Notice of Public Hearing

Pursuant to Section 22215 of Public Act 368 of 1978, as amended, the Michigan Department of Health and Human Services (MDHHS) will hold a hearing on Certificate of Need (CON) Review Standards.

Date: Thursday, July 25, 2019
Time: 9:30 a.m.
Location: South Grand Building
333 S. Grand Avenue, 1st floor
Grand Conference Room
Lansing, MI 48933

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CON Review Standards for Immune Effector Cell Therapy (IECT) Servicess

The CON Commission has determined that new standards are necessary for IECT Services pursuant to MCL 333.22215 of the Public Health Code, PA 368 of 1978, as amended, to ensure quality programs throughout the state. The proposed language defines IECT utilizing the following definitions in Section 2(1) of the standards:

1. (b) "CHIMERIC ANTIGEN RECEPTOR (CAR) T CELLS" MEANS A GENETICALLY MODIFIED T CELL USED IN IMMUNE EFFECTOR CELL THERAPY (IECT).

   (g) "IMMUNE EFFECTOR CELL THERAPY (IECT)" OR "CELLULAR THERAPY" MEANS CELLULAR IMMUNOTHERAPIES, AND OTHER TYPES OF BOTH AUTOLOGOUS AND ALLOGENEIC CELLS DERIVED FROM IMMUNE EFFECTOR CELLS TO TREAT CERTAIN THERAPEUTIC INDICATIONS. FOR PURPOSES OF CON, THIS TERM DOES NOT INCLUDE THERAPEUTIC CANCER VACCINES REGULATED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER) OR ADOPTIVE IMMUNOTHERAPEUTIC PRODUCTS THAT ARE CURRENTLY FDA APROVED AND ARE GIVEN TO PATIENTS IN THE OUTPATIENT SETTING, AS THESE STANDARDS PRODUCTS HAVE DIFFERENT MECHANISMS OF ACTION AND THEREFORE THESE STANDARDS SHALL NOT APPLY.

   (h) "IMMUNE EFFECTOR CELL THERAPY SERVICE" OR "IECT SERVICE" MEANS THE INFUSION OR TRANSFER OF IMMUNE EFFECTOR CELLS AND/OR IMMUNE EFFECTOR CELL THERAPIES INTO PATIENTS. THIS DEFINITION DOES NOT INCLUDE BONE MARROW OR STEM CELL TRANSPLANTATION.

   (i) "IMMUNE EFFECTOR CELLS" MEANS CELLS FROM THE HUMAN BODY THAT HAVE DIFFERENTIATED INTO A FORM CAPABLE OF MODULATING OR EFFECTING AN IMMUNE RESPONSE SUCH AS, BUT NOT LIMITED TO, B CELLS, DENDRITIC CELLS, NATURAL KILLER CELLS, AND T CELLS. THIS DEFINITION INCLUDES CAR T CELLS. FOR PURPOSES OF THESE STANDARDS, IMMUNE EFFECTOR CELLS TO BE USED IN IECT SERVICES MUST BE COLLECTED AND PROCESSED AT A FOUNDATION FOR THE ACCREDITATION OF CELLULAR THERAPY (FACT) ACCREDITATED FACILITY.

The basic requirement is to obtain and maintain accreditation with the Foundation for the Accreditation of Cellular Therapy (FACT) under the Immune Effector Cell Pathway. Regulatory oversight will ensure that programs have quality metrics to provide safe administration of these cells.

CON Review Standards for Psychiatric Beds and Services

The proposed language changes include the following:

1. Section 2:

a. Removed the definition of “base year” as it’s no longer used in the standard.

b. Defined “average occupancy rate” for clarity.

2. Section 3: A new bed need methodology. There is now one methodology for both adult and child/adolescent beds. The methodology incorporates a time series approach to predict future patient days and normative approach to distribute those patient days to the HSAs.
3. Old Section 5 is being removed as it’s no longer needed.
4. Added minimum occupancy requirements in last 12-months prior to application submission, as in hospital beds standards, for the existing psych hospital/unit before a new entity can acquire the facility, replace the facility, or relocate beds. Appropriate sections updated accordingly.
5. New Section 8 revised for clarity.
6. New Section 11: revised comparative review requirements to include more emphasis on access for indigent and high acuity populations. Formulas for comparative review have been simplified.
7. Appendices A and B are being removed as they are no longer needed.
8. The Addendum is being revised as follows:

   a. Adding high acuity psychiatric units.

   b. Increasing the percentage of the state bed need formula to increase the number of special pool beds.

   c. Revising the standard for med-psych units to allow freestanding psychiatric units with collaborative agreements with medical service hospitals.
9. Other technical edits.

CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services/Units

The proposed language changes include the following:

1. Revised the requirements for fixed lithotripsy units from 1,000 to 500 procedures per unit annually for the minimum required volume in the project delivery requirements, as well as replacement and acquisition, to be consistent with the newly approved language for initiation.
2. Section 4(5): Revised for clarity as “TO A NEW SITE” was inadvertently omitted previously.
3. Section 7(1)(c): For clarity, added the following language “A SEPARATE CON APPLICATION HAS BEEN SUBMITTED BY THE CSC AND EACH PROPOSED HOST SITE.”
4. Section 7(3): For clarity, added the following language “THE NORMAL ROUTE SCHEDULE, THE PROCEDURES FOR HANDLING EMERGENCY SITUATIONS, AND COPIES OF ALL POTENTIAL CONTRACTS RELATED TO THE MOBILE UESWL SERVICE AND ITS UNIT(S) SHALL BE INCLUDED IN THE CON APPLICATION SUBMITTED BY THE CENTRAL SERVICE COORDINATOR OR THE APPLICANT HOST SITE.”
5. Updated the factor for calculating projected UESWL procedures in Appendix A.
6. Other technical edits.

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Oral or written comments may be presented in person at the hearing on Thursday, July 25, 2019, or submitted in writing by sending an email to the following email address: MDHHS-ConWebTeam@michigan.gov

Please submit written comments no later than 5:00 p.m., Thursday, August 1, 2019.

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 phones and devices 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.

6/20/19