMISSION
201 Townsend Street, Lansing, Michigan
Tuesday, October 24, 2006, 9:00 a.m.

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Lansing, Michigan
Tuesday, October 24, 2006 - 9:07 a.m.

MS. MOORE: Good morning. I'm Andrea Moore, and I'm a departmental technician for the Certificate of Need Commission from the Policy Section of the Department of Community Health. Chairperson Norma Hagenow has asked the Department to conduct today's hearing. We're here taking testimony concerning the potential language changes of Certificate of Need Review Standards for BMT services, MRI services, PET Scanner services and Hospital Beds. The standards for BMT services are being reviewed and modified to include, but are not limited to, the "on-site" availability of services to include "or physically connected"; and minimum volume requirements for an "existing BMT service" with which a proposed new BMT program must enter into a "consulting agreement": Replace the minimum volume requirement for Foundation of Accreditation of Cell Therapy.

The standards for MRI services are being modified to include, but limited to, an added definition and weight of 2.5 (sic) for "special needs patients"; the change in the relocation zone from a 5-mile radius to a 10-mile radius for metropolitan statistical area counties. There is some clarifying language regarding the relocation of an MRI unit vs. a service; the change $500,000 to $750,000 under Section 2(1)(uu) for an "upgrade an existing MRI" definition; an added definition and weight for a "re-sedated patient"; an update of Section 12(1)(c)(vii)(C) to allow an MRI technologist to be registered by either the American Registry of Radiologic Technicians or the American Registry of Magnetic Resonance Imaging Technicians; add a requirement for expansion of a dedicated pediatric MRI service: the existing dedicated pediatric MRI unit must be meeting the minimum volume requirements for maintenance, which is 3,500 adjusted procedures per unit.

The standards for PET Scanner services are being reviewed and modified to include, but not limited to requirements for conversion of mobile to fixed PET services; utilizing fixed PET scanners to expand to a mobile service instead of initiating a mobile PET service; language that allows a "free" replacement of the current PET scanner to a PET/CT scanner; language to allow for relocation of the unit or service; requirements for a dedicated pediatric PET scanner; PET equivalents have been updated; the elimination of the 85/15 rule where at least 85 percent of the data for a single planning area in which 85 percent of the proposed PET service patient visits must be provided.

The standards for Hospital Beds are being reviewed and modified to include, but not limited to, changes to high occupancy language which includes a 10 percent factor for pediatric and OB, 80 percent occupancy for the previous, consecutive 24 months based on licensed and approved beds for all hospitals and a projected delivery requirements that require an achievement of a minimum occupancy of 75 percent over the last 12-month period in the three years after the new beds are put into operation and for each calendar year, or the number of new licensed beds shall be reduced to

achieve a minimum of 75 percent annual occupancy for the revised licensed bed complement; expanded comparative review requirements for applications subject to comparative review other than limited access areas which have their own comparative review language. A maximum of 25 points will be awarded for uncompensated care, 20 points for Medicaid volume and 25 points for impact on inpatient capacity (closure of a hospital), or 30 points for percentage of market share.

Copies of the proposed changes to the review standards are located on the back table. Comment cards need to be completed and provided if you wish to give testimony. We'd ask that you please sign in to the sign-in log. If you want to speak, I do need your comment cards. And if you have written testimony, if you'd please provide that at the same time.

As indicated on the Notice of Public Hearing, the Department is accepting additional written testimony via a

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link on our Web site at www.michigan.gov/con through Tuesday, October 31st at 5:00 p.m.

Today is Tuesday, October 24th. We will begin taking testimony, taking BMT first followed by MRI, PET and finally Hospital Beds. The hearing will continue until all testimony has been given, at which time we will adjourn. And this morning we are going to start with BMT services with Patrick O'Donovan.

MR. O'DONOVAN: Good morning. My name is Patrick O'Donovan, director of planning for Beaumont Hospitals. I'm here to support the proposed revisions in the Bone Marrow Transplant standards that were discussed at the September 19 C.O.N. Commission meeting. However, I must also express our view that the C.O.N. Commission has done a great disservice to cancer patients in this state by refusing to form a standard advisory committee to review the arcane 20-year-old BMT standards.

The C.O.N. Commission heard from two health systems that annually see about 4,000 new cancer patients each, systems that would like to begin bone marrow transplant programs to care for patients they currently serve. The Commission heard from a nationally recognized expert in the field of bone marrow transplant who testified that this procedure is being underutilized, a finding also reported in a recent article in the New England Journal of

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Medicine. They received documentation showing that only eight states in the U.S. continue to regulate Bone Marrow Transplant services under the C.O.N. programs, and no other state sets an arbitrary limit on the number of programs as does Michigan.

The C.O.N. Commission also heard objections to expanding the number of Bone Marrow Transplant programs from two of the existing BMT programs in the state, one of which sees less than 3,000 new cancer patients each year and one that sees less than 2,000. They stated that they have capacity in their programs to treat more patients; therefore, there is no need to review the BMT standards. Rather than establishing a SAC to objectively review data, including BMT applications for conditions other than cancer, the C.O.N. Commission chose to protect the franchise of existing BMT programs. This is contrary to every other non-bed C.O.N. standard change the Commission has made since

1988, which has been to eliminate comparative review in favor of needs-based, institution-specific standards. The Commission also disregarded the recommendations of the BMT work group they established to evaluate BMT, which, as Dr. Young reported, had recommended a SAC be formed.

In a state with one of the highest rate of cancer in the country, the citizens deserve to know if Michigan's 20-year-old BMT standards could be responsible for limiting

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access to lifesaving treatments, yet the Commission decided not to form a SAC to establish whether Michigan's restrictive BMT standards interfere with access to care. We believe this does a terrible disservice to cancer patients and other patients where stem cell treatments are being advanced and that the Commission has disregarded its responsibility to assure access to care, especially lifesaving care.

MS. MOORE: Thank you, Patrick. Next we'll have Robert Meeker from Spectrum Health.

MR. MEEKER: I'm Bob Meeker from Spectrum Health in Grand Rapids. Briefly, we'd like to support the technical changes that Andrea outlined that the Commission has recommended to the Bone Marrow Transplant services. And while we too are disappointed that a SAC was not established to look at access, particularly in our case, out-state access, we do appreciate the attention of the Commission and the directive that the Department examine that issue of western and northern Michigan and that we welcome the opportunity to work with the Department in that regard.

MS. MOORE: Is there anybody else that would like to give public testimony on BMT services? Hearing none, we will go ahead and go to MRI, and again, Bob Meeker from Spectrum Health.

MR. MEEKER: I'm still Bob Meeker from Spectrum

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Health. I think that the current changes recommended to the MRI standards represent several important improvements: the allowance for expansion of a dedicated pediatric service, the expansion of the relocation zone and many of the technical changes including additional weights and the upgrading or modernizing, updating the definition of what constitutes a replacement or an upgrade.

There are still a few issues outstanding. A work group has met to try to address those. We certainly expect that there will be a satisfactory resolution to those. The one that is of particular interest to Spectrum Health is extending what is commonly referred to as the "rural exception to allow hospitals to convert from mobile to fixed." And we are requesting that that be made a true mobile exception and that it apply to all rural hospitals and not just the first one in a given county. With that, we certainly support the changes that have been made.

MS. MOORE: Thank you, Bob. Is there any additional comments on MRI? Hearing none, we will continue on to PET and Bob Meeker from Spectrum Health.

MR. MEEKER: I can't remember my name, but I think I'm from Spectrum Health. We'd like to support the changes -- by in large the changes that have been made, the volume requirements for expansion, the allowance for relocation and for a dedicated PET unit. The one issue that

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we would like to question is the change in the length of time that cancer cases are committed to a given PET unit.

Currently it's for the lifetime of a unit, which we think is appropriate. The recommendation now is that it be reduced to three years, which we think is entirely too short. If the time is to be shortened -- and we don't agree that it should be, but if it is, it should be, we think, at least five years which is the depreciable life of a PET scanner.

MS. MOORE: Thank you, Bob. Patrick O'Donovan from Beaumont Hospitals?

MR. O'DONOVAN: Thank you. I'm Patrick O'Donovan from Beaumont Hospitals. I'm just here to support the PET standards as adopted for purposes of public comment at the September C.O.N. Commission and urge the Commission to adopt the final standards in December. Thank you.

MS. MOORE: Do I have any additional comments for PET scanners? Seeing none, we'll move on to Hospital Beds with Patrick O'Donovan from Beaumont Hospital.

MR. O'DONOVAN: Good morning again. Patrick O'Donovan from Beaumont Hospitals. I participated as a member of the Hospital Bed SAC, and I appreciate all the hard work by all involved in developing the recommended changes to the standards. Beaumont supports all of the proposed revisions to the standards for Hospital Beds with the exception of the proposed comparative review standards

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for Hospital Bed applications subject to comparative review. The goal of the C.O.N. program and comparative review standards is to balance cost, quality and access. The proposed comparative review standards have nothing at all related to cost or quality and do not appropriately address access. In particular we object to the awarding of needed beds or hospitals on the basis of the payor mix of the sponsoring organization.

During the SAC process we repeatedly asked what public policy objective is being served by focusing on the payor mix of the sponsoring organization as opposed to issues related to the cost, quality and access at the proposed facility. The only response we received is that the C.O.N. statute requires that Medicaid participation must be weighed as "very important" in a comparative review of applications for health facilities. However, as outlined by our legal counsel in a letter sent to the Commission, the meaning of, quote, "Medicaid participation," end quote, in the statute relates to the proposed health facility, not the Medicaid volume of the applicant organization. I've attached to my testimony another copy of that letter for your convenience.

Even if payor mix were an appropriate overriding criterion for awarding beds or hospitals, which we believe it is not, then the percentage of a hospital's gross charges

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that were Medicaid is an inaccurate way to measure a hospital's relative commitment to Medicaid patients. This is because hospitals serving high numbers of Medicaid patients receive disproportionate share payments that offset low Medicaid patient levels. These DSH payments, which vary markedly by hospital, are not taken into account in the scoring.

I've also included a simple example that shows the consequences that could occur if the proposed comparative review criteria are adopted. It shows that due to the payor mix of the applicant organization, Hospital B would get the nod over Hospital A even though Hospital A had more market presence, higher quality, intended to serve more

uncompensated care patients, received more local community support and had lower capital costs.

To illustrate further, if the Mayo Clinic applied the bill to a hospital in Michigan in the area of need, they would not be able to compete with an applicant that owned a 30-bed Michigan hospital that had low quality and 15 percent Medicaid. The fact is that hospitals take care of all the patients who seek care at their institutions regardless of payor mix, so payor mix should not be a factor in awarding new hospitals. Certainly patients do not choose hospitals based on payor mix. They look at physician credentials, number of procedures performed, recommendations from friends

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and family, et cetera.

The proposed comparative review criteria have not been well thought out and create inappropriate incentives. We urge you to reject them on that basis and take this issue -- take up this issue as part of a future Hospital Bed SAC or through some other Commission process such as a work group. Thank you.

MS. MOORE: Thank you. Phyllis Donaldson-Adams from Dykema Gossett?

MS. DONALDSON-ADAMS: My name is Phyllis Adams, and I'm a healthcare attorney at Dykema Gossett. I'm here representing two clients today, St. John Health and Oakwood Healthcare, Inc. They requested that I present comments and written testimony as to Section 13 of the proposed Hospital Bed standards. And we appreciate this opportunity to comment on the proposed language.

The written comments submitted by St. John and Oakwood include detailed observations and concerns about the proposed language. In short, despite good faith efforts by the Hospital Bed Standards Advisory Committee Work Group to develop this language, we do not believe that it received sufficient consideration and debate at the SAC level. In our judgment, there are material deficiencies in the proposed language that would be virtually certain to result in litigation if these standards were adopted and never

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applied.

Specific issues addressed in the written comments include applicability of the proposed language. Under the current standards, this language could only apply to new beds in the hospital. The Section 13 should state as much. In addition, there are inconsistencies with other sections of the standards and with the C.O.N. regulations in certain areas. Importantly, there are a lack of critical definitions, and although St. John and Oakwood both support including uncompensated care volume as part of the criteria, these definitions need to be explicitly laid out in the standards.

Despite our respect for the MDCH policy people, we believe that these definitions are an integral part of the standards and that those definitions need to be developed through the policymaking and rulemaking process of the C.O.N. Commission where there's the opportunity for public comment and input.

Other important definitions that are not addressed in the standards include hospital gross revenues and how those would be measured. "Common ownership and control" has been defined by the legislature and should be incorporated using the statutory definition. There are issues as to the "most recent cost report submitted" and how that would work

given that there are settled cost reports, filed cost

reports, adjustments to cost reports and appeals that could end up disrupting what the outcomes were in the cost report that was originally filed at the time with the C.O.N.

Additionally, the definition of, quote, "close a hospital," is unclear. There was some discussion about this in the SAC meeting, but there is no statutory definition of "close a hospital." Does it means ceasing to operate or that the beds are de-licensed? What if the hospital also has psychiatric beds? Do those need to be de-licensed? Does it mean that it's closed for just inpatient acute-care hospital services so that the facility could continue to provide ambulatory or outpatient services? Does it apply only to the actual license footprint of the hospital? And if so, what about ambulatory or outpatient services that are off campus. So again, many policy issues that are not addressed in the current standards.

In addition, we have some other substantive policy concerns about the draft language that are more fundamental. On certain areas, an applicant in a multi-hospital system would get zero points for its own uncompensated care volume and for any volume from any other active hospitals in its system just because one failed to file a cost report. We also believe that some of the information or the language in the standards discourages hospital closures and question the policy behind that.

Most importantly subsection 3(c) of Section 13 contains a fundamental flaw in the methodology as it would permit contradictory results as to which zip codes would be counted. We just took a quick diagram of one example, and you can come up with a whole bunch of different ways that the zip codes would be counted. So drawing a continuous line through those proposed hospital locations does not yield a consistent set of results in terms of which zip codes get counted.

So again, this language was presented at the last meeting of the SAC, which was unfortunate because I don't think that there was enough time for the SAC to really review the language and try to work through some of the policy issues that were there. Because of that, St. John and Oakwood would urge the Commission to defer action on the proposed language. Thanks very much. I have written comments.

MS. MOORE: Thank you. Bob Meeker from Spectrum Health.

MR. MEEKER: I'm Bob Meeker from Spectrum Health in Grand Rapids. We are in general supportive of the changes recommended to the Hospital Bed standards. We're particularly supportive of the changes to the high occupancy standards. We feel that these recommendations or these changes were the result of a fairly sophisticated and

detailed data analysis and are as supportable as any changes have been that have been made to C.O.N. review standards. Regarding the comparative review standards, while we are satisfied with the existing standards, we certainly would be supportive of improving them, particularly in the area of quality.

MS. MOORE: Thank you. Chip Falahee from Bronson?

MR. FALAHEE: I'm James Falahee from Bronson Healthcare Group. Before I talk about official comments, as

the vice chair of the SAC, I want to thank many of the members of the audience who participated in the SAC and in the multiple meetings and in the multiple hearings we had. Thank you for that participation. Mr. Ball and I very much appreciated it.

On behalf of Bronson, I'm here to say we strongly support the high occupancy language that's in the proposed standards. And we strongly support it because we've lived it for the last 6 years. In the last 6 years we have grown 40 percent. And what that means is, under the current standards, the 85 percent occupancy for 12 months or the 80 percent for 24 months, we meet both standards. And you don't want to be in a hospital that meets these standards because in our case, in one year we were on diversion 17 percent of the time. In the last 12 months we have been on diversion over 900 hours. We know that we have diverted at

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least 200 patients, and the number may be 2 to 3 times as high as that. So we've had patients that want to come to us, but we've had to divert them to other facilities in our area because we simply did not have enough beds.

We think that these high occupancy standards will help alleviate that problem throughout the State of Michigan, not just us at Bronson. Currently you can't add beds if you want to because of the current C.O.N. standards unless you get to the 85 percent. It's hard to get to. The 80 percent standard for 24 months is also hard to get to, but we think it's very reasonable. If you can't add beds under the current standards, what can you do? You can go spend money to buy bed licenses. We question whether that's a good use of public policy or money. In our case we've spent over $2 million in the last two years to buy 16 bed licenses. You can do the math. We question whether that money would be better spent building the beds rather than buying the bed licenses.

These new high occupancy standards will let us do that. It will let us build the beds and put the money into bricks and mortar and beds and equipment and not into buying a bed license. So we are strongly supportive of the standards. We think it addresses the issue of quality. We think quality care is better when a patient is in a hospital bed rather waiting in an emergency department or on

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diversion. We think it answers the access question as well because you can have better access to hospitals under these new high occupancy standards. And lastly, it hits on the cost issue. We can keep our costs down if we're spending money for bricks, mortar and equipment instead of hospital licenses. So we are strongly supportive of a high occupancy language.

MS. MOORE: Thank you. I have Barb Jackson from Economic Alliance.

MS. JACKSON: Good morning. Barbara Jackson, Economic Alliance. To prevent coming up four times like some of the other people, I'm doing mine all in one, so this is a one-size-fits-all testimony. I'm the regulatory director for the Economic Alliance for Michigan, and I wanted to speak to the various standards that we're talking about today.

In terms of the Hospital Bed standards, we commend the Hospital Bed SAC members for their hard work and deliberations. It was a tough road, and it was -- there was a lot of good work. We support the high occupancy change.

We agree there's no further need to address limited area access hospitals. We support retaining the two-mile replacement zone in large counties based on the rationale that it is easier to find appropriate land available in urban areas than rural.

We continue to support establishment of comparative review criteria although the most recent bed need number shows no true bed need in any sub area. In addition, we see no expected or future indication of bed need, given current patient utilization rates and the high occupancy factor.

So we urge adoption of these criteria, but we understand and appreciate others' concerns and feel that there is time to bring information to the forefront. We agree that it would be helpful to add factors for qualities and some of the other issues that people spoke to and, you know, want to at least do it in a way that we can operationalize it also.

There's no significant need between need for new beds and need for new hospitals. There are significant differences. Excuse me. Our board continues to reiterate that we're open to demonstrate community need to merit C.O.N. change. We went through a six-month SAC with very little evidence presented publically or via private conversation as to that. Although so far we haven't received data that supports community need, we do continue to be open to it. And, you know, the challenge to those who want it is to pull together evidence on those lines.

In terms of imaging standards for MRI and PET, we support the various technical changes that have been made to

the standards. We do continue to oppose combining clinical and research units whether for MRI, PET or other equipment. We maintain our long-standing support for exemption from the minimum volume requirements for 100 percent research training units of whatever type.

Although we don't want C.O.N. to become a barrier to medical personnel training or for applied research, our group has maintained its opposition to a situation where selected providers are able to initiate a service at lower indicated community need and ultimately lower clinical utilization. ALso we agree with some others' concerns regarding some key PET SAC recommendations. At the very least, based on quality considerations we think there should be minimum volume requirements in place for replacement of PET only scanners to PET/CT scanners and for additional mobile host sites to existing mobile routes.

Although not new to other services, we think that language supporting dedicated pediatric PET scanners is not necessary, and there are other ways to accommodate that need. We continue to support the concept of dedicated data for the duration of that program for which that data was committed.

In terms of BMT, again based on provider presentations and participation at the work group meetings, we have extensively reviewed this issue and make the

following recommendations: We see no demonstrated need for additional BMT programs in Planning Area 1, the east side of Michigan. We don't see any problems regarding cost accountability, access or quality of existing programs. Over the past five years BMT volumes have flattened and

decreased. So far there has been no evidence presented regarding future growth in BMT utilization. Other medical and pharmaceutical applications for diseases previous -- are in place previously treated by BMT. Data show that the majority of BMT procedures are performed by just two of the current providers for the service, and based on that we didn't -- we see no need for a SAC for additional programs in Planning Area 1. Again, based on geographic access, we could see a potential additional adult program on the west side of the state. Thanks for the opportunity to speak to these issues. Again, we commend everybody in the Commission for the process in place. Thank you.

MS. MOORE: Thank you, Barb. Is there anybody else that has any testimony that they would like to provide today on any of the services we've covered? Hearing none, we will be done for the day. Thank you for coming and thank you for your testimony.

(Proceedings concluded at 9:40 a.m.)

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