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: Tuesday, May 1, 2012

Time: 2:00 p.m.

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

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Heart/Lung and Liver (HLL) Transplantation Services

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

1. Section 1: Modified for consistency with other CON review standards.
2. 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
3. Section 6: Moved Medicaid participation requirements to its own section consistent with other CON review standards.
4. Section 8: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
5. Appendix A: Health Service Areas moved to an Appendix consistent with other CON review standards.
6. Other technical changes.

Hospital Beds

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

1. Section 1: Modified for consistency with other CON review standards.
2. Section 2: Definitions used only in certain section(s) 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:
     - o "Adjusted patient days" is defined as it's used in various sections of the standards.
     - o "Average adjusted occupancy rate" is defined as it's used in various sections of the standards.
     - o "Excluded hospitals" is defined and is used in various sections of the standards in conjunction with low occupancy.

- o “Hospital group” is defined and replaces the term “hospital subarea.”
- o “Underserved area” is defined and is used in various sections of the standards.

3. Section 3: Updated hospital groups methodology which is the former hospital subarea methodology. Note: The updated hospital groups methodology will be run using the 2010 MIDB data when the Commission takes final action.
4. Section 4: Updated the bed need methodology. Note: 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.
5. Section 5: Updated 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 in the standards will be eliminated.
6. 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 hospitals bed limit of 25.
   - Added low occupancy criteria under subsection (3) for the receiving licensed hospital under Section 8 – relocation.
7. 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.
   - Added replacement language under subsection (2) consistent with other bed standards.
   - Added low occupancy criteria under subsection (4) for replacement.
8. Section 8: Identified “source hospital” under subsection (2).
   - Added low occupancy criteria under subsection (3) for relocation.
9. 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.
10. Section 15: Added low occupancy criteria under subsection (2) for acquisition.
11. Section 16: Added language for quality assurance assessment program (QAAP), civil monetary penalties (CMP), and state and federal code deficiencies consistent with other CON review standards.
12. Updated/eliminated Appendices as applicable.
13. Addendum for Projects for HIV Infected Individuals has been eliminated.
14. 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. 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 catheterization lab.
   - Modified the definition of “MRI procedure” to include: Positron Emission Tomography (PET)/MRI Scanner Hybrids if used for MRI only procedures.
2. 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 catheterization service and is meeting its minimum volume requirements. Its open heart surgery service must be meeting its minimum volume requirements too. 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 standards requirements.

3. 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.
4. Section 14: Under subsection (1)(d)(iii), added project delivery requirements for data reporting for the MRI-Guided EPI UNIT similar to intra-operative MRI (IMRI). At a minimum, the data reported shall include how often the MRI-guided EPI unit is used and for what type of services, i.e., electrophysiology or diagnostic.
5. Other technical changes.

Positron Emission Tomography (PET) Scanner Services

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

1. 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/MRI 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.
2. Section 3(4)(d): Added language to exempt a host site that is initiating FDA-approved PET/MRI scanner hybrid service(s) from having to cease operation as a host site so that it can continue to conduct PET only scans.
3. Other technical changes.

Pancreas Transplantation Services

The proposed CON Review Standards for Pancreas Transplantation Services are being reviewed for deregulation under the CON Program.

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Oral or written comments may be presented in person at the hearing on Tuesday, May 1, 2012, or submitted in writing via online submission at www.michigan.gov/mdch/0,1607,7-132-2945_5106_5409_29279-196938.html, no later than 5:00 p.m., Tuesday, May 8, 2012. 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.

04/18/12