MICHIGAN DEPARTMENT OF COMMUNITY HEALTH

CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR
URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

(By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)

Section 1. Applicability

Sec. 1. ~~(1)~~ These standards are requirements for approval TO INITIATE, REPLACE, EXPAND, OR ACQUIRE AN UESWL SERVICE/UNIT ~~and delivery of services for all projects approved and Certificates of Need issued~~ under Part 222 of the Code. ~~that involve a urinary extracorporeal shock wave lithotripsy service/unit.~~

~~(2)~~ Urinary extracorporeal shock wave lithotripsy is a covered clinical service for purposes of Part 222 of the Code.

~~(3)~~ The Department shall use ~~sections 3, 4, 5, 6, 7, 8, 12, 13, 14, and 15, as applicable,~~THESE STANDARDS in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws~~.~~

~~(4) The Department shall use sections 10~~ and ~~11, as applicable, in applying~~ Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.

~~(5) The Department shall use Section 9, as applicable, in applying Section 22215(1)(b) of the Code, being Section 333.22215(1)(b) of the Michigan Compiled Laws.~~

Section 2. Definitions

Sec. 2. (1) For purposes of these standards:

~~(a) "Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.~~

(~~b~~a) "Central service coordinator" OR "CSC" means the organizational unit that has operational responsibility for a mobile UESWL service and its unit(s) and that is a legal entity authorized to do business in the state of Michigan.

(~~c~~b) "Certificate of Need Commission" or "Commission" means the Commission created pursuant to Section 22211 of the Code, being Section 333.22211 of the Michigan Compiled Laws.

(~~d~~c) "Code" means Act No. 368 of the Public Acts of 1978, as amended, being Section 333.1101 et seq. of the Michigan Compiled Laws.

(~~e~~d) "Complicated stone disease treatment capability" means the expertise necessary to manage all patients during the treatment of kidney stone disease. This includes, but is not limited to:

(i) A urology service that provides skilled and experienced ureteroscopic stone removal procedures and

(ii) Experienced interventional radiologic support.

(~~f~~e) "Department" means the Michigan Department of Community Health (MDCH).

(~~g~~f) "Existing mobile UESWL unit" means a CON-approved and operational UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(~~h~~g) "Existing UESWL service" means the utilization of a CON-approved and operational UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.

(~~i~~h) "Existing UESWL unit" means the utilization of a CON-approved and operational UESWL unit.

~~(j) "Expand an existing UESWL service" means the addition of one UESWL unit at an existing UESWL service.~~

(~~k~~i) "Hospital" means a health facility licensed under Part 215 of the Code.

(~~l~~j) "Host site" means the site at which a mobile UESWL unit is authorized to provide UESWL services.

~~(m) "Initiate a UESWL service" means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or relocation of an existing UESWL service or the renewal of a lease.~~

(~~n~~k) "Licensed site" means either of the following:

(i) In the case of a single site health facility, the location of the facility authorized by license and listed on that licensee's Certificate of Licensure.

(ii) In the case of a health facility with multiple sites, the location of each separate and distinct health facility as authorized by license and listed on that licensee's Certificate of Licensure.

~~(o) "Medicaid" means title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and1396r-8 to 1396v.~~

~~(p) "Metropolitan statistical area county" means a county located in a metropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.~~

(~~q~~l) "Michigan Inpatient Database" or "MIDB" means the database that is compiled by the Michigan Health and Hospital Association or successor organization. The database consists of inpatient discharge records from all Michigan hospitals and Michigan residents discharged from hospitals in border states for a specific calendar year.

~~(r) "Micropolitan statistical area county" means a county located in a micropolitan statistical area as that term is defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix B.~~

(~~s~~m) "Mobile UESWL unit" means a UESWL unit and transporting equipment operated by a central service coordinator that provides UESWL services to two or more host sites.

(~~t~~n) "Planning area" means the state of Michigan.

(~~u~~o) "Region" means the geographic areas set forth in ~~Section 12~~APPENDIX B.

~~(v) "Relocate a fixed UESWL unit" means a change in the location of a fixed UESWL unit(s) from the existing site to a different site within the relocation zone.~~

~~(w) "Relocate an existing UESWL service" means a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.~~

~~(x) "Relocation zone" means the geographic area that is within a 25-mile radius, within the state of Michigan, of the existing site of the UESWL service to be relocated.~~

(~~y~~p) "Renewal of a lease" means extending the effective period of a lease for an existing UESWL unit that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section ~~2(1)(z)~~4, or a change in the parties to the lease.

~~(z) "Replace an existing UESWL unit" means an equipment change of an existing UESWL unit, other than an upgrade, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. The term does not include an upgrade of an existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL unit to a mobile UESWL unit.~~

(~~aa~~q) "Retreatment" means a UESWL procedure performed on the same side of the same patient within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of a mobile service, the term includes a retreatment performed at a different host site if the initial treatment was performed by the same service.

~~(bb) "Rural county" means a county not located in a metropolitan statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the office of information regulatory affairs of~~

~~the United States office of management and budget, 65 F.R. p. 82238 (December 27, 2000) and as shown in Appendix C.~~

~~(cc) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of $125,000 or less in any consecutive 24-month period.~~

(~~dd~~r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the ureter by means of an endoscope that may or may not include laser technology.

(~~ee~~s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized into sand-like particles, which then may be passed through the urinary tract.

(~~ff~~t) "UESWL service" means either the CON-approved utilization of a UESWL unit(s) at one site in the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.

(~~gg~~u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL procedure.

(2) The definitions in Part 222 shall apply to these standards.

Section 3. Requirements ~~for approval for all applicants proposing~~ to initiate a urinary extracorporeal shock wave lithotripsy service

Sec. 3. ~~(1)~~ Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile, at a site that does not offer (or has not offered within the last consecutive 12-month period) approved UESWL services. The term does not include the acquisition or ~~relocation~~REPLACMENT of an existing UESWL service or the renewal of a lease.

(1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:

(a) The capability to provide complicated stone disease treatment on-site.

(b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section ~~13~~10(1).

(c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of the following:

(i) On-call availability of an anesthesiologist and a surgeon.

(ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.

(iii) On-site IV supplies and materials for infusions and medications, blood and blood products, and pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.

(iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator, general radiography and fluoroscopy, cystoscopy, and laboratory services.

(v) On-site crash cart.

(vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a cardiac intensive care unit.

(vii) On-site 23-hour holding unit.

Section 4. Requirements ~~for approval for applicants proposing~~ to replace an existing UESWL unit(s)

Sec. 4. Replace an existing UESWL unit means an equipment change of an existing UESWL unit, other than an upgrade, proposed by an applicant that results in that applicant operating the same number of UESWL units before and after the project completion. The term does not include an upgrade of an existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL unit to a mobile UESWL unit. REPLACEMENT ALSO MEANS a change in the location of a fixed UESWL unit(s) from the existing site to a different site~~within the relocation zone.~~, OR a change in the geographic location of an existing fixed UESWL service and its unit(s) from an existing site to a different site.

(1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that involves a capital expenditure of $125,000 or less in any consecutive 24-month period.

(2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate the following:

(a) 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.

(b) Each UESWL unit of the service proposing to replace a UESWL unit is projected to perform at least 1,000 UESWL procedures per unit per year pursuant to the methodology set forth in Section ~~13~~10.

(~~2~~3) An applicant proposing to replace a UESWL unit shall demonstrate one or more of the following:
(a) The existing equipment clearly poses a threat to the safety of the public.
(b) The proposed replacement UESWL unit offers technological improvements that enhance quality of care, increase efficiency, or reduce operating costs and patient charges.
(c) The existing equipment is fully depreciated according to generally accepted accounting principles.

(~~3~~4) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(~~1~~2):
(a) The proposed project involves replacing 1 existing fixed UESWL unit with 1 mobile UESWL unit.
(b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the region in which the fixed UESWL unit proposed to be replaced is located currently.
(c) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposed to operate when the results of the methodology in Section ~~13~~ 10 are combined for the following, as applicable:
(i) All licensed hospital sites committing MIDB data pursuant to Section ~~14~~11, as applicable, that are located in the region identified in subsection (c).
(ii) All sites that receive UESWL services from an existing UESWL service and propose to receive UESWL services from the proposed mobile unit and that are located in the region identified in subsection (c).
(d) A separate application from each host site is filed at the same time the application to replace a fixed unit is submitted to the Department.
(e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually pursuant to the methodology set forth in Section ~~13~~10.

(~~4~~5) An applicant proposing to relocate its existing UESWL service and its unit(s) shall demonstrate that the proposed project meets all of the following:
(a) The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).
(b) The UESWL service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
~~(c) The requirements of Sections 4 and 8, as applicable, have been met.~~
(~~d~~c) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).
(e) The proposed new site is in ~~the relocation zone within a 25-mile radius, within~~ the state of Michigan~~,~~ AND WITHIN A 25-MILE RADIUS of the existing site of the UESWL service to be relocated.
(~~f~~e) The UESWL service and its unit(s) to be relocated performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.
(~~g~~f) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~10~~9 of these standards.

(6) An applicant proposing to relocate a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:
(a) The existing UESWL service from which the UESWL unit(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.
~~(b) The requirements of Sections 4 and 8, as applicable, have been met.~~
(~~c~~b) The site to which the UESWL unit(s) will be relocated meets the requirements of Section 3(1)(c).

(~~d~~c) The proposed new site is in ~~the relocation zone within a 25-mile radius, within~~ the state of Michigan~~,~~ AND WITHIN A 25-MILE RADIUS of the existing site of the FIXED UESWL ~~service~~UNIT to be relocated.

(~~e~~d) Each existing UESWL unit(s) at the service from which a unit is to be relocated performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.

(~~f~~e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section ~~10~~9 of these Standards.

(F) FOR VOLUME PURPOSES, THE NEW SITE SHALL REMAIN ASSOCIATED WITH THE EXISTING UESWL SERVICE FOR A MINIMUM OF THREE YEARS.

(7) Equipment that is replaced shall be removed from service and disposed of or rendered considerably inoperable on or before the date that the replacement equipment becomes operational.

Section 5. Requirements for approval to expand an existing UESWL service

Sec. ~~8~~5. Expand an existing UESWL service means the addition of one UESWL unit at an existing UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:

(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.

(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section ~~13~~ 10 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.

(3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section ~~5~~7(1)(c).

~~**Additional requirements for approval for mobile UESWL services**~~

~~Sec. 5. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:~~

~~(a) The proposed mobile UESWL service meets the requirements of Section 3 or 4, as applicable.~~

~~(b) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section 13 are combined for the following, as applicable:~~

~~(i) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, that are located in the region identified in subsection (b).~~

~~(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).~~

~~(c) 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.~~

~~(2) The requirements of subsection (1)(a) and (1)(b) shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:~~

~~(a) The proposed host site is located in a rural or micropolitan statistical area county.~~

~~(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.~~

~~(c) A separate CON application has been submitted by the CSC and each proposed host site.~~

~~(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).~~

~~(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section 13 are combined for the following, as applicable:~~

~~(a) All licensed hospital sites committing MIDB data pursuant to Section 14, as applicable, are located in that region(s).~~

~~(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).~~

Section 6. Requirements ~~for approval for applicants proposing~~ to acquire an existing UESWL service and ~~its unit(s)~~ or an existing UESWL unit(s)

Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by purchase, lease, donation, or other comparable arrangement.

(1) An applicant proposing to acquire an existing fixed or mobile UESWL service and its unit(s) shall demonstrate that a proposed project meets all of the following:

(a) ~~The requirements of Sections 4 and 7, as applicable, have been met.~~

~~(b)~~ For an application for the proposed first acquisition of an existing fixed or mobile UESWL service, for which a final decision has not been issued after May 2, 1998, an existing UESWL service to be acquired shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on the date the acquisition occurs. The UESWL service and its unit(s) shall be operating at the applicable volume requirements set forth in Section ~~10~~ 9 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.

(~~c~~b) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first application approved pursuant to subsection (~~3~~A), for which a final decision has not been issued after MAY 2, 1998, an applicant shall be required to demonstrate that the UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(2) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:

(a) ~~The requirements of Section 4 and 7, as applicable, have been met.~~

~~(b)~~ For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.

(~~c~~b) The requirements of Section 3(1)(c) have been met.

Section 7. ~~Requirements for approval for applicants proposing to relocate an existing UESWL service and/or UESWL unit(s)~~

~~Sec. 7. (1) An applicant proposing to relocate its existing UESWL service and its unit(s) shall demonstrate that the proposed project meets all of the following:~~

~~(a) The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).~~

~~(b) The UESWL service to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.~~

~~(c) The requirements of Sections 4 and 8, as applicable, have been met.~~

~~(d) The site to which the UESWL service will be relocated meets the requirements of Section 3(1)(c).~~

~~(e) The proposed new site is in the relocation zone.~~

~~(f) The UESWL service and its unit(s) to be relocated performed an average of at least 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable data.~~

~~(g) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all applicable project delivery requirements set forth in Section 10 of these standards.~~

~~(2) An applicant proposing to relocate a fixed UESWL unit(s) of an existing UESWL service shall demonstrate that the proposed project meets all of the following:~~

~~(a) The existing UESWL service from which the UESWL unit(s) is to be relocated has been in operation for at least 36 months as of the date an application is submitted to the Department.~~

~~(b) The requirements of Sections 4 and 8, as applicable, have been met.~~

~~(c) The site to which the UESWL unit(s) will be relocated meets the requirements of Section 3(1)(c).~~

~~(d) The proposed new site is in the relocation zone.~~

~~(e) Each existing UESWL unit(s) at the service from which a unit is to be relocated performed at least an average of 1,000 procedures per fixed unit in the most recent 12-month period for which the Department has verifiable data.~~

~~(f) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project delivery requirements set forth in Section 10 of these Standards.~~ **Additional requirements for approval for mobile UESWL services**

Sec. ~~5~~7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall demonstrate that it meets all of the following:

~~(a) The proposed mobile UESWL service meets the requirements of Section 3 or 4, as applicable.~~

(~~b~~a) At least 100 UESWL procedures are projected in each region in which the proposed mobile UESWL unit is proposing to operate when the results of the methodology in Section ~~13~~10 are combined for the following, as applicable:

(i) All licensed hospital sites committing MIDB data pursuant to Section ~~14~~11, as applicable, that are located in the region identified in subsection (b).

(ii) All sites that receive UESWL services from an existing UESWL unit and propose to receive UESWL services from the proposed mobile unit are located in the region(s) identified in subsection (b).

(~~c~~b) 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.

(2) The requirements of SECTIONS 3, 4, AND subsection (1)(a) ~~and (1)(b)~~ shall not apply to an applicant that proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL service and its unit(s) operates predominantly outside of Michigan and all of the following requirements are met:

(a) The proposed host site is located in a rural or micropolitan statistical area county.

(b) All existing and approved Michigan UESWL service and its unit(s) locations (whether fixed or mobile) are in excess of 50 miles from the proposed host site and within a region currently served by a UESWL mobile service operating predominantly outside of Michigan.

(c) A separate CON application has been submitted by the CSC and each proposed host site.

(3) A central service coordinator proposing to add, or an applicant proposing to become, a host site on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the requirements of Section 3(1)(C).

(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site on an existing mobile UESWL service in a region not currently served by that service shall demonstrate that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL service is proposing to add a host site when the results of the methodology in Section ~~13~~ 10 are combined for the following, as applicable:

(a) All licensed hospital sites committing MIDB data pursuant to Section ~~14~~11, as applicable, are located in that region(s).

(b) All sites that receive UESWL services from an existing UESWL service and its unit(s) and propose to receive UESWL services from the proposed mobile service and its unit(s) are located in that region(s).

Section 8. ~~Requirements for approval to expand an existing UESWL service~~

~~Sec. 8. An applicant proposing to expand an existing UESWL service, whether fixed or mobile, unless otherwise specified, shall demonstrate the following:~~

~~(1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In computing this average, the Department will divide the total number of UESWL procedures performed by the applicant's total number of UESWL units, including both operational and approved but not operational fixed and mobile UESWL units.~~

~~(2) The applicant shall project an average of at least 1,000 procedures for each existing and proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section 13 of these standards for the second 12-month period after initiation of operation of each additional UESWL unit whether fixed or mobile.~~

~~(3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the existing or revised contracts between the central service coordinator and each host site(s) that includes the same stipulations as specified in Section 5(1)(c).~~

~~Section 9.~~ Requirements for ~~approval – all applicants~~MEDICAID PARTICIPATION

Sec. ~~9~~8. An applicant shall provide verification of Medicaid participation. An applicant that is a new provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided to the Department within six (6) months from the offering of service if a CON is approved.

Section ~~10~~9. Project delivery requirements ~~--~~ terms of approval for all applicants

Sec ~~10~~9. ~~(1)~~ An applicant shall agree that, if approved, UESWL SERVICES, INCLUDING ALL EXISTING AND APPROVED UESWL UNITS, ~~the project~~ shall be delivered in compliance with the following ~~terms of CON approval~~:

(~~a~~1) Compliance with these standards.

~~(b) Compliance with applicable operating standards.~~

(~~c~~2) Compliance with the following quality assurance standards:

(~~i~~a) ~~Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.~~

(~~ii~~b) The medical staff and governing body shall receive and review at least annual reports describing activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.

(~~iii~~c) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.

(~~iv~~d) An applicant shall develop and utilize a standing medical staff and governing body rule that provides for the medical and administrative control of the ordering and utilization of UESWL services.

(~~v~~e) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed an approved training program in the use of the lithotripter at an established facility with UESWL services.

(~~vi~~f) An applicant shall establish a process for credentialing urologists who are authorized to perform UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish specific credentialing requirements for any particular hospital or UESWL site.

(~~vii~~g) A urologist who is not an active medical staff member of an applicant facility shall be eligible to apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an applicant shall provide documentation of its process that will allow a urologist who is not an active medical staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall demonstrate that he or she meets the same requirements, established pursuant to the provisions of subsection (~~vi~~f), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

(~~viii~~h) An applicant shall provide UESWL program access to approved physician residency programs for teaching purposes.

(3) COMPLIANCE WITH THE FOLLOWING ACCESS TO CARE REQUIREMENTS:

(~~ix~~a) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:

(~~A~~i) Not deny ANY UESWL services to any individual based on inability to pay or source of payment,

(~~B~~ii) Provide ALL UESWL services to any individual based on clinical indications of need for the services, and

(~~C~~iii) Maintain information by payor and non-paying sources to indicate the volume of care from each source provided annually.

(b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.

(c) The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).

Compliance with selective contracting requirements shall not be construed as a violation of this term.

(4) COMPLIANCE WITH THE FOLLOWING MONITORING AND REPORTING REQUIREMENTS:

(a) Each UESWL unit, whether fixed or mobile, shall perform at least an average of 1,000 procedures per unit per year in the second 12 months of operation and annually thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved pursuant to these standards performed at least 100 procedures in each region that is served by the mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host sites in the same region shall be combined.

(~~x~~b) ~~An~~ THE applicant shall participate in a data collection network established and administered by the Department or its designee. The data may include, but is not limited to, annual budget and cost information; operating schedules; and demographic, diagnostic, morbidity and mortality information; primary diagnosis code; whether the procedure was a first or retreatment UESWL procedure; what other treatment already has occurred; outpatient or inpatient status; complications; and whether follow-up procedures (e.g., percutaneous nephrotomy) were required, as well as the volume of care provided to patients from all payor sources. An applicant shall provide the required data on a separate basis for each host site or licensed site in a format established by the Department and in a mutually-agreed-upon media. The Department may elect to verify the data through on-site review of appropriate records.

(~~xi~~c) The applicant shall provide the Department with ~~a~~ TIMELY notice ~~stating the date the approved UESWL service and its unit(s) is placed in operation and such notice shall be submitted to the Department~~OF THE PROPOSED PROJECT IMPLEMENTATION consistent with applicable statute and promulgated rules.

~~(xii) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years of operation and continue to participate annually thereafter.~~

~~(2) The operation of and referral of patients to the UESWL service shall be in conformance with 1978 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).~~

(~~3~~5) ~~The agreements and assurances required by this Section shall be in the form of a certification agreed to by the applicant or its authorized agent.~~

~~Section 11. Project delivery requirements - additional terms of approval for applicants involving mobile UESWL services~~

~~Sec. 11. (1) In addition to the provisions of Section 10, an applicant for a mobile UESWL service shall agree that the services provided by the mobile UESWL unit(s) shall be delivered in c~~Compliance with the following MOBILE UESWL ~~terms of CON approval~~REQUIREMENTS, IF APPLICABLE:

(a) The volume of UESWL procedures performed at each host site shall be reported to the Department by the central service coordinator.

(b) An applicant with an approved CON for a mobile UESWL service shall notify the Department and the local CON review agency, if any, at least 30 days prior to dropping an existing host site.

(c) Each mobile UESWL service shall establish and maintain an Operations Committee consisting of the central service coordinator's medical director and members representing each host site and the central service coordinator. This committee shall oversee the effective and efficient use of the UESWL unit, establish the normal route schedule, identify the process by which changes are to be made to the schedule, develop procedures for handling emergency situations, and review the ongoing operations of the mobile UESWL service and its unit(s) on at least a quarterly basis.

(d) The central service coordinator shall arrange for emergency repair services to be available 24 hours each day for the mobile UESWL unit equipment and the vehicle transporting the equipment.

(e) If the host site will not be performing the lithotripsy procedures inside the facility, it must provide a properly prepared parking pad for the mobile UESWL unit of sufficient load-bearing capacity to support the vehicle, a waiting area for patients, and a means for patients to enter the vehicle without going outside (such as a canopy or enclosed corridor). Each host site also must provide the capability for maintaining the confidentiality of patient records. A communication system must be provided between the mobile vehicle and each host site to provide for immediate notification of emergency medical situations.

(f) A mobile UESWL service shall operate under a contractual agreement that includes the provision of UESWL services at each host site on a regularly scheduled basis.

(~~2~~6) The agreements and assurances required by this Section shall be in the form of a certification agreed to by the applicant or its authorized agent.

~~Section 12. Regions~~

~~Sec. 12. The counties assigned to each region are as follows:~~

~~Region~~	~~Counties~~				
~~1~~	~~Livingston~~	~~Monroe~~	~~Macomb~~	~~Oakland~~	
~~St. Clair~~	~~Washtenaw~~	~~Wayne~~			
~~2~~	~~Clinton~~	~~Eaton~~	~~Hillsdale~~	~~Ingham~~	
~~Jackson~~	~~Lenawee~~				
~~3~~	~~Barry~~	~~Berrien~~	~~Branch~~	~~Calhoun~~	
~~Cass~~	~~Kalamazoo~~	~~St. Joseph~~	~~Van Buren~~		
~~4~~	~~Allegan~~	~~Ionia~~	~~Kent~~	~~Lake~~	
~~Mason~~	~~Mecosta~~	~~Montcalm~~	~~Muskegon~~		
~~Newaygo~~	~~Oceana~~	~~Osceola~~	~~Ottawa~~		

~~5~~	~~Genesee~~	~~Lapeer~~	~~Shiawassee~~		
~~6~~	~~Arenac~~	~~Bay~~	~~Clare~~	~~Gladwin~~	
	~~Gratiot~~	~~Huron~~	~~Iosco~~	~~Isabella~~	
	~~Midland~~	~~Ogemaw~~	~~Roscommon~~	~~Saginaw~~	
	~~Sanilac~~	~~Tuscola~~			
~~7~~	~~Alcona~~	~~Alpena~~	~~Antrim~~	~~Benzie~~	
	~~Crawford~~	~~Charlevoix~~	~~Cheboygan~~	~~Emmet~~	
	~~Gd. Traverse~~	~~Kalkaska~~	~~Leelanau~~	~~Manistee~~	
	~~Missaukee~~	~~Montmorency~~	~~Oscoda~~	~~Otsego~~	
	~~Presque Isle~~	~~Wexford~~			
~~8~~	~~Alger~~	~~Baraga~~	~~Chippewa~~	~~Delta~~	
	~~Dickinson~~	~~Gogebic~~	~~Houghton~~	~~Iron~~	
	~~Keweenaw~~	~~Luce~~	~~Mackinac~~	~~Marquette~~	
	~~Menominee~~	~~Ontonagon~~	~~Schoolcraft~~		

Section ~~13~~10. Methodology for projecting UESWL procedures

Sec. ~~13~~10. (1) The methodology set forth in this subsection shall be used for projecting the number of UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified in the most recent Michigan Inpatient Database available to the Department on the date an application is deemed complete shall be used for each licensed hospital site for which a signed data commitment form has been provided to the Department in accordance with the provisions of Section ~~14~~11. In applying inpatient discharge data in the methodology, each inpatient record shall be used only once and the following steps shall be taken in sequence:

(a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (SEE APPENDIX D FOR ICD-10-CM CODES) shall be counted.

(b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each licensed hospital site that is committing its inpatient discharge data to a CON application. If more than one licensed hospital site is committing inpatient discharge data in support of a CON application, the products from the application of the methodology for each licensed hospital site shall be summed.

(c) The result of subsection (b) is the total number of projected UESWL procedures for an application that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile service, that does not provide UESWL service, either fixed or mobile, as of the date an application is submitted to the Department.

(2) For a site or sites that provide UESWL services as of the date an application is submitted to the Department, the actual number of UESWL procedures performed at each site, during the most recent continuous 12-month period for which the Department has verifiable data, shall be the number used to project the number of UESWL procedures that will be performed at that site or sites.

(3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as applicable, shall be summed and the result is the projected number of UESWL procedures for the proposed UESWL unit for purposes of the applicable sections of these standards.

(4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide access to verifiable hospital-specific data and documentation using a format prescribed by the Department.

Section ~~14~~11. Requirements for MIDB data commitments

Sec. ~~14~~11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant shall demonstrate or agree to, as applicable, all of the following.

(a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL service shall not use any of its MIDB data in support of any other application for a UESWL service for 5 years following the date the UESWL service to which the MIDB data are committed begins to operate. The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON application.

(b) The licensed hospital site, or sites, committing MIDB data to a CON application has completed the departmental form(s) that agrees to or authorizes each of the following:

(i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.

(ii) An applicant shall pay all charges associated with verifying the MIDB data.

(iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection (1)(a).

(c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting patients regularly as of the date the director makes the final decision on that application under Section 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

(2) The Department shall consider an MIDB data commitment in support of an application for a UESWL service from a licensed hospital site that meets all of the following:

(a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an application is submitted to the Department.

(b) The licensed hospital site proposing to commit MIDB data is located in a region in which a proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one host site proposed in that region.

(c) The licensed hospital site meets the requirements of subsection (1), as applicable.

Section ~~15~~12. Effect on prior planning policies; comparative reviews

Sec. ~~15~~12. (1) These CON review standards supersede and replace the CON review standards for urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on ~~March 9, 2004~~ DECEMBER 11, 2007 and effective on ~~June 4, 2004~~ FEBRUARY 25, 2008.

(2) Projects reviewed under these standards shall not be subject to comparative review.

APPENDIX A

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section ~~13~~10(1)(b) used for calculating the projected number of UESWL procedures shall be ~~.94~~1.09.

(2) The Department may amend Appendix A by revising the factor in subsection (1) in accordance with the following steps:

(a) Steps for determining ~~preliminary~~ statewide UESWL adjustment factor:

(i) Determine the total statewide number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM codes 592.0, 592.1, or 592.9 (SEE APPENDIX D FOR ICD-10-CM CODES) for the most recent year for which Michigan Inpatient Database information is available to the Department.

(ii) Determine the total number of UESWL procedures performed in the state using the Department's Annual Hospital Questionnaire for the same year as the MIDB being used in subsection (i) above.

(iii) Divide the number of UESWL procedures determined in subsection (ii) above by the number of inpatient records determined in subsection (i) above.

(b) Steps for determining "urban/rural" adjustment factor:

(i) For each hospital, assign urban/rural status based on the 2000 census. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) AGGREGATE ~~The~~ the records from step (a)(i) ~~above will then be aggregated~~ by ZIP CODE "urban/rural" STATUS~~and zip code~~.

(iii) IDENTIFY THE ~~Zip~~ zip codes ~~that are totally~~IN WHICH ALL RECORDS ARE EITHER "urban" STATUS or "rural" STATUS. ~~will have the discharges~~AGGREGATE THE NUMBER OF RECORDS and ZIP CODE populations ~~aggregated for those respective groups~~SEPARATELY BY "URBAN/RURAL" STATUS.

(iv) For ~~the remaining~~ zip codes ~~with~~ HAVING RECORDS IN both "urban" and "rural" ~~components~~STATUS, CALCULATE the proportion of ~~the zip code in each part (urban or rural) will be calculated and applied to~~RECORDS IN "URBAN" AND "RURAL" BY DIVIDING THE RESPECTIVE NUMBER OF RECORDS BY THE TOTAL NUMBER OF RECORDS FOR THAT ZIP CODE. MULTIPLY the population ~~for that~~OF EACH zip code BY ITS RESPECTIVE "URBAN" AND "RURAL" PROPORTIONS.

(v) ~~These will then be a~~Aggregate~~d by discharge~~THE RECORDS AND and populationS FROM STEP (b)(iv) SEPARATELY by "urban/rural" status.

(vi) The sub-totals from step (v) will then be added to the sub-totals from step (iii) to produce totals for "urban" & "rural" separately ~~per 10,000 population~~. CALCULATE THE "URBAN" AND "RURAL" DISCHARGE RATES PER 10,000 (DRU AND DRR, RESPECTIVELY) BY DIVIDING THE TOTAL NUMBER OF RECORDS BY THE TOTAL POPULATION FOR EACH STATUS, THEN MULTIPLYING BY 10,000.

(vii) ~~The percentage difference between "urban" and "rural" discharge rates will be applied to the rate~~DIVIDE THE URBAN DISCHARGE RATE BY THE RURAL DISCHARGE RATE (DRU/DRR) TO CALCULATE THE "URBAN/RURAL" ADJUSTMENT FACTOR. MULTIPLY THE STATEWIDE ADJUSTMENT FACTOR identified in step (a)(iii) ~~above~~BY THE "URBAN/RURAL" ADJUSTMENT FACTOR. The result is the revised factor for calculating UESWL procedures.

(3) The Department shall notify the Commission when this revision is made and the effective date of the revision.

APPENDIX B

Counties assigned to each region are as follows:

Region	Counties			
1	Livingston	Monroe	Macomb	Oakland
	St. Clair	Washtenaw	Wayne	
2	Clinton	Eaton	Hillsdale	Ingham
	Jackson	Lenawee		
3	Barry	Berrien	Branch	Calhoun
	Cass	Kalamazoo	St. Joseph	Van Buren
4	Allegan	Ionia	Kent	Lake
	Mason	Mecosta	Montcalm	Muskegon
	Newaygo	Oceana	Osceola	Ottawa
5	Genesee	Lapeer	Shiawassee	
6	Arenac	Bay	Clare	Gladwin
	Gratiot	Huron	Iosco	Isabella
	Midland	Ogemaw	Roscommon	Saginaw
	Sanilac	Tuscola		
7	Alcona	Alpena	Antrim	Benzie
	Crawford	Charlevoix	Cheboygan	Emmet
	Gd. Traverse	Kalkaska	Leelanau	Manistee
	Missaukee	Montmorency	Oscoda	Otsego
	Presque Isle	Wexford		
8	Alger	Baraga	Chippewa	Delta
	Dickinson	Gogebic	Houghton	Iron
	Keweenaw	Luce	Mackinac	Marquette

CON REVIEW STANDARDS FOR UESWL SERVICES

Rural Michigan counties are as follows:

Alcona	Hillsdale	Ogemaw
Alger	Huron	Ontonagon
Antrim	Iosco	Osceola
Arenac	Iron	Oscoda
Baraga	Lake	Otsego
Charlevoix	Luce	Presque Isle
Cheboygan	Mackinac	Roscommon
Clare	Manistee	Sanilac
Crawford	Mason	Schoolcraft
Emmet	Montcalm	Tuscola
Gladwin	Montmorency	
Gogebic	Oceana	

Micropolitan statistical area Michigan counties are as follows:

Allegan	Gratiot	Mecosta
Alpena	Houghton	Menominee
Benzie	Isabella	Midland
Branch	Kalkaska	Missaukee
Chippewa	Keweenaw	St. Joseph
Delta	Leelanau	Shiawassee
Dickinson	Lenawee	Wexford
Grand Traverse	Marquette	

Metropolitan statistical area Michigan counties are as follows:

Barry	Ionia	Newaygo
Bay	Jackson	Oakland
Berrien	Kalamazoo	Ottawa
Calhoun	Kent	Saginaw
Cass	Lapeer	St. Clair
Clinton	Livingston	Van Buren
Eaton	Macomb	Washtenaw
Genesee	Monroe	Wayne
Ingham	Muskegon	

Source:

65 F.R., p. 82238 (December 27, 2000)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

APPENDIX D

ICD-9-CM TO ICD-10-CM CODE TRANSLATION

ICD-9 CODE	DESCRIPTION	ICD-10 CODE	DESCRIPTION
592.0	CALCULUS OF KIDNEY	N20.0	CALCULUS OF KIDNEY
		N20.2	CALCULUS OF KIDNEY WITH CALCULUS OF URETER
592.1	CALCULUS OF URETER	N20.1	CALCULUS OF URETER
		N20.2	CALCULUS OF KIDNEY WITH CALCULUS OF URETER
592.9	URINARY CALCULUS	N20.9	URINARY CALCULUS, UNSPECIFIED
		N22	CALCULUS OF URINARY TRACT IN DISEASES CLASSIFIED ELSEWHERE

"ICD-9-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE **INTERNATIONAL CLASSIFICATION OF DISEASES - 9TH REVISION - CLINICAL MODIFICATION,** PREPARED BY THE COMMISSION ON PROFESSIONAL AND HOSPITAL ACTIVITIES FOR THE U.S. NATIONAL CENTER FOR HEALTH STATISTICS.

"ICD-10-CM CODE" MEANS THE DISEASE CODES AND NOMENCLATURE FOUND IN THE INTERNATIONAL CLASSIFICATION OF DISEASES - 10TH REVISION - CLINICAL MODIFICATION, NATIONAL CENTER FOR HEALTH STATISTICS.