STATE OF MICHIGAN

DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED

PUBLIC HEARING ON REVIEW STANDARDS FOR:
HEART/LUNG AND LIVER (HLL) TRANSPLANTATION SERVICES
HOSPITAL BEDS
MAGNETIC RESONANCE IMAGING (MRI) SERVICES
POSITRON EMISSION TOMOGRAPHY (PET) SCANNER SERVICES
PANCREAS TRANSPLANTATION SERVICES

BEFORE NATALIE KELLOGG, DEPARTMENTAL TECHNICIAN TO CON

201 Townsend Street, Lansing, Michigan

Tuesday, May 1, 2012, 2:00 p.m.

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Lansing, Michigan

Tuesday, May 1, 2012 - 2:04 p.m.

MS. KELLOGG: I'm Natalie Kellogg, Departmental Technician to the Certificate of Need Commission from the CON Health Policy Section of the Department of Community Health. Chairperson Chip Falahee has directed the department to conduct today's hearing.

Please be sure that you've completed the sign-in log. Copies of the standards and comment cards can be found on the back table with the sign-in log. A comment card needs to be completed and provided to me, if you wish to give testimony.

Today we are reviewing the proposed CON review standards for Heart/Lung and Liver Transplantation Services. They're being reviewed and modified to include the following: Section 1: Modified for consistency with other CON review standards. Section 2: If a definition is used only in a certain section, the definition has been moved to that section to make it easier for the reader to identify the defined terms, specifically 2(1)(b): Comparative group has been moved to Section 7. 2(1)(f): Initiate or implement has been moved to Section 3. 2(1)(m): Qualifying project has been moved to Section 7. Section 6: Moved Medicaid participation requirements to its own section to be consistent with other CON review standards. Section 8: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services. Appendix A: Health Service Areas has been moved to an Appendix consistent with other CON review standards. And other technical changes. Is there anyone that would like to give testimony on the Heart/Lung and Liver Transplantation Services today? Seeing that we have none I'll move on to hospital beds.

CON review standards for Hospital Beds are being reviewed and modified to include the following: Section 1: Modified for consistency with other CON review standards. Section 2:

Definitions used only in certain sections have been moved to the applicable section to make it easier for the reader to identify the defined terms: Eliminated definitions that are no longer needed; modified definitions; added new definitions: "Adjusted patient days" is defined as it's used in various sections of the standards; "Average adjusted occupancy rate" is defined as it's used in various sections of the standards; "Excluded hospitals" is defined and is used in various sections of the standards in conjunction with low occupancy; "Hospital group" is defined and replaces the term "hospital subarea"; "Underserved area" is defined and is used in various sections of the standards. Section 3: Updated hospital groups methodology which is the former hospital subarea methodology. The updated hospital groups methodology will be run using the 2010 MIDB data when the Commission takes final action. Section 4: Updated the bed need methodology. The updated bed need methodology will be run using the 2010 MIDB data with a planning year of 2015 when the commission takes final action. Section 5: Updated to be consistent with other standards and current practice. The bed need numbers will continue to be posted on the web site as part of the hospital bed inventory, and the appendix and the standards will be eliminated.

Section 6: A hospital in a rural or micropolitan statistical area county shall result in a hospital of at least 25 beds, not 50 beds. This will eliminate the majority of waivers requested for small hospitals and is in alignment with the critical access hospital bed limit of 25. Also in section 6, added low occupancy criteria under subsection (3) for the receiving license hospital under Section 8, relocation.

Section 7: A hospital in a rural or micropolitan statistical area county shall result in a hospital of at least 25 beds, not 50 beds. This will eliminate the majority of waivers requested for

small hospitals and is in alignment with the critical access hospitals bed limit of 25. Also in section 7, added replacement language under subsection (2) consistent with other bed standards; added low occupancy criteria under subsection (4) for replacement. Section 8: Identified "source hospital" under subsection (2); added low occupancy criteria under subsection (3) for relocation. Section 9: Divided requirements into distinct groups: quality assurance, access to care, and monitoring and reporting. Annual volume requirements have been moved to the applicable project delivery requirements subsection. Section 15: Added low occupancy criteria under subsection (2) for acquisition.

Section 16: Added language for quality assurance assessment programs, otherwise known as QAAP, civil monetary penalties (CMP), and state and federal code deficiencies consistent with other CON review standards. Updated and eliminated appendices as applicable. The addendum for Projects for HIV-infected individuals has been eliminated. And other technical changes. Is there anyone that would like to give testimony today on the hospital beds standards? Seeing that we have none I will move on to MRI.

The proposed CON review standards for MRI Services are being reviewed and modified to include section 2: Under subsection (1)(bb), added new definition for "MRI-guided Electrophysiology intervention" or "MRI-guided EPI" means equipment specifically designed for the integrated use of MRI technology for the purposes of electrophysiology interventional procedures within a cardiac cath lab. Modified the definition of "MRI procedure" to include: Positron Emission Tomography (PET)/Scanner Hybrids if used for MRI-only procedures. Section 11: Added new language allowing for an MRI-guided EPI service to be located at a hospital that has an existing fixed MRI service that has been operational for 36 months and is meeting its

minimum volume requirements. The proposed site has an existing and operational therapeutic cardiac cath service and is meeting its minimum volume requirements.

Its open-heart surgery service must be meeting its minimum volume requirements as well. Further, the MRI-guided EPI unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the MRI-guided EPI unit to demonstrate need or to satisfy MRI CON review standard requirements. Section 12: Added new language allowing for the use of the PET/MRI scanner hybrid to be used for stand-alone MRI procedures.

There must be an approved PET CON, and it must be in compliance with applicable project delivery requirements as set forth in the CON review standards for PET. In addition, the FDA-approved PET/MRI scanner hybrid unit will not be subject to MRI volume requirements, and the applicant shall not utilize the procedures performed on the FDA-approved PET/MRI scanner hybrid unit to demonstrate need or to satisfy MRI CON review standards requirements. Section 14: Under subsection (1)(d)(iii), added project delivery requirements for data reporting for the MRI-guided EPI unit similar to IMRI. At a minimum, the data reported shall include how often the MRI-guided EPI unit is used and for what type of services, in example, electrophysiology or diagnostic. There were also other technical changes. Does anyone have any testimony they would like that offer today on MRI review standards. Seeing that we have none I will move on to PET scanner services.

Section 2(1)(q): Added to the existing definition of "PET scanner" to include FDA-approved PET/Magnetic Resonance Imaging (MRI) scanner hybrids. If the FDA-approved PET/MR scanner hybrid will be used for MRI scans only in conjunction with the PET scan, then no separate CON is required for that MRI use. Section 3(4)(d): Added language to exempt a host site that is initiating

FDA-approved PET MRI scanner hybrid service from having to cease operation as a host site so that it can continue to conduct PET-only scans. Other technical changes. Would anyone like to offer testimony today on the PET standards? Seeing that we have none I'll move on to pancreas.

The proposed CON review standards for pancreas transplantation services are being reviewed for deregulation under the CON program. If you wish to speak on the proposed standards you can provide a comment card.

As indicated on the Notice of Public Hearing, written testimony may be provided to the department via our web site at www.michigan.gov/con through Tuesday, May 8th, 2012, at 5:00 p.m. If we don't have any more testimony I will go ahead and adjourn the hearing. Hearing is adjourned.

(Proceeding concluded at 2:14 p.m.)