

URINARY EXTRACORPOREAL SHOCK WAVE LITHOTRIPSY (UESWL) SERVICES

WORKGROUP CHARGE

Approved by the Certificate of Need (CON) Commission on January 29, 2013

The UESWL workgroup will determine if the service (UESWL) should be deregulated, or if continuing to regulate, review the volume criteria for expansion.

MDCH Recommendations for CON Standards Scheduled for 2010 Review

Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards			
Should there be continued regulation of UESWL under CON?	No. MDCH recommends that the Commission consider deregulating UESWL services.		
Identified Issues	Issue Recommended for Review?	Recommended Course of Action to Review Issues:	Other/Comments:
Decrease the volume requirement for expansion of a mobile lithotripsy service.	No	None	There is no evidence of statewide implications or impact of the change on a statewide basis.

MDCH Staff Analysis of the Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards

Pursuant to MCL 333.22215 (1) (m), the Certificate of Need (CON) Commission is to "...review, and if necessary, revise each set of CON standards at least every 3 years." In accordance with the established review schedule on the Commission Work Plan, the UESWL Services Standards are scheduled for review in calendar year 2013.

Public Comment Period Testimony

The Department held a Public Comment Period to receive testimony regarding the Standards on October 10 - 24, 2012. Testimony was received from six (6) organizations and is summarized as follows:

1. Patrick O' Donovan, Beaumont Health System:

- Supports the continued regulation of this lithotripsy services.
- Recommends decreasing the volume requirement for expansion of a mobile lithotripsy route.
- Additionally, they believe that without adequate lithotripsy access, patients with kidney stones may have to undergo invasive ureteroscopy procedures.

2. Jorgen Madsen, United Medical Systems/Great Lakes Lithotripsy:

- Strongly believes that there should be continued regulation of the UESWL services, because lithotripsy is an outpatient service with a high potential for abuse. Unlike many other health services, lithotripsy is not considered a "designated health service" under Stark and physician self-referral is not restricted under those regulations.
- CON has lowered costs to providers within Michigan: Nationally, the charge by a mobile lithotripsy provider to the facility receiving

service is between \$2,200 and \$2,400 per procedure. However, in Michigan the rate charged is between \$1,400 and \$1,500 per procedure.

- Further, CON in Michigan acts as a deterrent for physicians who may otherwise have been lured into less than ideal schemes to bring in revenues.

3. *Sean Gehle, Ascension Health*

- Supports the continued regulation of lithotripsy services and does not recommend any changes to the current standards.

4. *Karen Kippen, Henry Ford Health System*

- Continues to support regulation of lithotripsy services because the current standards encourage and allows many facilities to share equipment.
- By sharing equipment, and the technologist that operates the equipment, also helps to ensure high quality service by maintaining consistent and relatively high volumes performed by the same technologists.
- Because lithotripsy is not covered by Stark regulations, the CON regulations help to reduce physician self-referral and keep the service in the most appropriate setting.

5. *Robert Meeker, Spectrum Health*

- Continues to support regulation of lithotripsy services.
- Strongly urges the Commission consider reducing the volume requirement for expanding the number of lithotripsy machines on a given mobile route.
- The current level of 1800 procedures per machine per year is unrealistically high and inhibits the ability of mobile lithotripsy providers to adequately serve the needs of patients.

6. *Ted Amland, Greater Michigan Lithotripsy*

- Supports continued regulation of lithotripsy services.
- Recommends reducing the volume requirement to 1,200 to expand a mobile route, which is more consistent with national experiences.
- Proposes a rural adjustment factor of two (2) be applied to rural host sites, both those currently providing and those applying to initiate lithotripsy services.
- Proposes allowance for using a temporary lithotripsy unit during downtimes for repairs, without having to apply for an emergency CON. This could potentially be addressed by allowing existing units to cross HSA boundaries.

Summary of Public Input:

Five (5) organizations submitted testimony containing reasons why UESWL should continue to be regulated under CON. The reasons they gave are as follows: if UESWL is deregulated, then physicians would have easier access to obtaining their own machine abuse would occur as these physicians would have a direct financial incentive to perform more litho procedures, and UESWL and other outpatient procedures are typically areas where abuse of this nature can occur. Proponents of continued regulation stated that a proliferation of equipment would occur if deregulation took place, and that CON provides an oversight role in UESWL treatments.

Regulation of Covered Service

Out of 36 states with CON programs, Michigan is one of 15 states which regulate Lithotripsy Services within CON.

UESWL Survey Data for 2011:

Facility No.	Type	Facility Name:	# Units	# Procedures
33M147	M	Great Lakes Lithotripsy	1	1,521
33M023	M	Great Lakes Lithotripsy, LLC	2	2,545
33M074	M	Great Lakes Lithotripsy, LLC	1	2,438
33.M103	M	Michigan CON, LLC	2	2,186
99.M167	M	Greater Michigan Lithotripsy	1	1,141
41M165	M	Spectrum Health – Butterworth	1	1,108
63M164	M	William Beaumont Hospital	1	1,067
TOTAL			9	12,006

Volume Requirement for Expansion

Section 8(1) of the Standards, requires that all of the applicant's existing UESWL units (both fixed and mobile) at the same geographic location as the proposed additional UESWL unit, 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 looking at the 2011 survey data, one of the nine (9) Central Service Coordinators (CSCs) would meet the current volume requirement for expansion.

For the most part, all are averaging a minimum of 1,334 procedures a year per unit.

MDCH Staff Recommendations

MDCH recommends de-regulation of UESWL services. MDCH has recommended deregulation of UESWL three times; 2005, 2007 and 2010. The MDCH recommendations are based on the fact that UESWL is well-established, it is a low-cost service, and current data suggests there is adequate access throughout the state.

Reimbursement rates for Lithotripsy have decreased: Most states do not regulate the purchase of lithotripters (or other urologic technologies) with CON.¹ Thus, if the treatment of genitourinary stones were supply sensitive then, we would have expected to see national capacity exceed the amount required by population health needs. Current data shows that reimbursement rates for lithotripsy have decreased, which suggests that abuse has not occurred nationally in unregulated areas. It has been noted to the Commission by public input that the cost of UESWL is lower in Michigan than in other states. MDCH, however, found that Michigan's costs are very near the national average.

Reimbursement policies limit physician office use: The Center for Medicare and Medicaid services (CMS) current reimbursement methodology effectively forces lithotripsy services provided to Medicare beneficiaries to be furnished "under arrangements with a hospital outpatient department. The Medicare reimbursement system (as well as certain technological considerations) strongly discourages the provision of lithotripsy services in a physician office setting."²

Further, the CMS methodology was developed because the established global rate for lithotripsy under Medicare's physician fee schedule does not currently incorporate a physician's overhead cost of the lithotripsy equipment.³ According to the 2012 Medicare Physician Fee Schedule Payment Rate for Lithotripsy, extracorporeal shock wave (CPT code 50590) nationally is \$821.67, while the Hospital Outpatient Payment Schedule rate is \$3,647.00. The reimbursement rate for lithotripsy procedures dropped around 21% due to Medicare's correction of an erroneous payment rate.⁴ CPT code 50590 (fragmenting of kidney stone) was set at a national average of \$2,102.29 upon its November 2011 release. On April 24, 2012 however, CMS adjusted the payment rate to \$1,665.59, a reduction of \$436.70 or 20.77%. The rate is retroactive to January 1, 2012.

¹ <http://www.aksm.com/Benefits/Final.Physician%20Ownership%20White%20Paper%20Oct%202010.pdf>

² <https://www.federalregister.gov/articles/2011/11/30/2011-28612/medicare-and-medicaid-programs-hospital-outpatient-prospective-payment-ambulatory-surgical-center>

³ <http://m.reedsmith.com/files/Publication/81b278ae-4de8-4327-bafb-6090195a6464/Presentation/PublicationAttachment/e76ea9e2-e3a8-4766-aa07-a78e4feb4062/hc0215.pdf>

⁴ <http://www.outpatientsurgery.net/news/2012/05/1-436-70-Less-for-Lithotripsy>

MICHIGAN CON COMMISSION MEETING

Outline of Testimony

January 29, 2013

A. Credibility / Who we are

- a. Ted Amland – VP of Operations for AKSM, the management company for Greater Michigan Lithotripsy (GML), with more than 25 years of Lithotripsy experience in field service, technical support, training, operations, logistics and management. AKSM provides urology services in 24 states, operates 60 Litho units and performs approximately 130,000 treatments annually, of which 30,000 are UESWL.
- b. AKSM & GML formed a partnership in January, 2005 and have performed nearly 24,000 treatments in Michigan since then on three mobile lithotripsy routes.

B. Our concern is that the number of cases required to expand the number of lithotripsy units on a mobile route is excessive and results in insufficient access to this service for the residents of Michigan.

- i. GML currently serves (23) facilities and we are at optimum capacity on all three (3) of our routes.
- ii. Our physicians **need** more access to our equipment so that patients can be treated in a timely manner and forego more invasive and costly alternative procedures.

C. The current standards require 1,800 procedures annually in order to expand an existing route

- a. With approximately 254 business days in a year, this would require treating approximately 7 cases each day

D. To illustrate how this would impact service to physicians and patients, let's look at GML Route 165

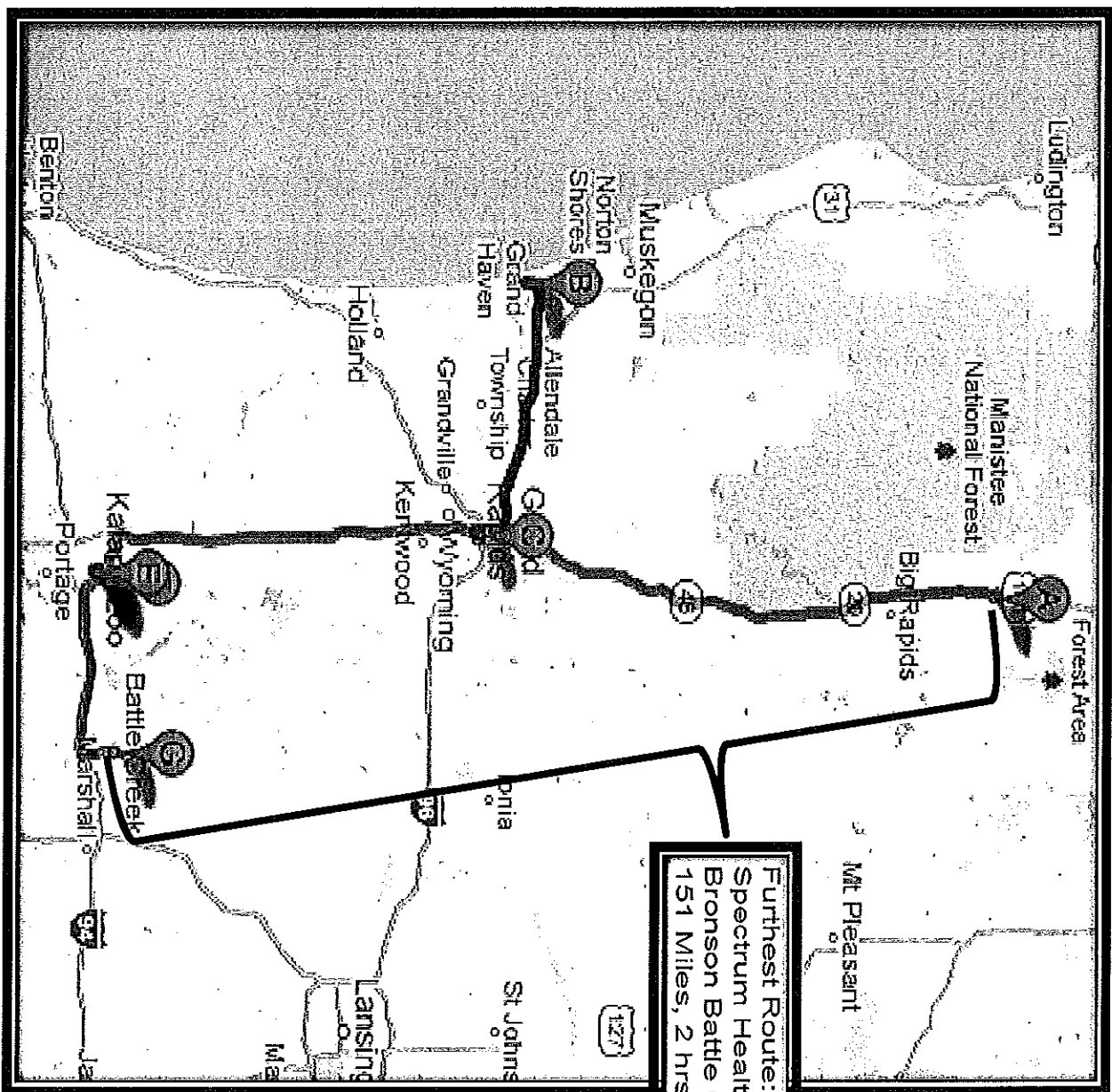
- a. This route encompasses over 9,000 square miles and provides UESWL to (6) hospitals and (1) surgery center in western Michigan.

E. In order to expand this route, the following actions would occur

- a. Treatment schedule changed to 6am – 8pm daily
- b. Additional technical and transport staff (14 hour DOT rule)
- c. Increased burden on:
 - i. Patients – fasting, work schedule
 - ii. Physicians – office hours, OR block time
 - iii. Hospital staff – Litho block time change, anesthesia demand
- d. Increased costs will cause higher deductibles and insurance payments
- e. Operating at this rate causes:
 - i. Higher than normal equipment failures
 - ii. Doesn't account for any delays in scheduling, hospital support, required ancillary procedures such as cystoscopy
 - iii. Increase human error due to higher stress levels
- f. We're proud of our record in this state of no adverse incidents, and we want to keep it that way.

F. In our experience in other states, we have found that when a single mobile unit exceeds 1,000 procedures per year, it's time to start planning to add a second machine to that route. Therefore, we respectfully request that the CON Commission establish a Workgroup to consider lowering the CON requirement for expanding a mobile lithotripsy route.

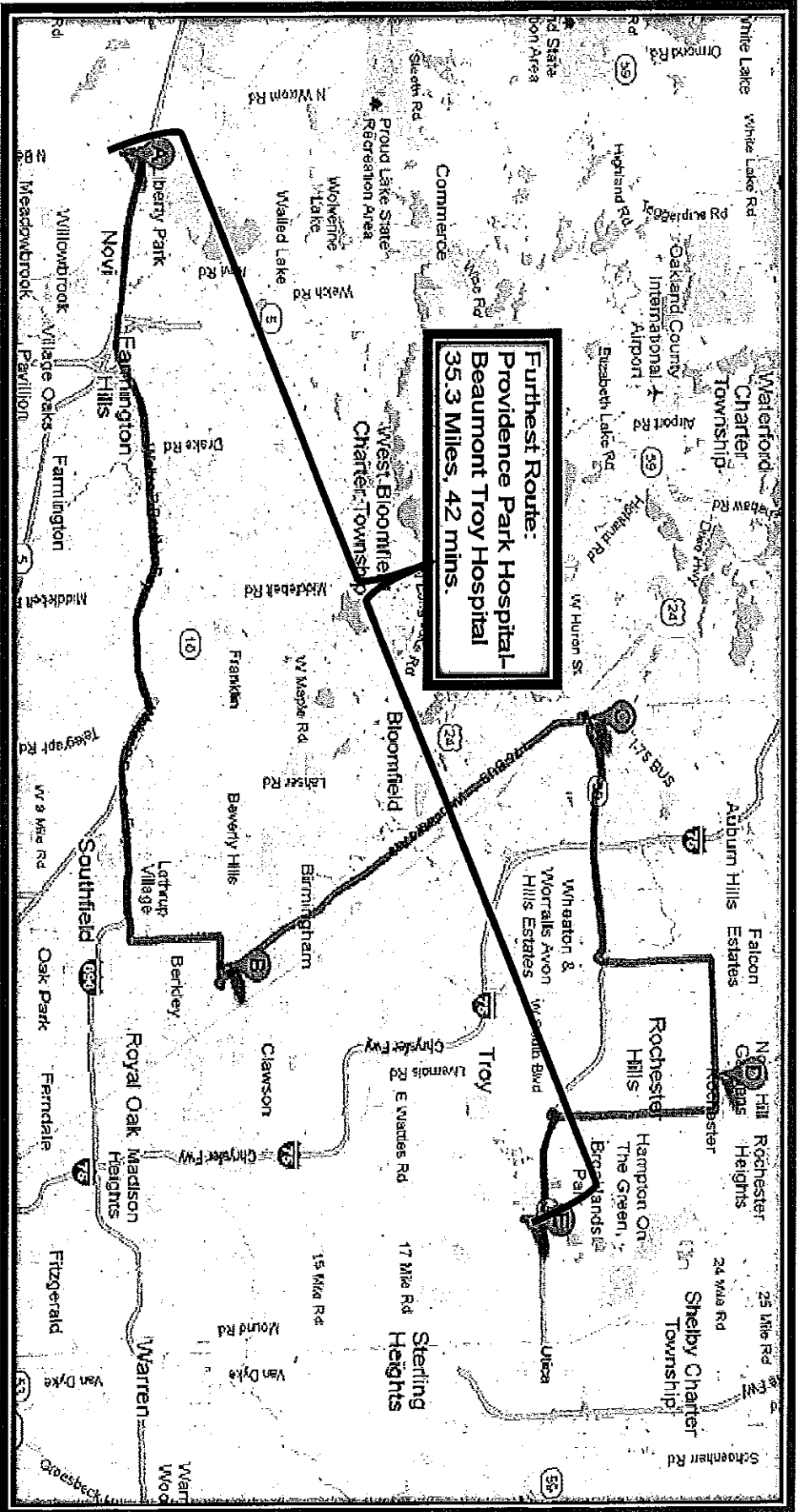
MDCH Mobile Lithotripsy Route 165 AKSM Unit 147



A	Spectrum Health Reed City Hospital	Reed City
B	North Ottawa Community Hospital	Grand Haven
C	Spectrum Health Butterworth Hospital	Grand Rapids
D	Healthcare Midwest Surgery Center	Kalamazoo
E	Bronson Methodist Hospital	Kalamazoo
F	Borgess Medical Center	Kalamazoo
G	Bronson Battle Creek Hospital	Battle Creek

MDCH Mobile Lithotripsy Route 164 AKSM Unit 146

SPECTRUM HEALTH

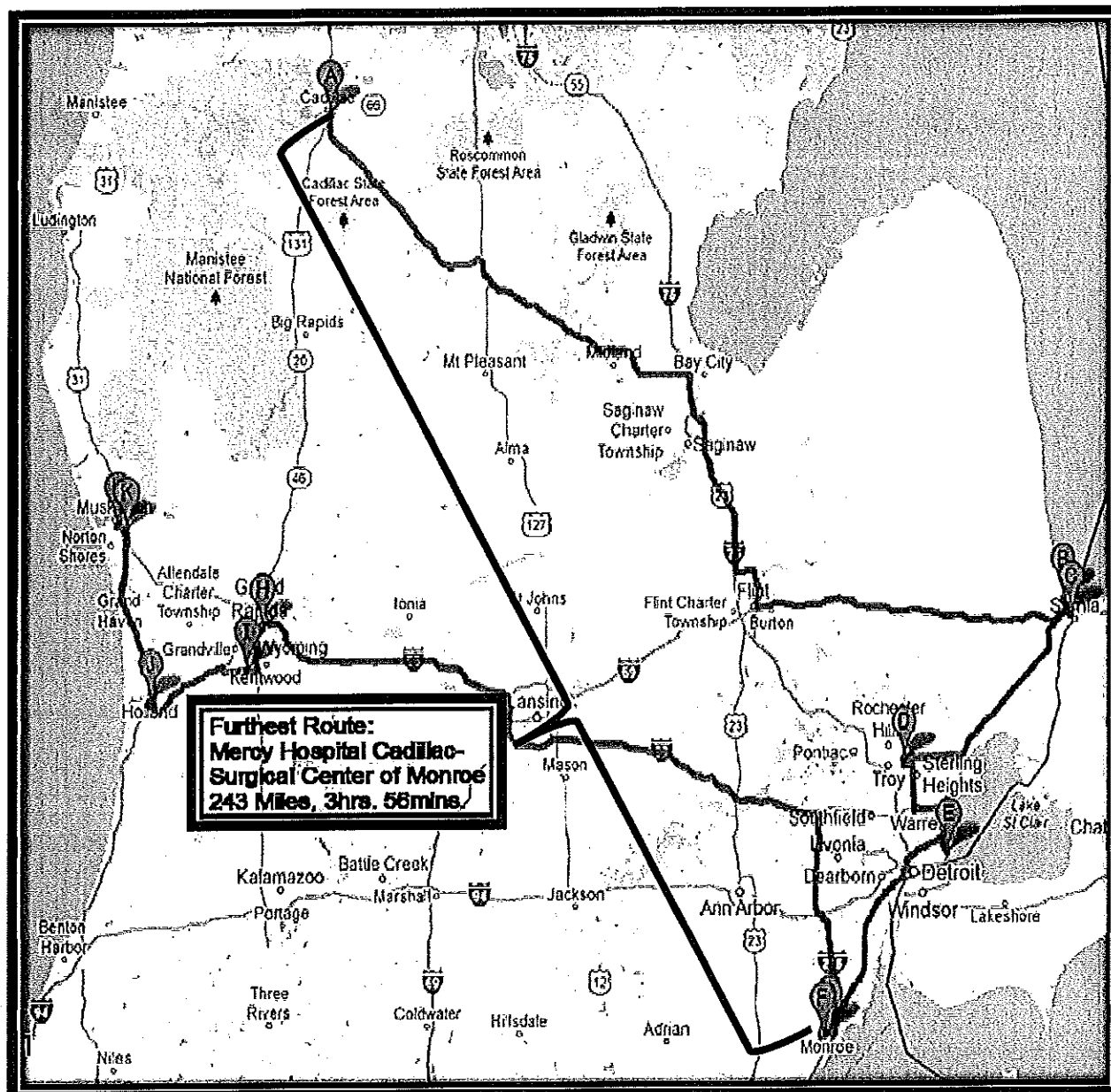


A	Providence Park Hospital	Novi
B	William Beaumont Hospital	Royal Oak
C	McLaren Osteopathic Hospital	Portiac
D	Crittenton Hospital	Rochester
E	William Beaumont Hospital	Troy

MDCH Mobile Lithotripsy Route 167
AKSM Unit 148

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SPECTRUM HEALTH



A	Mercy Hospital	Cadillac
B	Lakeshore Surgery Center	Fort Gratiot
C	Port Huron Hospital	Port Huron
D	William Beaumont Hospital	Troy
E	William Beaumont Hospital	Grosse Pointe
F	Surgical Institute of Monroe	Monroe
G	Mercy Memorial Hospital	Monroe
H	St. Mary's Healthcare	Grand Rapids
I	Metro Health Hospital	Byron Center
J	Holland Hospital	Holland
K	Muskegon Surgery Center	Muskegon
L	Mercy Health Partners-Hackley	Muskegon

Via email

February 26, 2013

c/o James B. Falahee, Jr., J.D.
Chair, CON Commission
Michigan Department of Community Health
Certificate of Need Policy Section
201 Townsend Street
Lansing, Michigan 48913

Dear Chairman Falahee and Distinguished Commissioners:

Thank you and the Certificate of Need Department for your continued dedication to proffering those decisions that ensure access to affordable, quality health care for residents of this great state of Michigan. I hereby submit this letter as formal testimony on behalf of my mother, who is unable to represent herself, but would if she could. My mother is a member of the public you serve, a Michigan resident now receiving Medicare and healthcare benefits under the Michigan Public School Retiree Plan. Though I understand this public testimony is a tad late, it is intended for your sincere consideration during this time while you consider 2013 Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services.

As one who understands the subject matter of UESWL and your CON review standards implicitly, I strongly support and urge continued regulation of lithotripsy services. In addition, I strongly urge you to carefully discern the most critically important facts and numbers before you prior to taking specific actions affecting performance standards of UESWL service, access to it, and the fair and reasonable cost to real people affected by your decisions. On behalf of my mother, and others who have no active, informed voice in this process, I strongly support several very distinct changes to be made in the standards for UESWL that may require a workgroup or Standards Advisory Committee (SAC) to be established.

Background

It is no secret that the main driver of our national deficits is healthcare. We are staring into the eyes of a monster borne of very near demands on our healthcare system posed by the aging baby boomers and by healthcare reform. The prices paid for healthcare services are too often wildly distorted in a system that bears no resemblance whatsoever to a "free market" system. When a patient/purchaser has no means for knowing what it will cost in advance to receive the care they need, nor the medical knowledge necessary to discern that which is appropriate, mostly during stressful times when sick and vulnerable they must instead trust that others will make these fair and just decisions in their best interest. No "free market" argument is ever remotely accurate in the describing our healthcare circumstance. Michigan CON charter is to protect the public against

unfair, unreasonable, and fraudulent practices in covered services by monitoring cost, quality, and access.

Following a mob-style coup in 2004 by Michigan urologists aided first by the large Chicago Syndicate, and then in 2005 by Spectrum Health and William Beaumont Hospital collaborating with the large Ohio Syndicate, two subsidiaries of large out-state syndicates were formed in Michigan and became the exclusive providers of lithotripsy service in the Lower Peninsula. These subsidiary syndicates are known as *Greater Michigan Lithotripsy* and *Great Lakes Lithotripsy*.

Information is widely available from all the CON Department documents from 2005–2010, reflecting numerous changes throughout the state as a result of this takeover of lithotripsy by the syndicates.

With the hostile takeover, these syndicates and their urologists conspired to gain the power necessary to substantially raise prices for mobile lithotripsy service in Michigan across the board. Their intimidating scheme permitted syndicators and urologists the ability to extract for themselves most fees paid to the facilities by insurance companies, the government, and patients for lithotripsy service. It only requires plain arithmetic to understand what happened. Since they became syndicated, it is easy to conservatively estimate that a couple hundred urologists in Michigan alone have by now extracted at least \$50,000,000 in “profit” (derived of payments from patients intended for facilities) for themselves by performing lithotripsy in Michigan in addition to what they already receive in normal professional fees paid to them for performing lithotripsy. This does not even reflect the additional millions paid as well to the Outfit bosses. This profit model was derived via base intimidation.

For lithotripsy service, under CPT billing code 50590, insurance companies, the government, and patients pay Michigan CON-approved facilities money that has been calculated to be fair and reasonable for covering facilities’ costs to provide: the lithotripter and technologist, operating room, recovery room, staff, lights, heat, overhead, billing services, insurance, brick and mortar, etc. It, again, merely requires simple arithmetic. When receiving an invoice for lithotripsy service from a facility, it is appropriate for a patient to believe that his payment will be used to cover costs in a transparent, fair, and reasonable manner for the services received. Patient invoices for lithotripsy services, however, do not provide the actual hidden detail when instead a facility turns over highly inflated payments to syndicates for the lithotripter and technologist. These highly inflated payments cause facilities instead to lose money unnecessarily on the transaction, in spite of what the patient is led to believe, which in turn requires a facility to either find money “elsewhere” to cover their own overhead costs for the service, or ultimately demand more money in turn from those who pay them. They rob “Peter” to pay the Outfit. The public deserves transparency in this insidious scheme, and to be respected with honest answers about why this scheme has been wrought upon them, especially in light of being a covered service under Michigan CON

guidelines for cost, quality, and access. Because of the Outfit's act so far of siphoning the \$50+ million in Michigan and \$Billions nationally, people like my mother and all those other victims affected by the lithotripsy syndicates must endure cuts in healthcare coverage, loss of coverage, increases in contributions for coverage, loss of pension programs, etc., and even worse, just so that the intimidating Outfit can get paid.

Cost

In the 2007 standards review period for UESWL service, I provided testimony to the Commission that, upon performing simple math, demonstrated the cost per case to provide mobile lithotripsy service with a lithotripter and technologist is \$385.00, or an annual cost of \$385,000 given a standard performance of 1000 cases/single lithotripsy unit. In the 2010 standards review period for UESWL, Mr. Jorgen Madsen provided these documents once again to the Commission, and stated that the costs for providing UESWL service had not changed since 2007. I can find no reason why these costs have had any legitimate reason to increase in the last three years.

The following table represents the simple math: Current charges for lithotripsy service by the Outfit in Michigan run anywhere from \$1500.00 to more than \$2300.00 per procedure according to Department documents. Current global facility payments for UESWL by insurance companies and the government aren't much more than this, and if they are, they should be questioned as suspect. It is quite simple to discern profitability, and what should be considered fair and reasonable for Michigan healthcare consumers.

Charge/patient	Patients/day	Patients/year	Total/year	% Net Profit
\$ 385.00	4	1000	\$ 385,000	Even
\$ 385.00	5	1250	\$ 481,250	25%
\$ 385.00	6	1500	\$ 577,500	50%
\$ 500.00	4	1000	\$ 500,000	30%
\$ 500.00	5	1250	\$ 625,000	62%
\$ 500.00	6	1500	\$ 750,000	95%
\$2400.00	4	1000	\$2,400,000	523%
\$2400.00	5	1250	\$3,000,000	680%
\$2400.00	6	1500	\$3,600,000	835%

This is not complicated. It is important to note that a single unit lithotripsy service need only treat four patients each day, five days per week for fifty weeks per year in order to comply with Michigan CON performance standards of 1000 cases. A single procedure takes roughly 45 minutes. Profit increases with efficiency. It is absurd to believe as some do, that cutting those performance standards in half, basically treating only two patients per day, somehow meets CON governance standards for cost, quality, and access. It is easy to see, however, where this is coming from. I strongly urge the Commission to adopt new CON cost standards which serve the people of Michigan by capping the maximum per patient payment made to lithotripsy services at \$500.00. A 95% profit by

providing efficient service is more than a fair and reasonable reward in today's desperate climate for healthcare consumers.

The game is clearly rigged where it shouldn't be, and permits the Outfit to skim their take from what everyone can easily discern to be otherwise fair and reasonable payment for covering facilities' costs for lithotripsy. For the inflated \$2400 fee, does a facility receive a higher quality mobile service? No. For the inflated fee does some sort of improved quality of service guarantee a lower retreatment rate or a higher success rate? No, and probably the inverse. Does mob syndication provide the patient with a quality standard that improves outcome? No. Does the syndicated urologist have the same patient care responsibility were he not syndicated? Yes. The only difference between a fee of \$385.00 and a fee of \$2400.00 for mobile lithotripsy is that tens of millions of Michigan dollars in ransom is paid to the Outfit, whom in turn with their tidy take pay off public officials (see FEC Report for Committee ID #Coo489419 "AKSM Urology PAC"), and ex-public Department of Justice officials (Thomas E. Zeno, esq.) in order to protect the racket.

Once the Outfit infiltrates the process, there is no means to negotiate fair pricing based on what is known by everyone to be true about cost. Intimidation by the Outfit practically extinguishes performance and often even the legitimate consideration of lower cost alternatives for kidney stone removal, significantly increases the number of patients treated with UESWL (see Michigan CON Activity Reports) in spite of a plummeting Michigan population overall, increases UESWL retreatment rates, and most poignantly silences any statistically significant, actionable research programs that may otherwise address in proper measure the very disturbing known concerns about very real risk for life-altering, harmful adverse effects of UESWL.

Quality

In 1984, UESWL technology sailed through the FDA approval process in a short period of time. Since then, the FDA has required no critical long term follow up reporting about this technology to evaluate safety and efficacy, regardless of deeply grave concerns raised in the medical literature about harmful effects. Adverse events for lithotripsy are only required to be reported to them on a voluntary basis. Simultaneously in 1984, a handful of entrepreneurial American urologists began the process of syndicating their peers, building the Outfit that has become a massive national UESWL enterprise. This was possible by carefully fixing prices for services at highly inflated rates in order to secure a so-called "market value" favorable to the Outfit for paying off urologists, and for eliminating competitors who might come in at legitimate lower price points with better quality service. Since right around that same time, 1984, there has become an exploding epidemic 3,600% increase in the rate of acute kidney failure in the United States, the likes of which we have not seen.

As CON Commissioners you are not practicing medicine, however, as arbiters of cost, quality, and access concerns in Michigan healthcare delivery, I suggest you conduct a

thorough review of the medical literature for kidney disease, UESWL, CDC statistical reports for renal failure, dialysis, etc. This is very important information. There is an urgent need to correlate this information, because there is mind numbing radio silence by urologists, the majority whom are syndicated into the Outfit. The public would otherwise reasonably expect the urology profession to be advocating for real answers about harmful effects by undertaking critical, actionable UESWL research. In fact, not performing this research could legitimately be considered a serious breach of trust and responsibility to patient care. The reason this research is not happening could arguably be due to the massive, controlling multibillion dollar Outfit's interest for protecting their perversely conflicted financial enterprise.

With the Outfit so astutely adept over thirty years at organizing to inflate consumer prices in a closed market, syndicating the majority of urologists in this country, and showing clear and compelling capacity to administrate a crooked financial product for themselves, surely they could organize their time, power, intellect, and energies for the sake of "doing no harm." This would be nice. But it won't happen unless the public makes it happen.

There are very troubling concerns about both the short- and long-term adverse effects of UESWL treatments causing renal and other trauma, life-altering ill effects such as hypertension, diabetes, renal failure, pancreatic failure, cardiac arrhythmias, and yes, death. Death, yes, here in Michigan, caused by UESWL. But there are no studies large enough in the medical literature to warrant actions for limiting UESWL performance in response to what are highly measurable, but instead are carefully concealed, life-threatening risks.

The very distinct smoke signals about renal failure and the adverse effects of UESWL from the few brave academic urologists in the medical literature must be taken very seriously. But their studies are just never large enough to cause actions within the Outfit for altering UESWL practices. These dangerously unexamined risks are not conveyed appropriately to patients. For instance, a review of the literature showed a long-term reduction of function in the individual human kidney after SWL in some cases of a solitary kidney and in some cases with an untreated contralateral kidney. "Because there is no evidence that an untreated contralateral kidney aids the long-term recovery of the function of a treated kidney in all cases, simultaneous or separate bilateral renal SWL would not influence this long-term reduction in renal function, which was felt to occur with multiple renal stones and repeat SWL." (J Endourol 1994. Dec 8(6): 395-9.) Wow. Then, "This acute SW damage can be severe, can lead to scarring with a permanent loss of functional renal volume, and has been linked to potentially serious long-term adverse effects. A recent retrospective study linking lithotripsy to the development of diabetes mellitus has further focused attention on the possibility that SWL may lead to life-altering chronic effects. Thus, it appears that what was once considered to be an entirely safe means to eliminate renal stones can elicit potentially severe unintended consequences." ([Semin Nephrol.](#) 2008 Mar; 28(2):200-13)

Following UESWL, blood levels for BUN and Creatinine are tested. However, neither of these tests explains anything of damage that may have been done to the treated kidney, so therefore are false representations for the “safety” of UESWL. It is widely known that the untreated kidney will produce normal blood levels of BUN and Creatinine when the contralateral kidney is absent or non-functioning. This is a deeply flawed representation of “safety.” The actual damage caused to the treated kidney is not adequately evaluated, and therefore neither is any longer term adverse effect of the trauma on renal function.

One said in conclusion, “SWL results in a clinically significant long-term reduction in renal function.”(J Endourol. 1994 Feb; 8(1); 15-9.) Another, “the safe limits of extracorporeal shock wave lithotripsy in humans have yet to be established. Further study regarding this issue and the potential long-term adverse effects of extracorporeal shock wave lithotripsy is needed urgently.”(J Urol. 1989 Mar;141(3 Pt 2):793-7). And yet another, “Both clinical and experimental reports clearly show that shock wave lithotripsy (SWL) causes acute renal effects in a majority, if not all, treated kidneys.” And another, “At 19 years of follow up, SWL for renal and proximal ureteral stones was associated with the development of hypertension and diabetes mellitus. The incidence of these conditions was significantly higher than in a cohort of conservatively treated patients with nephrolithiasis.” (J Urol. 2006. May; 175(5): 1742-7). But nothing actionable is being published or being done. Diabetes mellitus and hypertension cause renal failure, notwithstanding the pure traumatic events posed by UESWL.

When the study was published by the Mayo Clinic in 2006, the American Urological Association requested a response from within, and published a whitepaper:

<http://www.auanet.org/content/media/whitepaper.pdf>

This whitepaper was basically a wasted review of the medical literature, because the AUA already knows there is nothing actionable in the literature. It can be argued that actionable research is missing on purpose. Please note the physician (business) disclosures in this official whitepaper.

The cost of renal failure in life and in treasure is staggering in this country, and in Michigan.

It is not rocket science to consider that when there is clear evidence and awareness for a procedure causing the kind of trauma that may necessitate nephrectomy, splenectomy, or cause massive hemorrhage, renal failure, and/or death, our concern should be heightened about what this procedure is really doing to people in the long term. It is a traumatic procedure. Anecdotes are not enough. It is no big secret that money has been covering up that the brains of our national gladiators, the NFL, are permanently damaged by concussive effects. Is there really no concern for taking legitimate action to address renal function after trauma? Apparently there is not.

If a patient has had a kidney stone once, they're at significantly increased risk of having another. If this patient has been treated at first with UESWL and there has been unmeasured harm to the kidney, or other organs for that matter, then what will happen if a kidney stone forms in the patient's contralateral kidney and is then treated again with UESWL? It is important to understand the impact of what are only partially examined effects of lithotripsy trauma on the lives of real people, the other victims who pay the high price for this as well, and what the epidemic of acute renal failure is doing to our country. It is indeed arguable that high cost of UESWL syndicates may be far, far greater than meets the eye at first glance. But we will not get the answers we need to know from the Outfit. Obviously.

When others suggest that UESWL is not "invasive," whereas Ureteroscopy is "invasive," as an argument to double the access to UESWL services, be afraid. There is nothing proven in the medical literature about UESWL being more safe or more effective than Ureteroscopy. In fact, the questions raised in the literature about serious trauma and overall safety of UESWL suggest otherwise. However, badly needed research to address these real concerns has been neglected by urologists over these past 30 syndicated years, arguably on purpose. Why bite the hand that feeds?

I would suggest it is long time to come clean about UESWL. And if the urologists, those very professionals we trust in our society to act honestly and impartially on our own behalves, won't properly or adequately perform the research to fully measure the risk of harm by UESWL, then who will? Who will? Who will be the arbiter, then, of "quality?" Who will care to understand the true cost?

I urge you to conduct your own thorough medical literature and statistical review as I did. You may need to go no further than Michigan's Genesee and Lapeer Counties to see a snapshot of what has been happening.

The neglect by an entire national class of physicians (by no means is this unique to Michigan) to perform the obviously needed UESWL research is not an issue of competence. These are doctors. They were the smartest kids, and medical school was the hardest thing to do. It is an issue of character. They have no problem whatsoever organizing in massive groups of complex syndicates boasting of 2500 urologist members, 2000 urologist members, 1500 urologist members, within an Outfit that spans the entire country in order to drive up the cost of providing lithotripsy service nationwide. But there is a clear, cold, calculated neglect to organize for the purpose of conducting the badly needed research they know is necessary to tell the truth about dangerous risks of UESWL. They have known since at least 1989, and have done practically nothing. Thirty years performing UESWL. What you will find in the medical literature tells the precise story of what you will not find in the medical literature; any actionable research. No studies long-term or large enough in writing to warrant any red flags about their very real concerns. Mind you, there are many concerned urologists. But the vast majority of

them are afraid to speak up. It is practically impossible by now to find any unaffected, unbiased medical leadership on this subject amongst them. The Outfit is too powerful.

Far more than merely capping payments made to mobile lithotripsy service providers, a thorough, impartial, independent review of UESWL will provide you with clearer understanding of what might be known about both the life and treasure involved were UESWL not affected by the Outfit's control over information concerning this traumatic procedure. You simply cannot take the concept of "quality" for granted. I strongly urge you to know the subject matter.

Last year alone, Medicare spent \$32,900,000,000 on acute renal failure in the United States. This is an unimaginable annual figure considering these are patients who first suffer in dire misery before facing certain death from their disease. One out of five of these patients die every year from their renal failure. The cost is just staggering. With proper attention, and money spent appropriately, these conditions can more often than not be prevented. Protecting UESWL from well-warranted scrutiny must stop. If the urologists and the Outfit won't be forthright with the answers we need, the public deserves real answers for these failures from our governing authorities. The cost is simply far too high. It is not nothing. There must be impartial, informed oversight for those who are picking winners and losers in life and death circumstances for a very pretty penny.

Were there to be an organized Outfit for every medical procedure, then what? This is not complicated. "Quality" must mean something, and the paying public has a right to be respected and kept clearly informed. It is time for the needle to start moving in the right direction concerning hyper-inflated healthcare costs for no good reason and quality care that can be measured honestly. UESWL must be met with the critical unbiased scrutiny it deserves.

With one hand picking the pockets of Michigan healthcare consumers, the "AKSM Urology PAC" aided by Michigan urologists has used the other hand to feed this money to the likes of Ohio's John Boehner and his "The Freedom Project." My mother, and I would guess many other Michigan residents whose wallets have been emptied, would like an answer to these questions: Who's "Freedom?" And, who's "Freedom" to do what?

Access

Access to UESWL is obviously not a problem in Michigan. One need only examine the CON Activity Reports. Eliminating the costly, inaccessible fixed-based lithotripters solved that problem. Now the question of too much access must be answered. It is time for the paying public to understand in a transparent way who is treated with UESWL, and why they are treated with UESWL instead of lower cost alternatives. The paying public should know answers the urology community refuses to give them about who is harmed by this procedure. I would suggest that a tracking mechanism be adopted for UESWL

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similar to that of MRI standards for “Available Adjusted Procedures,” which may include a statewide registry. This is a critical problem that must be met with a transparent solution. With increased access, increased responsibility for the facts must be exacted.

Summary

We support and urge capping the charge by lithotripsy service providers to facilities at \$500.00/procedure. We support and urge an informed, impartial SAC be formed to address a process for knowing the true cost that UESWL has wrought upon Michigan.

Michigan alone is by far not the “problem” related to what is happening with UESWL syndication in the United States. But, Michigan can be the solution. The choice before you is to reject intimidation by the Outfit in favor of reducing healthcare costs for real people and improving the quality of knowledge we have about a traumatic procedure and its relationship to a deeply catastrophic epidemic of deadly kidney disease. We urge you to find other means to support urologists in legitimate ways to do their good work. We urge you to do the right thing.

Thank you for your service.

Sincerely,

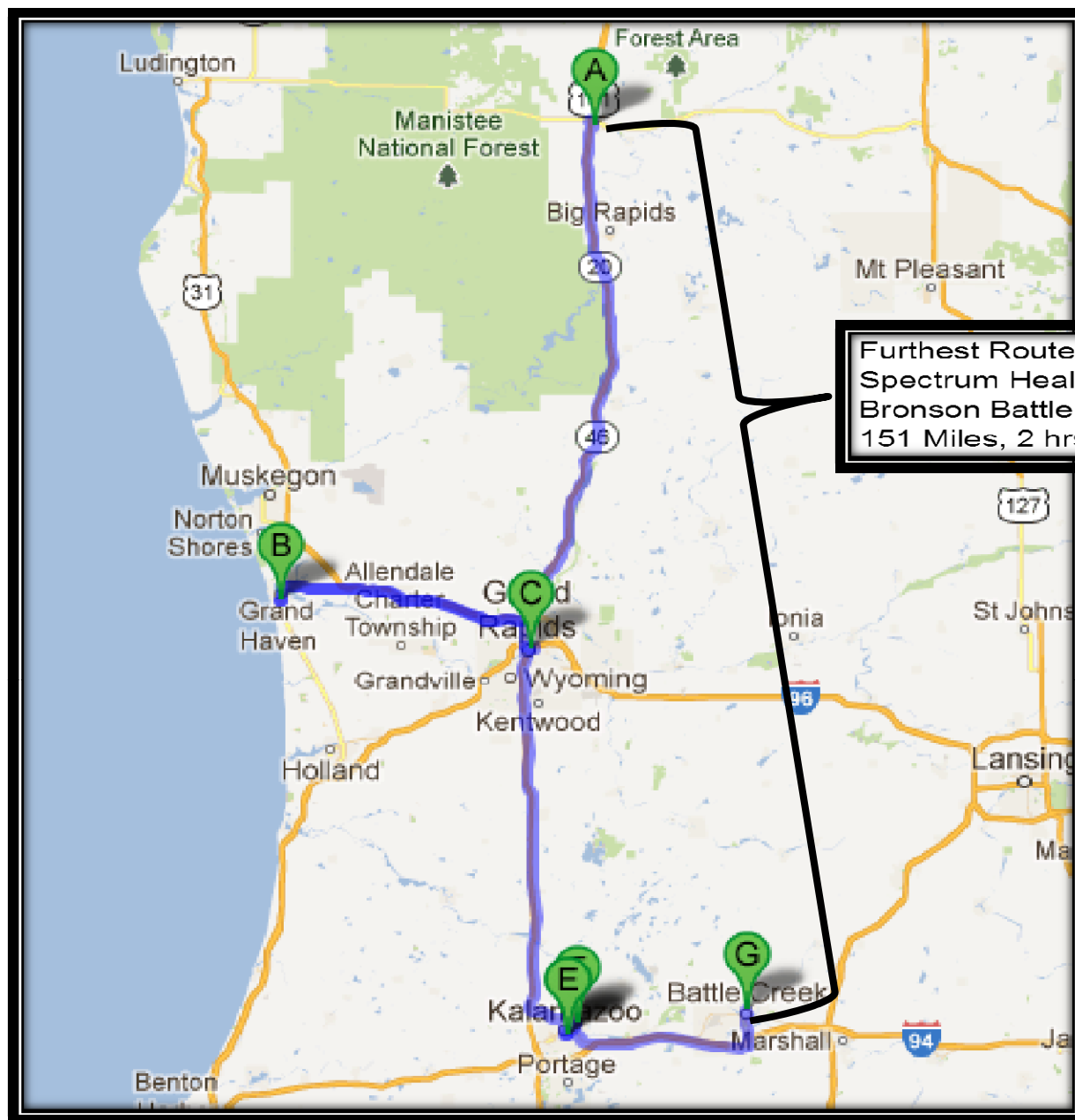
Anne Mitchell
ae_mitchell@comcast.net

Cc: The Public

MDCH Mobile Lithotripsy Route 165

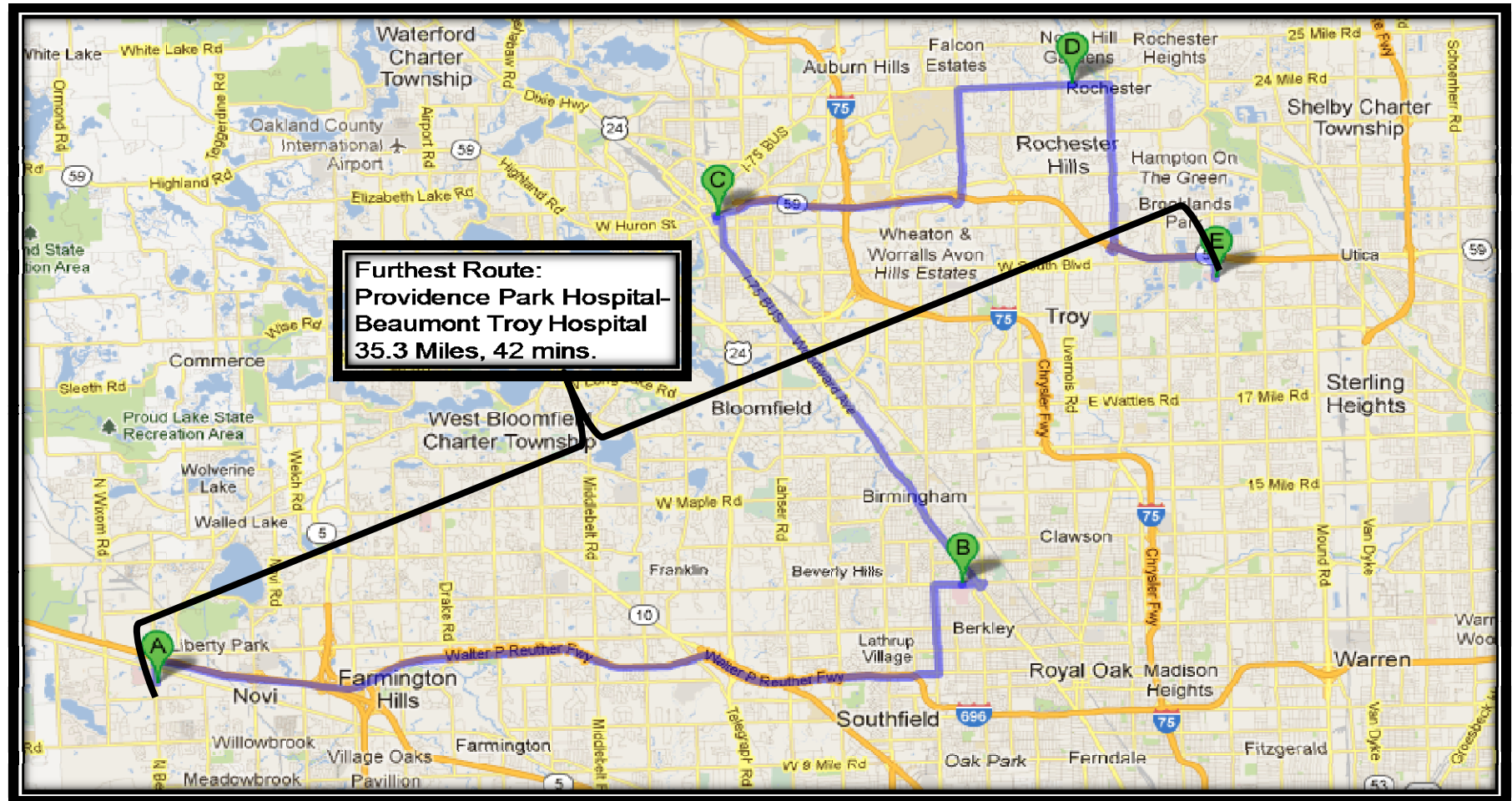
AKSM Unit 147

23

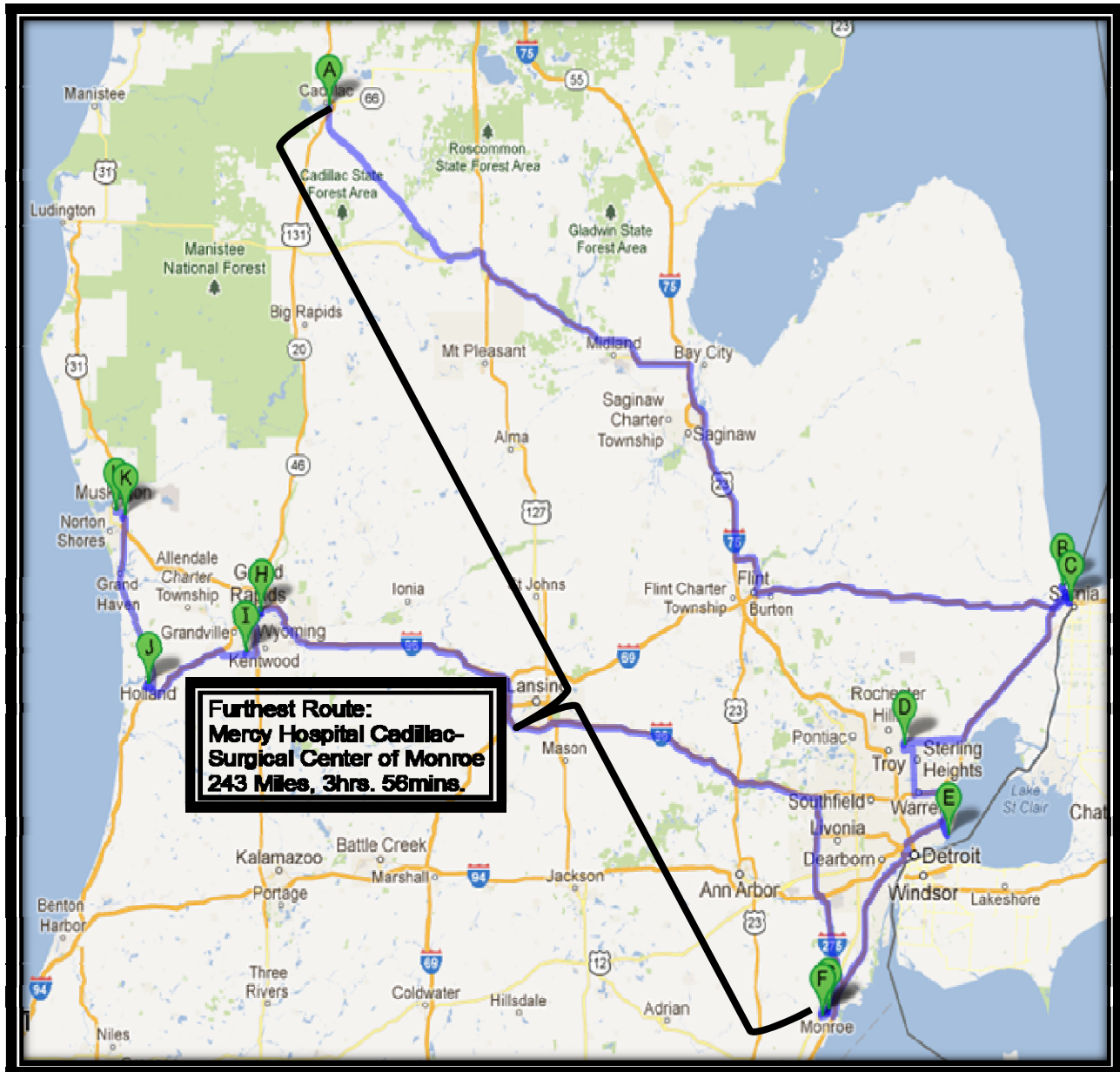


Furthest Route:
Spectrum Health Reed City-
Bronson Battle Creek
151 Miles, 2 hrs. 15 mins.

A	Spectrum Health Reed City Hospital	Reed City
B	North Ottawa Community Hospital	Grand Haven
C	Spectrum Health Buttenworth Hospital	Grand Rapids
D	Healthcare Midwest Surgery Center	Kalamazoo
E	Bronson Methodist Hospital	Kalamazoo
F	Borgess Medical Center	Kalamazoo
G	Bronson Battle Creek Hospital	Battle Creek



A	Providence Park Hospital	Novi
B	William Beaumont Hospital	Royal Oak
C	McLaren Osteopathic Hospital	Pontiac
D	Crittenton Hospital	Rochester
E	William Beaumont Hospital	Troy



A	Mercy Hospital	Cadillac
B	Lakeshore Surgery Center	Fort Gratiot
C	Port Huron Hospital	Port Huron
D	William Beaumont Hospital	Troy
E	William Beaumont Hospital	Grosse Pointe
F	Surgical Institute of Monroe	Monroe
G	Mercy Memorial Hospital	Monroe
H	St. Mary's Healthcare	Grand Rapids
I	Metro Health Hospital	Byron Center
J	Holland Hospital	Holland
K	Muskegon Surgery Center	Muskegon
L	Mercy Health Partners-Hackley	Muskegon

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 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, 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) "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) "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) "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) "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) "Department" means the Michigan Department of Community Health (MDCH).

(g) "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) "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) "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) "Hospital" means a health facility licensed under Part 215 of the Code.
- (l) "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) "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 and 1396r-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) "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) "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) "Planning area" means the state of Michigan.
- (u) "Region" means the geographic areas set forth in Section 12.
- (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) "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), 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) "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) "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) "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) "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) "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) 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(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. (1) 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.

(2) 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) An applicant that demonstrates that it meets the requirements in this subsection shall not be required to demonstrate compliance with Section 4(1):

- (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 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 (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.

(4) 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. 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. (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 of these standards in the second 12 months after the date the service and its unit(s) is acquired, and annually thereafter.
- (c) For any application for proposed acquisition of an existing fixed or mobile UESWL service, except the first application approved pursuant to subsection (3), 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) 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.

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

Sec. 9. 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. Project delivery requirements -- terms of approval for all applicants

Sec 10. (1) An applicant shall agree that, if approved, the project shall be delivered in compliance with the following terms of CON approval:

- (a) Compliance with these standards.
- (b) Compliance with applicable operating standards.
- (c) Compliance with the following quality assurance standards:
 - (i) 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) 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) An applicant shall accept referrals for UESWL services from all appropriately licensed health care practitioners.
 - (iv) 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) 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) 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) 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), that a urologist on an applicant facility's active medical staff must meet in order to perform UESWL procedures.

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

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

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

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

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

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

(x) An 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) The applicant shall provide the Department with a 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 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) 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 compliance with the following terms of CON approval:

(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) 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 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

Section 13. Methodology for projecting UESWL procedures

Sec. 13. (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. 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 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. Requirements for MIDB data commitments

Sec. 14. (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. Effect on prior planning policies; comparative reviews

Sec. 15. (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 and effective on June 4, 2004.

(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(1)(b) used for calculating the projected number of UESWL procedures shall be .94.

(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 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) The records from step (a)(i) above will then be aggregated by "urban/rural" and zip code.

(iii) Zip codes that are totally "urban" or "rural" will have the discharges and populations aggregated for those respective groups.

(iv) For the remaining zip codes with both "urban" and "rural" components, the proportion of the zip code in each part (urban or rural) will be calculated and applied to the population for that zip code.

(v) These will then be aggregated by discharge and population 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.

(vii) The percentage difference between "urban" and "rural" discharge rates will be applied to the rate identified in step (a)(iii) above. 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**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