

# Notice of Public Hearing

Pursuant to Section 22215 of Public Act 306 of 1969, as amended, the Michigan Department of Community Health (MDCH) will hold a hearing on Certificate of Need (CON) Review Standards.

**Date:** Wednesday, February 10, 2010

**Time:** **9:30 a.m.**

[Bone Marrow Transplantation (BMT) Services, Heart/Lung & Liver (HLL) Transplantation Services, and Magnetic Resonance Imaging (MRI) Services]

**Location:** Capitol View Building  
201 Townsend Street, 1<sup>st</sup> floor  
MDCH Conference Center Room B  
Lansing, MI 48913

## **BONE MARROW TRANSPLANTATION (BMT) SERVICES**

The proposed CON Review Standards for BMT Services are being reviewed and modified to include the following:

1. Under Section 1, modified the language consistent with recent changes in other CON review standards.
2. Definition for "licensed site" clarified based on current Department practice.
3. Under Section 2(1)(t), redefined planning area to add a second adult planning area.
4. Under Section 2(1)(w), added a definition for Tumor Registry as referenced in Section 8.
5. "Implementation plan" moved to Section 3(4).
6. Under Section 3(5), identified a cap of three in planning area one and a cap of one in planning area two.
7. Under Section 3(6), the volume projection for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
8. Under Section 3(10), added language to clarify that the written consulting agreement must be with an existing in-state or out-of-state Foundation for the Accreditation of Cellular Therapy (FACT) accredited transplant unit that performs both allogeneic and autologous transplants for either adult and/or pediatrics.
9. Under Section 3(10)(a)(iv)(A) and (B), reduced the number of site visits to three.
10. Under sections 3(10)(b)(i), 7(1)(c)(i)(D) and (E), 7(1)(c)(iv)(A) and (B), 7(1)(c)(vi)(D), 7(1)(d)(v), modified language based on the recommendation that autologous only programs would no longer be allowed.
11. Acquisition language (previous Section 8) moved to Section 4. For administrative feasibility, changed "the CON granted pursuant to this Section shall automatically expire" to "the Department may expire the CON granted pursuant to this Section."
12. Under Section 5(3)(a), modified to award points based on the straight-line distance to the nearest existing BMT program of the type applied for (adult or pediatric) instead of being based on the number of BMT services within the health service area (HSA).
13. Clarified Section 5(3)(b)(ii) based on administrative practice.
14. Under Section 5(3)(d), added language to award points based on the number of necessary support services/personnel as identified in Section 6 (project delivery requirements) that the applicant has available on-site on the date the application is submitted to the Department.
15. Based on current administrative practice, modified the language in Section 5(4) consistent with recent changes in other CON review standards.

16. Split Section 7(1)(c)(iv)(C) into two subsections: 7(1)(c)(iv)(C) and (D).
17. Under Section 7(1)(d)(i)(A) and (B), the volume maintenance for adult BMT services is increased from 10 to 30 of which at least 10 are allogeneic transplant procedures. The volume projection for pediatric BMT services remains at 10 but at least 5 must be allogeneic transplant procedures.
18. Under Section 8, added language to identify the source of data for documentation of projections.
19. Other technical changes.

## **HEART/LUNG & LIVER (HLL) TRANSPLANTATION SERVICES**

The proposed CON Review Standards for HLL Transplantation Services are being reviewed and modified to include the following:

1. Under Section 1, modified the language consistent with recent changes in other CON review standards.
2. "Implementation plan" moved to Section 3(2).
3. Definition for "licensed site" clarified based on current Department practice.
4. Removed definition for "transplant and health policy center" as it is no longer referenced in the standards.
5. Removed definition for "transplant support program" as it is not referenced in the standards.
6. Under Section 3(5), added liver transplantation services to the joint sharing arrangement language.
7. Under Section 5(1) and (2), added language relevant to the joint sharing arrangement and consistent with Section 4(1) and (2).
8. Based on current administrative practice, modified the language in Section 6(4) consistent with recent changes in other CON review standards.
9. Added language under Section 7(1)(c)(ii) to clarify the requirements to comply with the Organ Procurement and Transplantation Network (OPTN). Removed sections 8, 9, and 10 as they are no longer needed given the clarification to Section 7(1)(c)(ii).
10. Updated the language under Section 7(1)(c)(ix) as required by the federal OPTN.
11. Other technical changes.

## **MAGNETIC RESONANCE IMAGING (MRI) SERVICES**

The proposed CON Review Standards for MRI Services are being reviewed and modified to include the following:

1. Added clarifying language under sections 2(1)(zz)(ii) and 3(6).
2. Added an exception to the criteria for conversion of a mobile to a fixed MRI in Section 3(2)(b)(iv) to allow for a for-profit freestanding facility with 2,000 MRI adjusted procedures and at least 25% of the MRI visits have a payer source of Medicaid and/or no charge to convert from a mobile to a fixed.
3. Added acquisition language under Section 7(1)(c) to acquire a fixed MRI service and its unit(s) that was initiated under Section 3(2)(b)(iv).
4. Under Section 12(3), added a project delivery requirement to require an applicant approved under Section 3(2)(b)(iv) to agree to continue to provide at least 25% of the MRI visits with a payer source of Medicaid and/or no charge during the first 12 months of operation and annually thereafter for at least 10 years.
5. Based on administrative practice and for consistency, changed "deemed complete" to "deemed submitted" throughout the standards.



Oral or written comments may be presented in person at the hearing on Wednesday, February 10, 2010, or submitted in writing via online submission at [www.michigan.gov/mdch/0,1607,7-132-2945\\_5106\\_5409-147062--,00.html](http://www.michigan.gov/mdch/0,1607,7-132-2945_5106_5409-147062--,00.html), no later than 5:00 p.m., February 17, 2010. If your comment is in written form, please provide a copy to the court reporter at the conclusion of your testimony. If you have any questions or concerns, please contact Tania Rodriguez at 517-335-6708.

*Be sure all cellular telephones and pagers are turned off or set to vibrate during the hearing.*

*The hearing location is accessible for persons with physical disability. Interpreters will be available for the hearing impaired, if requested, seven days in advance.*

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