

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, April 9, 2015
Time: 9:30 a.m.
Location: Capitol View Building
201 Townsend Street, 1st floor
MDCH Conference Center Room B & C
Lansing, MI 48913



Cardiac Catheterization (CC) Services

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

1. Section 2: Definitions have been modified, and new definitions have been added as follows:
 - "Cardiac catheterization service" means the provision of one or more of the following types of procedures: adult diagnostic cardiac catheterizations; ~~pediatric diagnostic cardiac catheterizations~~; adult therapeutic cardiac catheterizations; and pediatric ~~therapeutic~~ cardiac catheterizations. This definition was updated.
 - "ELECTIVE PERCUTANEOUS CORONARY INTERVENTION (PCI)" MEANS A PCI PROCEDURE PERFORMED ON A NON-EMERGENT BASIS. Definition added to allow for elective PCI without on-site open heart surgery.
 - "ELECTIVE PCI SERVICES WITHOUT ON-SITE OPEN HEART SURGERY (OHS)" MEANS PERFORMING PCI, PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA), AND CORONARY STENT IMPLANTATION ON AN ORGANIZED, REGULAR BASIS IN A HOSPITAL HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE AND A PRIMARY PCI SERVICE BUT NOT HAVING OHS ON-SITE AND ADHERING TO PATIENT SELECTION AS OUTLINED IN THE SCAI/ACC/AHA EXPERT CONSENSUS DOCUMENT: 2014 UPDATED ON PCI WITHOUT ON-SITE SURGICAL BACKUP AND PUBLISHED IN CIRCULATION 2014, 129:2610-2626 AND ITS UPDATE OR FURTHER GUIDELINE CHANGES. Definition added to allow for elective PCI without on-site open heart surgery.
 - "Primary percutaneous coronary intervention (PCI)" means a PCI performed on an acute myocardial infarction (AMI) patient with confirmed ST elevation or new left bundle branch block ON AN EMERGENT BASIS. This definition was updated.
 - "PRIMARY PCI SERVICE WITHOUT ON-SITE OHS" MEANS PERFORMING PRIMARY PCI ON AN EMERGENT BASIS IN A HOSPITAL HAVING A DIAGNOSTIC CARDIAC CATHETERIZATION SERVICE. Definition added for clarity.
 - "Therapeutic cardiac catheterization service" means providing therapeutic cardiac catheterizations on an organized, regular basis in a laboratory to treat and resolve anatomical and/or physiological problems in the heart. Procedures include PCI, PTCA, atherectomy, stent, laser, cardiac valvuloplasty, balloon atrial septostomy, catheter ablation, cardiac permanent pacemaker, ICD device implantations, transcatheter valve, other structural heart disease procedures, ~~percutaneous transluminal coronary angioplasty (PTCA)~~ and WITH coronary stent implantation and left sided arrhythmia therapeutic procedures. The term does not include the intra coronary administration of drugs where that is the only therapeutic intervention. This definition was updated.
2. Section 3(3): Revised consistent with current practice.
3. Section 4: New section that provides the requirements to initiate primary PCI service without on-site OHS (previously included in Section 3) or elective PCI services without on-site OHS services (new to standards). To be considered for an elective PCI service without on-site OHS services, the applicant shall have operated a primary PCI service for one year prior to the date of application. If the applicant was not approved as a primary PCI service prior to the effective date of the new standards, then, in

addition, the applicant shall demonstrate that there is no PCI or OHS service within 60 radius miles or 60 minutes travel time from the proposed site.

4. Section 7: Modified the language consistent with other CON review standards to clarify that any acquisition of a cardiac catheterization service, after the first acquisition, on or after February 27, 2012, must be meeting volume requirements to be acquired.
5. Section 10(2): Revised consistent with current practice and national guidelines. Included a requirement for applicant hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS service, or elective PCI services without on-site OHS service to participate with a data registry administered by the Department or its designee (currently BMC2) that monitors quality and risk adjusted outcomes.
6. Section 10(4): Revised language for consistency with other changes in the standards as well as consistency with other CON review standards.
7. Section 10(5): Updated the quality reporting criteria for primary and elective PCI for hospitals providing therapeutic cardiac catheterization services, primary PCI services without on-site OHS services, or elective PCI services without on-site OHS service.
8. Section 10(6) and (7): Added for administrative feasibility and consistent with other CON review standards.
9. Section 12: Added requirements for documentation of projections for applicants proposing to initiate an elective PCI service without on-site OHS services.
10. Appendix A: Updated the counties based on the 2010 Census data.
11. Other technical edits.

Megavoltage Radiation Therapy (MRT) Services/Units

The proposed CON Review Standards for MRT Services/Units are being reviewed and modified to include the following. The CON Commission is also seeking input regarding specific quality metrics that may be considered for inclusion in the proposed standards.

1. Section 2: Definitions have been modified, moved, and/or deleted if no longer needed, and new definitions have been added as follows:
 - "DEDICATED STEREOTACTIC RADIOSURGERY UNIT" MEANS AN MRT UNIT FOR WHICH MORE THAN 90 PERCENT OF CASES WILL BE TREATED WITH RADIOSURGERY. The term wasn't previously defined.
 - "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, ~~or~~ cerebrovascular system abnormalities, OR CERTAIN BENIGN CONDITIONS are treated with radiation which is delivered by a MRT unit. This definition was updated.
 - "Simulation" means the precise mock-up of a patient treatment with an apparatus that uses a diagnostic x-ray tube, MAGNETIC RESONANCE IMAGING DEVICE, OR COMPUTED TOMOGRAPHY SCANNER, WHICH IS USED IN REPRODUCING THE TWO-DIMENSIONAL OR THREE-DIMENSIONAL INTERNAL OR EXTERNAL GEOMETRY OF THE PATIENT, FOR USE IN TREATMENT PLANNING AND DELIVERY ~~and duplicates an MRT unit in terms of its geometrical, mechanical, and optical properties.~~ This definition was updated.
 - "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units: (i) ~~gamma knife~~, (ii) dedicated stereotactic radiosurgery unit, (iii) dedicated total body irradiator (TBI), OR (iviii) an OR-based IORT unit, ~~or (v) cyber knife~~. This definition was updated.
 - (w) "Treatment visit" means one patient encounter during which MRT is administered AND BILLED. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit. Definition updated for clarification.
2. Section 4(1)(a) and (d): Updated language to allow for replacement of a special purpose unit with a non-special purpose unit . The site at which a special purpose unit is replaced shall continue to operate a non-special purpose unit.
3. Section 5(2)(a): Updated language to reflect that if expanding an existing MRT service with a special purpose MRT unit, that the applicant shall demonstrate that the existing and approved special purpose

MRT units are averaging 1,000 ETVs in the most recent 12-month period in addition to the non-special MRT units averaging 8,000 ETVs in the most recent 12-month period.

4. Section 6: Modified the language consistent with other CON review standards to clarify that any acquisition of an MRT service, after the first acquisition, on or after November 21, 2011, must be meeting volume requirements to be acquired.
5. Section 10 Table 1 Equivalent Treatments: Updated to better reflect current practice.
6. Section 11(2)(e)(ii): Revised as the American College of Radiology (ACR) and the American Society for Radiation Oncology (ASTRO) are no longer one organization, but two separate organizations.
7. Appendix B: Updated the counties based on the 2010 Census data.
8. Other technical edits.

Positron Emission Tomography (PET) Scanner Services

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

1. Section 6(1) and (2): Modified the language consistent with other CON review standards to clarify that any acquisition of a PET service, after the first acquisition, on or after November 21, 2011, must be meeting volume requirements to be acquired.
2. Section 11(4)(a): Technical edit.
3. Section 19: Technical edit.
4. Appendix C: Updated the counties based on the 2010 Census data



Oral or written comments may be presented in person at the hearing on Thursday, April 9, 2015, or submitted in writing via online submission at:

http://www.michigan.gov/mdch/0,4612,7-132-2945_5106_5409_29279-325143--,00.html

Please submit written comments no later than 5:00 p.m., Thursday, April 16, 2015.

If your comment is in written form at the hearing, please provide a copy of your testimony.

If you have any questions or concerns, please contact Tania Rodriguez at 517-335-6708.

Be sure all cellular telephones 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.