

1 **MICHIGAN DEPARTMENT OF COMMUNITY HEALTH AND HUMAN SERVICES**

2
3 **CERTIFICATE OF NEED (CON) REVIEW STANDARDS FOR**
4 **URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES**
5

6 (By authority conferred on the CON Commission by Section 22215 of Act No. 368 of the Public Acts of
7 1978, as amended, and sections 7 and 8 of Act No. 306 of the Public Acts of 1969, as amended, being
8 sections 333.22215, 24.207, and 24.208 of the Michigan Compiled Laws.)
9

10 **Section 1. Applicability**

11
12 Sec. 1. These standards are requirements for approval to initiate, replace, expand, or acquire an
13 UESWL service/unit under Part 222 of the Code. Urinary extracorporeal shock wave lithotripsy is a
14 covered clinical service for purposes of Part 222 of the Code. The Department shall use these standards
15 in applying Section 22225(1) of the Code, being Section 333.22225(1) of the Michigan Compiled Laws
16 and Section 22225(2)(c) of the Code, being Section 333.22225(2)(c) of the Michigan Compiled Laws.
17

18 **Section 2. Definitions**

19
20 Sec. 2. (1) For purposes of these standards:

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

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

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

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

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

32 (ii) Experienced interventional radiologic support.

33 (e) "Department" means the Michigan Department of **Community Health AND HUMAN SERVICES**
34 **(MDCHMDHHS).**

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

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

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

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

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

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

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

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

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

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

- 56 (n) "Planning area" means the state of Michigan.
 57 (o) "Region" means the geographic areas set forth in Appendix B.
 58 (p) "Renewal of a lease" means extending the effective period of a lease for an existing UESWL unit
 59 that does not involve either the replacement/upgrade of a UESWL unit, as defined in Section 4, or a
 60 change in the parties to the lease.
 61 (q) "Retreatment" means a UESWL procedure performed on the same side of the same patient
 62 within 6 months of a previous UESWL procedure performed at the same UESWL service. In the case of
 63 a mobile service, the term includes a retreatment performed at a different host site if the initial treatment
 64 was performed by the same service.
 65 (r) "Ureteroscopic stone removal procedure" means a stone removal procedure conducted in the
 66 ureter by means of an endoscope that may or may not include laser technology.
 67 (s) "Urinary extracorporeal shock wave lithotripsy" or "UESWL" means a procedure for the removal
 68 of kidney stones that involves focusing shock waves on kidney stones so that the stones are pulverized
 69 into sand-like particles, which then may be passed through the urinary tract.
 70 (t) "UESWL service" means either the CON-approved utilization of a UESWL unit(s) at one site in
 71 the case of a fixed UESWL service or at each host site in the case of a mobile UESWL service.
 72 (u) "UESWL unit" means the medical equipment that produces the shock waves for the UESWL
 73 procedure.

74
 75 (2) The definitions in Part 222 shall apply to these standards.
 76

77 **Section 3. Requirements to initiate a urinary extracorporeal shock wave lithotripsy service**
 78

79 Sec. 3. Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile,
 80 at a site that does not offer (or has not offered within the last consecutive 12-month period) approved
 81 UESWL services. The term does not include the acquisition or replacement of an existing UESWL
 82 service or the renewal of a lease.
 83

- 84 (1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
 85 (a) The capability to provide complicated stone disease treatment on-site.
 86 (b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
 87 (c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of
 88 the following:
 89 (i) On-call availability of an anesthesiologist and a surgeon.
 90 (ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
 91 (iii) **EITHER On-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH**
 92 **FACILITY, IV supplies and materials for infusions and medications, blood and blood products, and**
 93 **pharmaceuticals, including vasopressor medications, antibiotics, and fluids and solutions.**
 94 (iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator,
 95 general radiography and fluoroscopy, cystoscopy, and laboratory services.
 96 (v) On-site crash cart.
 97 (vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a
 98 cardiac intensive care unit.
 99 (vii) **EITHER On-site OR THROUGH A CONTRACTUAL AGREEMENT WITH ANOTHER HEALTH**
 100 **FACILITY, A 23-hour holding unit.**

101
 102 **(2) AN APPLICANT PROPOSING TO INITIATE A FIXED UESWL SERVICE THAT MEETS THE**
 103 **FOLLOWING REQUIREMENTS SHALL NOT BE REQUIRED TO BE IN COMPLIANCE WITH**
 104 **SUBSECTION (1)(B):**

- 105 **(a) THE APPLICANT HOSPITAL IS CURRENTLY AN EXISTING MOBILE UESWL HOST SITE.**
 106 **(b) THE APPLICANT HOSPITAL HAS PERFORMED AN AVERAGE OF AT LEAST 500**
 107 **PROCEDURES ANNUALLY FOR THE PAST THREE YEARS PRIOR TO SUBMITTING AN**
 108 **APPLICATION.**

109 (c) THE APPLICANT HOSPITAL OPERATES AN EMERGENCY ROOM THAT PROVIDES 24-
110 HOUR EMERGENCY CARE SERVICES AND AT LEAST 80,000 VISITS WITHIN THE MOST RECENT
111 12-MONTH PERIOD FOR WHICH DATA, VERIFIABLE BY THE DEPARTMENT, IS AVAILABLE.

112 (d) THE APPLICANT HOSPITAL SHALL INSTALL AND OPERATE THE FIXED UESWL UNIT AT
113 THE SAME SITE AS THE EXISTING HOST SITE.

114 (e) THE APPLICANT HOSPITAL SHALL CEASE OPERATION AS A HOST SITE AND NOT
115 BECOME A HOST SITE FOR AT LEAST 12 MONTHS FROM THE DATE THE FIXED SERVICE
116 BECOMES OPERATIONAL.

117 118 **Section 4. Requirements to replace an existing UESWL unit(s)** 119

120 Sec. 4. Replace an existing UESWL unit means an equipment change of an existing UESWL unit,
121 other than an upgrade, proposed by an applicant that results in that applicant operating the same number
122 of UESWL units before and after the project completion. The term does not include an upgrade of an
123 existing UESWL unit, changing a mobile UESWL unit to a fixed UESWL unit, or changing a fixed UESWL
124 unit to a mobile UESWL unit. Replacement also means a change in the location of a fixed UESWL unit(s)
125 from the existing site to a different site, OR a change in the geographic location of an existing fixed
126 UESWL service and its unit(s) from an existing site to a different site.

127
128 (1) "Upgrade an existing UESWL unit" means any equipment change, other than a replacement, that
129 involves a capital expenditure of \$125,000 or less in any consecutive 24-month period.

130
131 (2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate the following:
132 ~~—(a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at~~
133 ~~least 1,000 UESWL procedures per unit during the most recent continuous 12-month period for which the~~
134 ~~Department has verifiable data.~~

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

137
138 ~~—(3) An applicant proposing to replace a UESWL unit shall demonstrate one or more of the following:~~

139 (a) The existing equipment clearly poses a threat to the safety of the public.

140 (b) The proposed replacement UESWL unit offers technological improvements that enhance quality
141 of care, increase efficiency, or reduce operating costs and patient charges.

142 (c) The existing equipment is fully depreciated according to generally accepted accounting principles.

143
144 (43) An applicant that demonstrates that it meets the requirements in this subsection shall not be
145 required to demonstrate compliance with Section 4(2):

146 ~~—(a) The proposed project involves replacing~~PROPOSING TO REPLACE 1 existing fixed UESWL unit
147 with 1 mobile UESWL unit SHALL DEMONSTRATE THAT THE PROPOSED PROJECT MEETS ALL OF
148 THE FOLLOWING-:

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

152 (b) The proposed mobile unit will serve at least 1 host site that is located in a region other than the
153 region in which the fixed UESWL unit proposed to be replaced is located currently.

154 (c) At least 100 UESWL procedures are projected in each region in which the proposed mobile
155 UESWL unit is proposed to operate when the results of the methodology in Section 10 are combined for
156 the following, as applicable:

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

159 (ii) All sites that receive UESWL services from an existing UESWL service and propose to receive
160 UESWL services from the proposed mobile unit and that are located in the region identified in subsection
161 (c).

162 (d) A separate application from each host site is filed at the same time the application to replace a
163 fixed unit is submitted to the Department.

164 (e) The proposed mobile UESWL unit is projected to perform at least 1,000 procedures annually
165 pursuant to the methodology set forth in Section 10.
166

167 (54) An applicant proposing to ~~relocate~~ **REPLACE its AN** existing **FIXED** UESWL service and its
168 unit(s) **TO A NEW SITE** shall demonstrate that the proposed project meets all of the following:

169 (a) ~~The UESWL service and its unit(s) to be relocated is a fixed UESWL unit(s).~~
170 ~~(b)~~ The UESWL service to be ~~relocated~~ **REPLACED** has been in operation for at least 36 months as
171 of the date an application is submitted to the Department **UNLESS THE APPLICANT MEETS THE**
172 **REQUIREMENT IN SUBSECTION (d)(i) OR (ii).**

173 (eb) The site to which the UESWL service will be ~~relocated~~ **REPLACED** meets the requirements of
174 Section 3(1)(c).

175 (ec) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site
176 of the UESWL service to be ~~relocated~~ **REPLACED.**

177 (ed) The UESWL service and its unit(s) to be ~~relocated~~ **REPLACED** performed an average of at least
178 1,000 procedures per unit in the most recent 12-month period for which the Department has verifiable
179 data **UNLESS ONE OF THE FOLLOWING REQUIRMENTS ARE MET:-**

180 (i) **THE OWNER OF THE BUILDING WHERE THE SITE IS LOCATED HAS INCURRED A FILING**
181 **FOR BANKRUPTCY UNDER CHAPTER SEVEN (7) WITHIN THE LAST THREE YEARS;**

182 (ii) **THE OWNERSHIP OF THE BUILDING WHERE THE SITE IS LOCATED HAS CHANGED**
183 **WITHIN 24 MONTHS OF THE DATE OF THE SERVICE BEING OPERATIONAL; OR**

184 (iii) **THE UESWL SERVICE BEING REPLACED IS PART OF THE REPLACEMENT OF AN ENTIRE**
185 **HOSPITAL TO A NEW GEOGRAPHIC SITE AND HAS ONLY ONE (1) UESWL UNIT.**

186 (fe) The applicant agrees to operate the UESWL service and its unit(s) in accordance with all
187 applicable project delivery requirements set forth in Section 9 of these standards.
188

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

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

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

195 (c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site
196 of the fixed UESWL unit to be ~~relocated~~ **REPLACED.**

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

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

202 (f) For volume purposes, the new site shall remain associated with the existing UESWL service for a
203 minimum of three years.
204

205 (76) Equipment that is replaced shall be removed from service and disposed of or rendered
206 considerably inoperable on or before the date that the replacement equipment becomes operational.
207

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

209
210 Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing
211 UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile,
212 unless otherwise specified, shall demonstrate the following:

213
214 (1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic
215 location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures
216 per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In
217 computing this average, the Department will divide the total number of UESWL procedures performed by

218 the applicant's total number of UESWL units, including both operational and approved but not operational
219 fixed and mobile UESWL units.

220
221 (2) The applicant shall project an average of at least 1,000 procedures for each existing and
222 proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section
223 10 of these standards for the second 12-month period after initiation of operation of each additional
224 UESWL unit whether fixed or mobile.

225
226 (3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the
227 existing or revised contracts between the central service coordinator and each host site(s) that includes
228 the same stipulations as specified in Section 7(1)(c).

229
230 **Section 6. Requirements to acquire an existing UESWL service or an existing UESWL unit(s)**
231

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

235
236 (1) ~~An-THE applicant proposing to acquire an existing fixed or mobile UESWL service and its unit(s)~~
237 ~~shall not be required to be in compliance with the volume requirement applicable to the seller/lessor on~~
238 ~~the date the acquisition occurs demonstrate that AIF THE proposed project meets all-ONE of the~~
239 following:

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

246 (b) ~~THE EXISTING FIXED OR MOBILE UESWL SERVICE IS OWNED BY, IS UNDER COMMON~~
247 ~~CONTROL OF, OR HAS A COMMON PARENT AS THE APPLICANT, AND THE UESWL SERVICE~~
248 ~~SHALL REMAIN AT THE SAME SITE.~~

249
250 (2) ~~For any application for proposed acquisition of an existing fixed or mobile UESWL service, except~~
251 ~~the first-AN application approved pursuant to subsection (a1), for which a final decision has not been~~
252 ~~issued after May 2, 1998, an applicant shall be required to demonstrate that the UESWL service and its~~
253 ~~unit(s) to be acquired performed an average of at least 1,000 procedures per unit in the most recent 12-~~
254 ~~month period for which the Department has verifiable data.~~

255
256 (23) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing
257 UESWL service shall demonstrate that the proposed project meets all of the following:

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

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

263
264 (4) ~~The UESWL service and its unit(s) shall be operating at the applicable volume requirements set~~
265 ~~forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is~~
266 ~~acquired, and annually thereafter.~~

267
268 **Section 7. Additional requirements for approval for mobile UESWL services**
269

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

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

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

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

279 (b) The normal route schedule, the procedures for handling emergency situations, and copies of all
280 potential contracts related to the mobile UESWL service and its unit(s) shall be included in the CON
281 application submitted by the central service coordinator.

282
283 (2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that
284 proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL
285 service and its unit(s) operates predominantly outside of Michigan and all of the following requirements
286 are met:

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

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

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

292
293 (3) A central service coordinator proposing to add, or an applicant proposing to become, a host site
294 on either an existing or a proposed mobile UESWL service shall demonstrate that it meets the
295 requirements of Section 3(1)(C).

296
297 ~~—(4) A central service coordinator proposing to add, or an applicant proposing to become, a host site
298 on an existing mobile UESWL service in a region not currently served by that service shall demonstrate
299 that at least 100 UESWL procedures are projected in each region in which the existing mobile UESWL
300 service is proposing to add a host site when the results of the methodology in Section 10 are combined
301 for the following, as applicable:~~

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

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

307 **Section 8. Requirements for Medicaid participation**

308
309
310 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new
311 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
312 to the Department within six (6) months from the offering of service if a CON is approved.

313 **Section 9. Project delivery requirements terms of approval for all applicants**

314
315
316 Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved
317 UESWL units, shall be delivered in compliance with the following:

318
319 (1) Compliance with these standards.

320
321 (2) Compliance with the following quality assurance standards:

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

324 (b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care
325 practitioners.

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

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

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

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

341 (g) An applicant shall provide UESWL program access to approved physician residency programs for
342 teaching purposes.

343

344 (3) Compliance with the following access to care requirements:

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

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

347 (ii) Provide all UESWL services to any individual based on clinical indications of need for the
348 services, and

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

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

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

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

356

357 (4) Compliance with the following monitoring and reporting requirements:

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

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

373 (c) The applicant shall provide the Department with timely notice of the proposed project
374 implementation consistent with applicable statute and promulgated rules.

375

376 (5) Compliance with the following mobile UESWL requirements, if applicable:

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

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

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

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

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

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

397
398 (6) The agreements and assurances required by this Section shall be in the form of a certification
399 agreed to by the applicant or its authorized agent.

400
401 **Section 10. Methodology for projecting UESWL procedures**

402
403 Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of
404 UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is
405 submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified
406 in the most recent Michigan Inpatient Database available to the Department on the date an application is
407 deemed complete shall be used for each licensed hospital site for which a signed data commitment form
408 has been provided to the Department in accordance with the provisions of Section 11. In applying
409 inpatient discharge data in the methodology, each inpatient record shall be used only once and the
410 following steps shall be taken in sequence:

411 (a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM
412 codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.

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

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

421
422 (2) For a site or sites that provide UESWL services as of the date an application is submitted to the
423 Department, the actual number of UESWL procedures performed at each site, during the most recent
424 continuous 12-month period for which the Department has verifiable data, shall be the number used to
425 project the number of UESWL procedures that will be performed at that site or sites.

426
427 (3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as
428 applicable, shall be summed and the result is the projected number of UESWL procedures for the
429 proposed UESWL unit for purposes of the applicable sections of these standards.

430
431 (4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide
432 access to verifiable hospital-specific data and documentation using a format prescribed by the
433 Department.

434
435 **Section 11. Requirements for MIDB data commitments**

436
437 Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant
438 shall demonstrate or agree to, as applicable, all of the following.

439 (a) A licensed hospital site whose MIDB data is used in support of a CON application for a UESWL
440 service shall not use any of its MIDB data in support of any other application for a UESWL service for 5
441 years following the date the UESWL service to which the MIDB data are committed begins to operate.

442 The licensed hospital site shall be required to commit 100% of its inpatient discharge data to a CON
443 application.

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

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

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

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

450 (c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting
451 patients regularly as of the date the director makes the final decision on that application under Section
452 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

453
454 (2) The Department shall consider an MIDB data commitment in support of an application for a
455 UESWL service from a licensed hospital site that meets all of the following:

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

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

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

463

464 **Section 12. Effect on prior planning policies; comparative reviews**

465

466 Sec. 12. (1) These CON review standards supersede and replace the CON review standards for
467 urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on
468 ~~March 18~~ **SEPTEMBER 25, 2014** and effective on ~~June~~ **DECEMBER 22, 2014**.

469

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

471

Factor For Calculating Projected UESWL Procedures

(1) Until changed by the Department, the factor to be used in Section 10(1)(b) used for calculating the projected number of UESWL procedures shall be 1.09104.

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

(a) Steps for determining 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 COUNTY CLASSIFICATIONS FOUND IN APPENDIX C. "Metropolitan statistical area counties" will be assigned "urban" status, and "micropolitan statistical area" and "rural" counties will be assigned "rural" status.

(ii) Aggregate the records from step (a)(i) by zip code "urban/rural" status.

(iii) Identify the zip codes in which all records are either "urban" status or "rural" status. Aggregate the number of records and zip code populations separately by "urban/rural" status.

(iv) For zip codes having records in both "urban" and "rural" status, Calculate the proportion of 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 of each zip code by its respective "urban" and "rural" proportions.

(v) Aggregate the records 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. 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) 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) 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

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Counties assigned to each region are as follows:

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

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Rural Michigan counties are as follows:

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

Micropolitan statistical area Michigan counties are as follows:

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

Metropolitan statistical area Michigan counties are as follows:

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

Source:

75 F.R., p. 37245 (June 28, 2010)
Statistical Policy Office
Office of Information and Regulatory Affairs
United States Office of Management and Budget

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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

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"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.