

Notice of Public Hearing

Pursuant to Section 22215 of Public Act 306 of 1969, as amended, the Michigan Department of Health and Human Services (MDHHS) will hold a hearing on Certificate of Need (CON) Review Standards.

Date: Thursday, January 25, 2018
Time: 9:30 a.m.
Location: South Grand Building
333 S. Grand Avenue, 1st floor
Grand Conference Room
Lansing, MI 48933



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

The proposed language changes include the following:

1. Updated the Department name throughout the document.
2. Section 3(1)(c)(iii) and (vii): FSOE and ASC sites can't typically meet these requirements. The change is for administrative feasibility. (Note: The option for a contractual agreement was removed in 1998.)
 - EITHER On-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.
 - EITHER On-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH FACILITY, A 23-hour holding unit.
3. Section 3(2): Added requirements to convert from mobile to fixed UESWL services. The change is consistent with other CON covered mobile modalities that offer conversion.
 - (2) AN APPLICANT PROPOSING TO INITIATE A FIXED UESWL SERVICE THAT MEETS THE FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH SUBSECTION (1)(B):
 - (a) THE APPLICANT IS CURRENTLY AN EXISTING MOBILE UESWL HOST SITE.
 - (b) THE APPLICANT HOSPITAL HAS PERFORMED AN AVERAGE OF AT LEAST 500 PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN APPLICATION.
 - (c) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-HOUR EMERGENCY CARE SERVICES AND AT LEAST 80,000 VISITS WITHIN THE MOST RECENT 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.
 - (d) THE APPLICANT HOSPITAL SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.
 - (e) THE APPLICANT HOSPITAL SHALL CEASE OPERATION AS A HOST SITE AND NOT BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE BECOMES OPERATIONAL.
4. Section 4(2): Removed the volume requirement for replacement. This is similar to other CON covered clinical services.
5. Section 4(3): Modified as follows. This will still allow for conversion from fixed to mobile, but the service will have to demonstrate compliance with the volume requirement. If a host site was converted to a fixed unit for better access to UESWL services at that site, then converting it back to a mobile unit seems to defeat that purpose. This language was originally written to convert fixed units to mobile.
 - (3) An applicant ~~that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(2):~~
(a) —The proposed project involves replacing PROPOSING TO REPLACE 1 existing fixed UESWL unit with 1 mobile UESWL unit SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF THE FOLLOWING-;

(ba) EACH EXISTING UESWL UNIT OF THE SERVICE PROPOSING TO REPLACE A UESWL UNIT HAS AVERAGED AT LEAST 1,000 UESWL PROCEDURES PER UNIT DURING THE MOST RECENT CONTINUOUS 12-MONTH PERIOD FOR WHICH THE DEPARTMENT HAS VERIFIABLE DATA.

6. Section 4(4): The 36-month in operation requirement is waived if one of the following has been met. Reduced regulation allows for facilities to more easily replace an existing fixed UESWL service to a new location in certain situations that are unforeseen to the applicant (same as MRI and CT language).
 - (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
 - (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL;Removed volume requirements for replacement of an existing fixed UESWL service and its unit(s) to a new site in certain situations that are unforeseen to the applicant (same as MRI and CT language):
 - (i) THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;
 - (ii) THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR
 - (iii) THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.
7. Section 6 has been modified to allow for the acquisition of a fixed or mobile UESWL service not meeting volume requirements by an entity if the UESWL service is 1) owned by the applicant, 2) is under common control by the applicant, or 3) has a common parent as the applicant. The acquisition of an UESWL service does not change the location of the service. The service would have to meet all other applicable UESWL standards and project delivery requirements. Reduced regulation allows for facilities to more easily realign their assets when part of a larger health system.
8. Section 7(4) has been removed. This will give mobile routes more flexibility to change the route to accommodate changes that may be caused by facilities converting to a fixed unit.
9. Appendix A: The factor for calculating projected UESWL procedures has been updated.
10. Other technical edits.



Oral or written comments may be presented in person at the hearing on Thursday, January 25, 2018, 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, February 1, 2018.

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.