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, November 3, 2011

Time: 9:30 a.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)(b): Modified the definition "billable procedure" to read as follows: "Billable procedure' means a CT procedure billed as a single unit under procedure codes in effect on December 31, 2010, and performed in Michigan."
- 3. Section 2(1)(p): Added a definition for "excess CT equivalents."
- 4. Section 2(1)(v): Added a definition for "health service area" or "HSA."
- 5. Section 4(3): Removed minimum volume requirements for HSA 8 to encourage dental CT scanner service in the Upper Peninsula.
- 6. Section 7(1)(d): Added a one-time exemption of having to meet the volume requirements for replacing an obsolete CT scanner.
- 7. 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.
- 8. 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.
- 9. 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.
- 10. Section 22(4): Added language that only excess CT equivalents may be used for projections when initiating CT services.
- 11. Section 24: Added HSAs to the standards.

Cardiac Catheterization (CC) Services

The proposed CON Review Standards for Cardiac Catheterization Services 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.

Clarified definitions.

Modified definition for cardiac catheterization procedure to exclude the implantation of cardiac permanent pacemakers and implantable cardioverter defibrillators (icd) devices that are performed in an interventional radiology laboratory or operating room.

- Modified definition for therapeutic cardiac catheterization service to include transcatheter valves, other structural heart disease procedures, and left sided arrhythmia procedures.
- 3. Section 3: Sections 3, 4, 5, 6, and 7 were combined as these sections related to the initiation of a CC service, and the section was modified for consistency with other CON review standards for initiation of CC services.
 - Subsection 4 was modified to reflect the SACs recommendation of the minimum 500 procedure equivalents to initiate, in which 400 must be within the category of CC procedures.
 - Projection procedures for initiation of primary PCI decreased from 48 to 36.
 - Annual maintenance volume requirements have been moved to the project delivery requirements.
- 4. Section 4: The replacement section will cover both the replacement of the laboratory and equipment as well as replacing the existing service to a new geographical site as part of replacing the entire hospital.
 - Replacement of a laboratory or equipment will no longer require the applicant to meet set volume requirements. Upgrades to existing CC services, without replacement of the laboratory or equipment will not require CON review/approval.
 - Clarified replacement definition as it applies to CC laboratories and relocation of CC service to a new site.
- 5. Section 5: Eliminated the requirement to project procedure equivalents.

 Modified the volume requirement for existing and approved laboratories to 1,400 procedure equivalents, and minimum threshold must be met in each applicable service category.
- 6. Section 6: Added language for acquisition consistent with other CON review standards which includes the following:
 - Acquisition of CC services as part of the overall acquisition of a hospital.
 - Renewal of lease for angiography x-ray equipment without volume requirements.
- 7. Section 7: Added language to define and outline requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL).
- 8. Section 8: Modified language consistent with other CON review standards on Medicaid participation requirement.
- 9. Section 9: Divided requirements into distinct groups: quality assurance, access to care, monitoring and reporting, and specialized services.
 - Annual volume requirements have been moved to the applicable project delivery requirements subsection.
- 10. Section 10: Language under the previous Section 11(2) was deleted to allow for the counting of peripheral catheterizations under expansion. Further, due to elimination of volume requirements for replacement, this language is no longer necessary.
 - The procedures and weight equivalents were modified for simplification.

- 11. Section 11: Modified the language to reflect the minimum projected volume requirement from 48 to 36 ST segment elevation AMI cases for primary PCI services.
- 12. Other technical changes.

Surgical Services (SS)

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

- 1. Section 1: Modified for consistency with other CON review standards. Moved subsection 3 to Section 2 within definition (m), "Freestanding surgical outpatient facility."
- 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.
- 3. Section 3: Modified to reflect either 1.0 exemption for a room used exclusively for trauma care or a 0.5 exemption for a room that is not used exclusively for trauma care.
- 4. Section 5: The replacement section will cover both the replacement of the OR as well as replacing the existing OR to a new geographical site.
- 5. Section 8: Added language to define and outline requirements for a hybrid operating room/cardiac catheterization laboratory (OR/CCL).
- 6. Section 9: Modified language consistent with other CON review standards on Medicaid participation requirement.
- 7. Section 10: Divided requirements into distinct groups: quality assurance, access to care, and monitoring and reporting for consistency with other CON review standards.
- 8. Other technical changes.

Oral or written comments may be presented in person at the hearing on Thursday, November 3, 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, November 10, 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.

10/11/11