

**Michigan Department of Community Health (MDCH) Comments and
Recommendations
for Certificate of Need (CON) Review Standards
Scheduled for 2009 Review
Presented to CON Commission February 5, 2009**

BONE MARROW TRANSPLANTATION (BMT) SERVICES			
(Please refer to MDCH staff summary of comments for additional detail - attached)			
All Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues	Other/Comments
1. Continued regulation of BMT under CON.	Yes	MDCH recommends further discussion.	
2. Increase the number of allowed adult BMT centers.	Yes	MDCH recommends further discussion.	
3. Allow for a second adult planning area within the state.	No	None.	BMT is a highly specialized service that should use the entire state as the planning area.
4. Make technical changes and updates that provide uniformity in all CON standards, i.e., revisions to reference of online system.	Yes	Draft recommended changes.	
<p>Recommendation: MDCH recommends further discussion to gather information/research for the Commission regarding whether there remains a need to regulate BMT services, a need to maintain the existing cap, or a need to modify the existing cap. Additional discussion items will include issues of access, stem cell research, cancer treatments, and appropriate need methodology. The information would be used by the Commission at a future meeting to determine what subsequent steps it should take to address the issue.</p> <p>The Department recommends that the Commission assign the responsibility to draft any necessary technical language changes to the standards to the Department. Language changes for these standards should all be moved forward to public hearing simultaneously.</p>			

BONE MARROW TRANSPLANTATION (BMT) SERVICES
 Summary of 10/16/08 Public Hearing Comments and Department Comments
 Prepared by: MDCH

Considerations from 10/16/08 Public Hearing.	
<p>Public Hearing Summary: The complete oral and written testimonies are included in the February 5, 2009 CON Commission meeting binders. The agencies represented were as follows:</p> <ul style="list-style-type: none"> • Blue Cross/Blue Shield (Verbal and Written): Believes that there is no need to formally address the BMT standards at this time. More specifically, based on a number of reasons listed, there aren't any compelling reasons or data showing there is an increased need in additional BMT programs. Reasons given were based upon outcomes of the informal BMT workgroup and state-wide BMT service trends. • University of Michigan Health System (Written): The current standards should stand as is and there is no need to re-open them at this time. They state that current expert clinical opinion is that the current capacity in Michigan is adequate and forecasts indicate no drastic change in the number of patients needing this service. Additionally, they go on to say that replication of this high cost and low volume service at additional locations within the state could, potentially, adversely impact the quality and research potential by diluting the available patient population, yet would not yield any significant access benefits. • Karmanos Cancer Institute (Written): Supports the BMT standards as they are currently written. They state that the current standards provide for the primary tenants of CON – cost, quality, and access – to be maintained. Additionally, patient needs in Michigan are being met by the three existing BMT programs. Lastly, they state that the standards as they are written now ensure that patients have access to the highest quality BMT programs and that costs are maintained through eliminating excessive capacity. • Economic Alliance of Michigan (Verbal and Written): EAM's position is two-fold. First, they state that unless there is new compelling evidence of the need for additional transplant services, they feel, at this time, the 	<p>Policy Issues to be Addressed</p> <p>Issues to consider for further discussion:</p> <ol style="list-style-type: none"> 1. Remove the cap on allowing only three adult BMT centers in the state of Michigan. <ul style="list-style-type: none"> ▪ The number of these types of transplants performed at the centers has remained relatively stable over the last seven years (2000 to 2007). There have been no significant increases or decreases. ▪ The limited number of specialized staff would prevent proliferation of this service. ▪ Removing the cap would eliminate comparative review. This would make the standards more administratively feasible. ▪ There are currently no adult BMT centers in west Michigan. Removing the cap would allow such transplant center to be opened and run on this side of the state. There are two pediatric BMT centers, one in west Michigan and the other in southeast Michigan. ▪ West Michigan currently has a pediatric bone marrow transplant center located at Spectrum. ▪ Currently, all adult bone marrow transplantation centers are located in southeast Michigan, and all are meeting the volume requirement of 10 annually. 2. To modify the cap requirement either by increasing or decreasing the number of transplant centers in Michigan. <ul style="list-style-type: none"> • Uncertain of what the cap should be set at, whether it be increased or decreased. There have been no scientific bases identified upon which to base an appropriate number.

<p>standard is fine as is. The second part, however, goes on to state that they hold a position that there may be a need for additional geographic distribution of the BMT centers. More specifically, to mirror the pediatric transplant services, to have two planning areas, one on the west side of the state and the other on the east side.</p> <ul style="list-style-type: none"> • St. John Health (Written): Would like a SAC formed to review the BMT standard and to eliminate the cap of three BMT programs in Michigan. Otherwise, St. John urges the commission to eliminate BMT from being a covered clinical service under CON. • Spectrum Health (Written): Would like to redefine the planning areas for adult BMT to mirror what pediatric planning areas are. <ul style="list-style-type: none"> ○ Spectrum has drafted potential language changes for sections 2, 3 and 4 of the standards. See written testimony for language suggestions. • Beaumont Hospitals (Written): Wants the BMT standards to be reviewed and changed in regards to the limit of only allowing three transplant centers. Would like to see a SAC formed to revise the standards or would like to see the BMT standards rescinded. Additionally, they provided rationale as to why they should be allowed to provide BMT services. 	
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1. Review current language on what defines a planning area. Note: Consideration from 10/16/08 Public Hearing.

<p>Current Standards</p> <p>Section 2. Definitions</p> <p>(u) "Planning area" means:</p> <p>(i) for an adult bone marrow transplantation service, the state of Michigan.</p> <p>(ii) for a pediatric bone marrow transplantation service, either:</p> <p>(A) planning area one that includes the counties in health service areas 1, 2, 5, and 6, and the following counties in health service area 7: Alcona, Alpena, Cheboygan, Crawford, Montmorency, Oscoda, Otsego, and Presque Isle; or</p> <p>(B) planning area two that includes the counties in health service areas 3, 4, and 8, and the following counties in health service area 7: Antrim, Benzie, Charlevoix, Emmet, Grand Traverse, Kalkaska, Leelanau, Manistee, Missaukee, and Wexford.</p>	<p>Policy Perspective</p> <p>MDCH does not support modifying the planning area. BMT is a highly specialized service that should use the entire state as the planning area. There should be a single planning area for this service in Michigan.</p>
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2. Review current requirement for the number of BMT centers in Michigan. Note: Consideration from 10/16/08 Public Hearing.	
<p>Current Standards</p> <p>Section 3. Requirements for approval for applicants proposing to initiate a bone marrow transplantation service</p> <p>(5)(a) An applicant shall demonstrate that the number of existing adult bone marrow transplantation services in the planning area identified in Section 2(1)(u)(i) does not exceed three (3) adult bone marrow transplantation services and that approval of the proposed application will not result in the total number of adult bone marrow transplantation services exceeding three (3) in the planning area.</p> <p>(b) An applicant shall demonstrate that the number of existing pediatric bone marrow transplantation services does not exceed two (2) pediatric bone marrow transplantation services in planning area one identified in Section 2(1)(u)(ii)(A) or one (1) pediatric bone marrow transplantation service in planning area two identified in Section 2(1)(u)(ii)(B) and that approval of the proposed application will not result in the total number of pediatric bone marrow transplantation services exceeding the need for each specific pediatric planning area.</p>	
3. Review current language on the additional requirements for applying for a BMT program. Note: Consideration from 10/16/08 Public Hearing.	
<p>Current Standards</p> <p>Section 4. Additional requirements for applications included in comparative reviews</p> <p>Sec. 4. (1) Any application subject to comparative review under Section 22229 of the Code, being Section 333.22229 of the Michigan Compiled Laws, or these standards, shall be grouped and reviewed with other applications in accordance with the CON rules applicable to comparative reviews.</p> <p>(2)(a) A qualifying project will have points awarded based on the number of bone marrow transplantation services, adult or pediatric, as applicable, listed on the Department inventory in the health service area in which the proposed</p>	

service will be located, on the date the application is submitted to the Department, as shown in the following schedule:

Number of BMT

Transplant Services

(adult or pediatric, as applicable) Points
in HSA Awarded

Two or more services 0

One service 2

No services 4

(b) A qualifying project will have up to 4 points awarded based on the percentage of the medical/surgical indigent volume at the licensed hospital site at which the proposed bone marrow transplantation service will be provided in accordance with the following:

(i) For each applicant in the same comparative group, determine the medical/surgical indigent volume, rounded to the nearest whole number, for each licensed hospital site at which a bone marrow transplantation service is proposed to be provided. Determine the licensed hospital site that has the highest indigent volume in the same comparative group. Divide the medical/surgical indigent volume for that licensed hospital site by 4.0. The result is the indigent volume factor.

(ii) For each applicant in the same comparative group, divide the medical/surgical indigent volume by the indigent volume factor determined in subdivision (i). The result, to the first decimal place, is the number of points that will be awarded to each applicant pursuant to this subsection. For purposes of this subsection, indigent volume means the ratio of a hospital's indigent charges to its total charges expressed as a percentage as determined by the Michigan Department of Community Health Medical Services Administration pursuant to Chapter VIII of the Medical Assistance Program Hospital Manual. The indigent volume data being used for rates in effect at the time the application is deemed submitted will be used by the Department in determining the number of points awarded to each qualifying project.

(c) A qualifying project will have 2 points awarded if an applicant documents

that, during the 36-month period prior to the date an application is submitted to the Department, at least 15 patients received pre- and post-transplant care at the licensed hospital site at which the bone marrow transplant procedures will be performed and were referred for and received a bone marrow transplant at an existing bone marrow transplantation service, and submits documentation from the existing bone marrow transplantation service(s) of these referrals.
CON Review Standards for Bone Marrow Transplantation Services CON-229
Approved 9/16/08 Effective 11/13/08 Page 7 of 13