

1 MICHIGAN DEPARTMENT OF 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**

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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 Health and Human Services (MDHHS).

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

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

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

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

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

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

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

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

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

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

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

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

73
74 (2) The definitions in Part 222 shall apply to these standards.

75
76 **Section 3. Requirements to initiate a urinary extracorporeal shock wave lithotripsy service**

77
78 Sec. 3. Initiate a UESWL service means to begin operation of a UESWL unit, whether fixed or mobile,
79 at a site that does not offer (or has not offered within the last consecutive 12-month period) approved
80 UESWL services. The term does not include the acquisition or replacement of an existing UESWL
81 service or the renewal of a lease.

- 82
83 (1) An applicant proposing to initiate a UESWL service shall demonstrate each of the following:
- 84 (a) The capability to provide complicated stone disease treatment on-site.
- 85 (b) At least 1,000 procedures are projected pursuant to the methodology set forth in Section 10(1).
- 86 (c) The proposed UESWL service shall be provided at a site that provides, or will provide, each of
87 the following:
- 88 (i) On-call availability of an anesthesiologist and a surgeon.
- 89 (ii) On-site Advanced Cardiac Life Support (ACLS)-certified personnel and nursing personnel.
- 90 (iii) Either on-site or through a contractual agreement with another health facility, IV supplies and
91 materials for infusions and medications, blood and blood products, and pharmaceuticals, including
92 vasopressor medications, antibiotics, and fluids and solutions.
- 93 (iv) On-site general anesthesia, EKG, cardiac monitoring, blood pressure, pulse oximeter, ventilator,
94 general radiography and fluoroscopy, cystoscopy, and laboratory services.
- 95 (v) On-site crash cart.
- 96 (vi) On-site cardiac intensive care unit or a written transfer agreement with a hospital that has a
97 cardiac intensive care unit.
- 98 (vii) Either on-site or through a contractual agreement with another health facility, a 23-hour holding
99 unit.

- 100
101 (2) An applicant proposing to initiate a fixed UESWL service that meets the following requirements
102 shall not be required to be in compliance with subsection (1)(b):
- 103 (a) The applicant hospital is currently an existing mobile UESWL host site.
- 104 (b) The applicant hospital has performed an average of at least 500 procedures annually for the past
105 three years prior to submitting an application.
- 106 (c) The applicant hospital operates an emergency room that provides 24-hour emergency care
107 services and at least 80,000 visits within the most recent 12-month period for which data, verifiable by the
108 Department, is available.
- 109 (d) The applicant hospital shall install and operate the fixed UESWL unit at the same site as the
110 existing host site.

111 (e) The applicant hospital shall cease operation as a host site and not become a host site for at least
112 12 months from the date the fixed service becomes operational.

114 **Section 4. Requirements to replace an existing UESWL unit(s)**

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

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

126 (2) An applicant proposing to replace an existing UESWL unit(s) shall demonstrate one or more of
127 the following:

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

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

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

132 (3) An applicant proposing to replace 1 existing fixed UESWL unit with 1 mobile UESWL unit shall
133 demonstrate that the proposed project meets all of the following:

134 (a) Each existing UESWL unit of the service proposing to replace a UESWL unit has averaged at
135 **least 1,000 UESWL procedures per MOBILE unit AND 500 PER FIXED UNIT** during the most recent
136 continuous 12-month period for which the Department has verifiable data.

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

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

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

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

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

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

151 (4) An applicant proposing to replace an existing fixed UESWL service and its unit(s) to a new site
152 shall demonstrate that the proposed project meets all of the following:

153 (a) The UESWL service to be replaced has been in operation for at least 36 months as of the date an
154 application is submitted to the Department unless the applicant meets the requirement in subsection (d)(i)
155 or (ii).

156 (b) The site to which the UESWL service will be replaced meets the requirements of Section 3(1)(c).

157 (c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site
158 of the UESWL service to be replaced.

159 **(d) The UESWL service and its unit(s) to be replaced performed an average of at least 4,000,500**
160 procedures per unit in the most recent 12-month period for which the Department has verifiable data
161 unless one of the following requirements are met:

- 165 (i) the owner of the building where the site is located has incurred a filing for bankruptcy under
166 chapter 7 within the last three years;
- 167 (ii) the ownership of the building where the site is located has changed within 24 months of the date
168 of the service being operational; or
- 169 (iii) the UESWL service being replaced is part of the replacement of an entire hospital to a new
170 geographic site and has only one (1) UESWL unit.
- 171 (e) the applicant agrees to operate the UESWL service and its unit(s) in accordance with all
172 applicable project delivery requirements set forth in Section 9 of these standards.

173
174 (5) An applicant proposing to replace a fixed UESWL unit(s) of an existing UESWL service **TO A**
175 **NEW SITE** shall demonstrate that the proposed project meets all of the following:

- 176 (a) The existing UESWL service from which the UESWL unit(s) is to be replaced has been in
177 operation for at least 36 months as of the date an application is submitted to the Department.
- 178 (b) The site to which the UESWL unit(s) will be replaced meets the requirements of Section 3(1)(c).
- 179 (c) The proposed new site is in the state of Michigan and within a 25-mile radius of the existing site
180 of the fixed UESWL unit to be replaced.
- 181 (d) Each existing UESWL unit(s) at the service from which a unit is to be replaced performed at least
182 an average of **4,0500** procedures per fixed unit in the most recent 12-month period for which the
183 Department has verifiable data.
- 184 (e) The applicant agrees to operate the UESWL unit(s) in accordance with all applicable project
185 delivery requirements set forth in Section 9 of these Standards.
- 186 (f) For volume purposes, the new site shall remain associated with the existing UESWL service for a
187 minimum of three years.

188
189 (6) Equipment that is replaced shall be removed from service and disposed of or rendered
190 considerably inoperable on or before the date that the replacement equipment becomes operational.

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

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193
194 Sec. 5. Expand an existing UESWL service means the addition of one UESWL unit at an existing
195 UESWL service. An applicant proposing to expand an existing UESWL service, whether fixed or mobile,
196 unless otherwise specified, shall demonstrate the following:

197
198 (1) All of the applicant's existing UESWL units, both fixed and mobile, at the same geographic
199 location as the proposed additional UESWL unit, have performed an average of at least 1,800 procedures
200 per UESWL unit during the most recent 12-month period for which the Department has verifiable data. In
201 computing this average, the Department will divide the total number of UESWL procedures performed by
202 the applicant's total number of UESWL units, including both operational and approved but not operational
203 fixed and mobile UESWL units.

204
205 (2) The applicant shall project an average of at least 1,000 procedures for each existing and
206 proposed fixed and mobile UESWL unit(s) as a result from the application of the methodology in Section
207 10 of these standards for the second 12-month period after initiation of operation of each additional
208 UESWL unit whether fixed or mobile.

209
210 (3) An applicant proposing to expand an existing mobile UESWL service must provide a copy of the
211 existing or revised contracts between the central service coordinator and each host site(s) that includes
212 the same stipulations as specified in Section 7(1)(c).

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

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215
216 Sec. 6. Acquisition of an existing UESWL service or existing UESWL unit(s)" means obtaining
217 possession or control of an existing fixed or mobile UESWL service or existing UESWL unit(s) by
218 purchase, lease, donation, or other comparable arrangement.

220 (1) The applicant shall not be required to be in compliance with the volume requirement applicable to
221 the seller/lessor on the date the acquisition occurs if the proposed project meets one of the following:

222 (a) It is the first acquisition of the existing fixed or mobile UESWL service for which a final decision
223 has not been issued after May 2, 1998.

224 (b) The existing fixed or mobile UESWL service is owned by, is under common control of, or has a
225 common parent as the applicant, and the UESWL service shall remain at the same site.

226
227 (2) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except
228 an application approved pursuant to subsection (1), an applicant shall be required to demonstrate that the
229 UESWL service and its unit(s) to be acquired performed an average of at least 1,000 procedures per
230 **MOBILE unit AND 500 PER FIXED UNIT in the most recent 12-month period for which the Department**
231 **has** verifiable data.

232
233 (3) An applicant proposing to acquire an existing fixed or mobile UESWL unit(S) of an existing
234 UESWL service shall demonstrate that the proposed project meets all of the following:

235 (a) For any application for proposed acquisition of an existing fixed or mobile UESWL unit(s), an
236 applicant shall be required to demonstrate that the UESWL unit(s) to be acquired performed an average
237 **of at least 1,000 procedures per MOBILE unit AND 500 PROCEDURES PER FIXED UNIT in the most**
238 **recent 12-month period for which the Department has verifiable data.**

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

240
241 (4) The UESWL service and its unit(s) shall be operating at the applicable volume requirements set
242 forth in Section 9 of these standards in the second 12 months after the date the service and its unit(s) is
243 acquired, and annually thereafter.

244 **Section 7. Additional requirements for approval for mobile UESWL services**

245
246
247 Sec. 7. (1) An applicant proposing to begin operation of a mobile UESWL service in Michigan shall
248 demonstrate that it meets all of the following:

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

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

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

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

259 **(c) A SEPARATE CON APPLICATION HAS BEEN SUBMITTED BY THE CSC AND EACH**
260 **PROPOSED HOST SITE.**

261
262 (2) The requirements of sections 3, 4, and subsection (1)(a) shall not apply to an applicant that
263 proposes to add a Michigan site as a host site if the applicant demonstrates that the mobile UESWL
264 service and its unit(s) operates predominantly outside of Michigan and all of the following requirements
265 are met:

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

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

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

271
272 (3) A central service coordinator proposing to add, or an applicant proposing to become, a host site
273 **on either an existing or a proposed mobile UESWL service shall demonstrate that it meets ALL OF the**
274 **FOLLOWING:**

- 275 (a) THE requirements of Section 3(1)(C).
276 (b) THE NORMAL ROUTE SCHEDULE, THE PROCEDURES FOR HANDLING EMERGENCY
277 SITUATIONS, AND COPIES OF ALL POTENTIAL CONTRACTS RELATED TO THE MOBILE UESWL
278 SERVICE AND ITS UNIT(S) SHALL BE INCLUDED IN THE CON APPLICATION SUBMITTED BY THE
279 CENTRAL SERVICE COORDINATOR OR THE APPLICANT HOST SITE.

280 281 **Section 8. Requirements for Medicaid participation**

282
283 Sec. 8. An applicant shall provide verification of Medicaid participation. An applicant that is a new
284 provider not currently enrolled in Medicaid shall certify that proof of Medicaid participation will be provided
285 to the Department within six (6) months from the offering of service if a CON is approved.

286 287 **Section 9. Project delivery requirements terms of approval for all applicants**

288
289 Sec 9. An applicant shall agree that, if approved, UESWL services, including all existing and approved
290 UESWL units, shall be delivered in compliance with the following:

- 291 (1) Compliance with these standards.
- 292 (2) Compliance with the following quality assurance standards:
- 293 (a) The medical staff and governing body shall receive and review at least annual reports describing
294 activities of the UESWL service, including complication rates, morbidity data, and retreatment rates.
- 295 (b) An applicant shall accept referrals for UESWL services from all appropriately licensed health care
296 practitioners.
- 297 (c) An applicant shall develop and utilize a standing medical staff and governing body rule that
298 provides for the medical and administrative control of the ordering and utilization of UESWL services.
- 299 (d) An applicant shall require that each urologist serving as a UESWL surgeon shall have completed
300 an approved training program in the use of the lithotripter at an established facility with UESWL services.
- 301 (e) An applicant shall establish a process for credentialing urologists who are authorized to perform
302 UESWL procedures at the applicant facility. This shall not be construed as a requirement to establish
303 specific credentialing requirements for any particular hospital or UESWL site.
- 304 (f) A urologist who is not an active medical staff member of an applicant facility shall be eligible to
305 apply for limited staff privileges to perform UESWL procedures. Upon request by the Department, an
306 applicant shall provide documentation of its process that will allow a urologist who is not an active medical
307 staff member to apply for medical staff privileges for the sole and limited purpose of performing UESWL
308 procedures. In order to be granted staff privileges limited to UESWL procedures, a urologist shall
309 demonstrate that he or she meets the same requirements, established pursuant to the provisions of
310 subsection (e), that a urologist on an applicant facility's active medical staff must meet in order to perform
311 UESWL procedures.
- 312 (g) An applicant shall provide UESWL program access to approved physician residency programs for
313 teaching purposes.
- 314 (3) Compliance with the following access to care requirements:
- 315 (a) An applicant, to assure appropriate utilization by all segments of the Michigan population, shall:
- 316 (i) Not deny any UESWL services to any individual based on inability to pay or source of payment,
317 (ii) Provide all UESWL services to any individual based on clinical indications of need for the
318 services, and
319 (iii) Maintain information by payor and non-paying sources to indicate the volume of care from each
320 source provided annually.
- 321 (b) An applicant shall participate in Medicaid at least 12 consecutive months within the first two years
322 of operation and continue to participate annually thereafter.
- 323 (c) The operation of and referral of patients to the UESWL service shall be in conformance with 1978
324 PA 368, Sec. 16221, as amended by 1986 PA 319; MCL 333.16221; MSA 14.15 (16221).
- 325 Compliance with selective contracting requirements shall not be construed as a violation of this term.
- 326
327
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329

330 (4) Compliance with the following monitoring and reporting requirements:
331 (a) Each UESWL unit, ~~whether fixed or mobile~~, shall perform at least an average of 1,000 procedures
332 per MOBILE unit AND 500 PER FIXED UNIT per year in the second 12 months of operation and annually
333 thereafter. The central service coordinator shall demonstrate that a mobile UESWL unit approved
334 pursuant to these standards performed at least 100 procedures in each region that is served by the
335 mobile unit. For purposes of this requirement, the number of UESWL procedures performed at all host
336 sites in the same region shall be combined.

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

346 (c) The applicant shall provide the Department with timely notice of the proposed project
347 implementation consistent with applicable statute and promulgated rules.
348

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

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

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

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

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

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

368 (f) A mobile UESWL service shall operate under a contractual agreement that includes the provision
369 of UESWL services at each host site on a regularly scheduled basis.
370

371 (6) The agreements and assurances required by this Section shall be in the form of a certification
372 agreed to by the applicant or its authorized agent.
373

374 **Section 10. Methodology for projecting UESWL procedures**

375
376 Sec. 10. (1) The methodology set forth in this subsection shall be used for projecting the number of
377 UESWL procedures at a site or sites that do not provide UESWL services as of the date an application is
378 submitted to the Department. In applying the methodology, actual inpatient discharge data, as specified
379 in the most recent Michigan Inpatient Database available to the Department on the date an application is
380 deemed complete shall be used for each licensed hospital site for which a signed data commitment form
381 has been provided to the Department in accordance with the provisions of Section 11. In applying
382 inpatient discharge data in the methodology, each inpatient record shall be used only once and the
383 following steps shall be taken in sequence:

- 384 (a) The number of inpatient records with a diagnosis, either principal or nonprincipal, of ICD-9-CM
 385 codes 592.0, 592.1, or 592.9 (see Appendix D for ICD-10-CM Codes) shall be counted.
- 386 (b) The result of subsection (a) shall be multiplied by the factor specified in Appendix A for each
 387 licensed hospital site that is committing its inpatient discharge data to a CON application. If more than
 388 one licensed hospital site is committing inpatient discharge data in support of a CON application, the
 389 products from the application of the methodology for each licensed hospital site shall be summed.
- 390 (c) The result of subsection (b) is the total number of projected UESWL procedures for an application
 391 that is proposing to provide fixed or mobile UESWL services at a site, or sites in the case of a mobile
 392 service, that does not provide UESWL service, either fixed or mobile, as of the date an application is
 393 submitted to the Department.
- 394
- 395 (2) For a site or sites that provide UESWL services as of the date an application is submitted to the
 396 Department, the actual number of UESWL procedures performed at each site, during the most recent
 397 continuous 12-month period for which the Department has verifiable data, shall be the number used to
 398 project the number of UESWL procedures that will be performed at that site or sites.
- 399
- 400 (3) For a proposed UESWL unit, except for initiation, the results of subsections (1) and (2), as
 401 applicable, shall be summed and the result is the projected number of UESWL procedures for the
 402 proposed UESWL unit for purposes of the applicable sections of these standards.
- 403
- 404 (4) An applicant that is projecting UESWL procedures pursuant to subsection (1) shall provide
 405 access to verifiable hospital-specific data and documentation using a format prescribed by the
 406 Department.

407
 408 **Section 11. Requirements for MIDB data commitments**

409
 410 Sec. 11. (1) In order to use MIDB data in support of an application for UESWL services, an applicant
 411 shall demonstrate or agree to, as applicable, all of the following.

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

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

- 419 (i) The Michigan Health and Hospital Association may verify the MIDB data for the Department.
- 420 (ii) An applicant shall pay all charges associated with verifying the MIDB data.
- 421 (iii) The commitment of the MIDB data remains in effect for the period of time specified in subsection
 422 (1)(a).

423 (c) A licensed hospital site that is proposing to commit MIDB data to an application is admitting
 424 patients regularly as of the date the director makes the final decision on that application under Section
 425 22231(9) of the Code, being Section 333.22231(9) of the Michigan Compiled Laws.

426
 427 (2) The Department shall consider an MIDB data commitment in support of an application for a
 428 UESWL service from a licensed hospital site that meets all of the following:

- 429 (a) The licensed hospital site proposing to commit MIDB data to an application does not provide, or
 430 does not have a valid CON to provide, UESWL services, either fixed or mobile, as of the date an
 431 application is submitted to the Department.
- 432 (b) The licensed hospital site proposing to commit MIDB data is located in a region in which a
 433 proposed fixed UESWL service is proposed to be located or, in the case of a mobile unit, has at least one
 434 host site proposed in that region.
- 435 (c) The licensed hospital site meets the requirements of subsection (1), as applicable.

436
 437 **Section 12. Effect on prior planning policies; comparative reviews**

439 Sec. 12. (1) These CON review standards supersede and replace the CON review standards for
440 urinary extracorporeal shock wave lithotripsy (UESWL) services approved by the CON Commission on
441 ~~September 25, 2014~~ **MARCH 27, 2018** and effective on ~~December 22, 2014~~ **MAY 29, 2018**.

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

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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 **1.494353**.

(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 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.