

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: Thursday, July 14, 2011

Time: 1:00 p.m.

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



Computed Tomography (CT) Scanner Services

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

1. Section 1: Modified the language consistent with recent changes in other CON review standards.
2. Section 2(1)(p): Added a definition for "excess CT equivalents."
3. Section 2(1)(v): Added a definition for "health service area" or "HSA."
4. Section 4(3): Removed minimum volume requirements for HSA 8 to encourage dental CT scanner service in the Upper Peninsula.
5. Section 7(1)(d): Added a one-time exemption of having to meet the volume requirements for replacing an obsolete CT scanner.
6. Sections 13(3): Modified pilot language for hospital-based portable CT scanners. In addition to level I and level II trauma facilities, eligibility would be extended to those facilities that performed >100 craniotomies in the most recent 12-month period verifiable by the Department.
7. Section 13(7): Renewed the pilot project to obtain sufficient data to fully evaluate the use of these scanners. Applications must be received on or before December 1, 2013, all provisions will expire on December 31, 2016, and be of no further force and effect unless the Commission makes them a permanent part of the CT scanner services standards.
8. Section 19(5): Added language that allows portable CT scanners to be used in adult or pediatric intensive care units (ICU) by qualifying pilot program institutions and must be limited to brain scanning of those patients who are being treated in an ICU or for non-diagnostic, intraoperative guidance in an operating room. Also, added specific reporting requirements for those approved under the pilot language for hospital-based portable CT scanners: 1) number of adult studies (age≥18), 2) number of pediatric studies (age<18), 3) number of studies performed using a portable CT on the same patient while that patient is in an ICU, and 4) number of patients scanned on a portable CT that underwent subsequent scanning on a fixed CT within 12 hours of the portable CT scan.
9. Section 22(4): Added language that only excess CT equivalents may be used for projections when initiating CT services.
10. Section 24: Added HSAs to the standards.
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. Section 10: Removed the pilot language under Section 10(9).
2. Other technical changes.

Megavoltage Radiation Therapy (MRT) Services/Units

1. Section 1: Modified for consistency with other CON review standards.
2. Section 2: A definition that is used only in a certain section has been moved to the applicable section to make it easier for the reader to identify the defined terms.
3. Section 3: Appendices A & B were updated using current data.
4. Section 4: Sections 4 and 10 were combined as these sections related to the initiation of an MRT service, as well as requirements for HMRT units.
5. Section 5: The replacement section will cover both the replacement of the unit as well as replacing the existing service to a new geographical site.
Replacement of a unit(s) will no longer require the applicant to meet a set volume requirement. Upgrades to existing MRT units will not require CON review/approval.
6. Section 7: Added language to allow for the first acquisition of a MRT service without meeting the maintenance volume requirement. This provision is similar to other standards.
7. Section 8: The number of dedicated research MRT units is limited to two at any one site, and the site must already offer MRT services.
Language added allowing for dedicated research MRT units to be used primarily for research purposes with the intent being that at least 70% will be dedicated research and no more than 30% clinical visits.
8. Section 11: Table has been updated.
9. Section 14: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services for consistency with other CON review standards.
10. Other technical changes.

Positron Emission Tomography (PET) Scanner Services

1. Section 1: Modified for consistency with other CON review standards.
2. Section 2: Definitions related to equivalency methodology removed based on a proposed simpler methodology for replacement and expansion.
A definition that is used only in a certain section has been moved to the applicable section to make it easier for the reader to identify the defined terms.
3. Section 3: Sections 3 and 4 were combined as these sections related to the initiation of a PET service, as well as requirements for mobile services and host site conversions.
Added language in 3(2) to allow applicants to not only contract for special services from hospitals within the same planning area but also from hospitals that may be near the proposed site but not within the planning area (25-mile radius of the proposed site).
Modified the conversion methodology for host sites to convert to a fixed PET scanner service.
Simplified Section 3(6) to make it easier to read.
Section 3(7)(c) applies both to new fixed PET scanner services as well to host sites that have converted from mobile to fixed services.
Section 3(8)(c) continues to allow existing host sites to change from one existing mobile provider to another provider; however, a minimum volume requirement was added at 50 PET equivalents at the applicant host site.

4. Section 4: The replacement section will cover both the replacement of the scanner as well as replacing the existing service to a new geographical site.
Replacement of a scanner(s) will no longer require the applicant to meet a set volume requirement. Upgrades to existing PET scanners, without the replacement of the scanner(s), will not require CON review/approval.
5. Section 5: Modified expansion methodology and updated PET equivalents.
Section 5(3) added to allow a fixed PET scanner service that has re-initiated a host site at the fixed site to expand to another fixed PET scanner if both the fixed scanner(s) and host site average enough volume to justify expansion (similar volumes as fixed site expansion).
6. Section 6: Added language to allow for the first acquisition of a PET scanner service without meeting the maintenance volume requirement. This provision is similar to other standards.
Section 6(2) adds a volume requirement threshold for acquisition of a fixed or mobile PET scanner service.
Section 6(3) adds a volume requirement threshold to acquire an existing host site.
Section 6(4) adds language for renewal of lease.
7. Section 7: The number of dedicated research PET scanners is limited to three at any one site, and the site must already offer PET services.
Language added allowing for dedicated research PET scanners to be used primarily for research purposes with the intent being that at least 70% will be dedicated research with no more than 30% being clinical scans.
8. Section 8: The number of dedicated pediatric research PET scanners is limited to two at any one site.
Language added allowing for dedicated pediatric research PET scanners to be used primarily for research purposes with the intent being that at least 70% will be dedicated research with no more than 30% being clinical scans.
9. Section 9: New section for positron emission mammography (PEM).
Section 9(1) identifies requirements for adding a fixed PEM scanner to an existing fixed PET scanner site.
Section 9(2) identifies requirements for adding a mobile PEM scanner to an existing mobile PET scanner service.
Section 9(3) identifies requirements for initiating mobile PEM scanner services as a host site.
Section 9(4) identifies requirements for adding an existing PEM scanner host site to an existing mobile PEM scanner service.
10. Section 11: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services for consistency with other CON review standards.
Added language Section (2)(d) to assure all services set forth in Section 3, subsections (1) through (4), are maintained for the life of the PET scanner service.
Added a minimum maintenance volume requirement (500 equivalents), except when an applicant is proposing to replace a PET scanner.
Added requirements for PEM scanners.
11. Section 17: The methodology has been simplified and the table has been updated.
12. Other technical changes.



Oral or written comments may be presented in person at the hearing on Thursday, July 14, 2011, or submitted in writing via online submission at www.michigan.gov/mdch/0,1607,7-132-2945_5106_5409_29279-196938--,00.html, no later than 5:00 p.m., Thursday, July 21, 2011. 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.

6/28/11