

# 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, August 3, 2017  
**Time:** 9:30 a.m.  
**Location:** South Grand Building  
333 S. Grand Avenue, 1<sup>st</sup> floor  
Grand Conference Room  
Lansing, MI 48933



## CON Review Standards for Surgical Services

The proposed language changes include the following:

1. Updated the Department name throughout the document.
2. Section 4(3)(a): Added language regarding commitment letters and the use of historical surgical cases for initiation.
3. Section 11(2)(e): Added new language regarding commitment letters and the use of historical surgical cases for initiation as shown below. Less regulation will ease the process for the applicant when using its own data to initiate:
  - (e) SUBSECTION 11(2)(d) SHALL NOT APPLY IF THE PROPOSED PROJECT INVOLVES THE INITIATION OF A SURGICAL SERVICE AT A NEW FSOF OR A NEW ASC AT A NEW GEOGRAPHICAL SITE UTILIZING THE HISTORICAL SURGICAL CASES OF THE APPLICANT AND THE NEW SERVICE IS OWNED BY THE SAME APPLICANT. THE APPLICANT FACILITY COMMITTING SURGICAL DATA HAS COMPLETED THE DEPARTMENTAL FORM THAT CERTIFIES THE SURGICAL CASES WERE PERFORMED AT THE COMMITTING FACILITY AND THE SURGICAL CASES WILL BE TRANSFERRED TO THE PROPOSED SURGICAL FACILITY FOR NO LESS THAN 3 YEARS SUBSEQUENT TO THE INITIATION OF THE SURGICAL SERVICE PROPOSED BY THE APPLICANT.
4. Other technical edits.

## 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): FSOF 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 HAS PERFORMED AT LEAST 500/1000 PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN APPLICATION.

- (c) THE APPLICANT SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT THE SAME SITE AS THE EXISTING HOST SITE.
  - (d) THE APPLICANT 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(5): 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.
5. 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.
6. Appendix A: The factor for calculating projected UESWL procedures has been updated.
7. Other technical edits.



Oral or written comments may be presented in person at the hearing on Thursday, August 3, 2017, or submitted in writing by sending an email to the following email address:

[MDHHS-ConWebTeam@michigan.gov](mailto:MDHHS-ConWebTeam@michigan.gov)

Please submit written comments no later than 5:00 p.m., Thursday, August 10, 2017.

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.*