

CERTIFICATE OF NEED

UESWL PUBLIC HEARING

February 3, 2004

Lake Ontario Room – Michigan Library & Historical Center
702 West Kalamazoo Street
Lansing, Michigan

ORAL TESTIMONY

Proceedings scheduled to start at 9:30 a.m.; actual start time was 9:30 a.m.)

MS. ROGERS: Good morning. My name is Brenda Rogers; I am Special Assistant to the Certificate of Need Commission from the Department of Community Health. Chairperson, Renee Turner-Bailey, has asked the Department to conduct today's hearing.

We are here today to take testimony concerning proposed revisions to the review standards for Urinary Extracorporeal Shock Wave Lithotripsy or UESWL. The proposed Certificate of Need review standards for UESWL are being reviewed to include, but are not limited to the following: Elimination of comparative review, addition of comprehensive kidney stone treatment centers or CKSTC's, expansion of UESWL services and addition of Medicaid participation requirements in rural county definition update, pursuant to PA 619 of 2002.

Please be sure that you have signed the sign-in log. Packets and cards can be found on the table. A card is to be completed if you wish to provide testimony. Please hand your card to me if you wish to speak. Additionally, if you have written testimony, please provide a copy as well.

As indicated on the Notice of Public Hearing, written testimony may be provided to the Department through February 10, 2004, at 5:00 p.m.

We will begin the hearing by taking testimony from those of you who wish to speak. The hearing will continue until all testimony has been given, at which time we will adjourn. Today is Tuesday, February 3rd, 2004, and we are now taking testimony. Mark Mailloux, University of Michigan.

MR. MAILLOUX: Good morning. My name is Mark Mailloux from the University of Michigan Health System. I'm here representing the Health System and the Urological faculty, and specifically Dr. James Montie, the chair. And I would like to read to you a letter from Dr. Montie. "We at the University of Michigan Health System are speaking today on behalf of the proposed Comprehensive Kidney Stone Treatment Center (CKSTC) put forth in the draft Certificate of Need Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy Services. Let me say, at the outset, that we are very supportive of the concept of a Comprehensive Kidney Stone Treatment Center. In Urology, as in other disciplines such as Cancer and Cardiac Services, extreme specialization has begun to give way to a more coordinated approach to health care. The ability to combine previously disparate disciplines and sub-disciplines has, in many instances, resulted both in better patient care as well as in improved patient satisfaction. The ability to select from a broad array of treatment methodologies can and does allow us to provide the best treatment option for this particular patient, in this particular circumstance. A CKSTC would offer exactly that choice for patients.

In order to facilitate this comprehensive concept in the most optimal way possible, we feel that the proposed standards can and should be strengthened in several key aspects.

First, in the definition section for a CKSTC, the concept of 'comprehensive' ought to be broadened to include the use of either a fixed or mobile lithotripsy unit. Advances in technology no longer necessarily require a bulky, fixed unit for stone treatment and that should be recognized in the Standards. It should also be noted that Fixed UESWL units which were used exclusively for this purpose are now multi-functional, which allow not only shock wave lithotripsy, but can also be utilized for other urological endoscopic procedures such as cystoscopy, ureteroscopy, and renal endoscopy.

In addition, the definition should specify all of the tools that a CKSTC must have available for patient treatment in order to qualify for this designation. The Standards should specify, therefore, that a CKSTC has available and uses both flexible and standard endoscopes for treatment of bladder, ureteral, and renal stones. A CKSTC should also have specific lithotripsy devices such as holmium lasers, ultrasonic, and electrohydraulic lithotripsy devices necessary to treat urinary stones. This final aspect is generally lost in a uni-dimensional service, offering only lithotripsies. Like the old observation goes, when your only tool is a hammer, every problem looks like a nail. A CKSTC should also have the expertise to provide metabolic evaluation and treatment of patients with recurrent stones.

Secondly, the CKSTC should either support or have a formal affiliation with a Urological Residency program. A comprehensive program, such as a CKSTC, utilizing all cutting-edge technologies, must be in a position to train the future generation of physicians. These centers are in the distinctly unique position to be able to offer the breadth of knowledge and expertise of training to continue to expand the field by 'pushing the envelope.'

Finally, a CKSTC must be viewed in its entirety for lithotripter replacement considerations. As a site that performs many secondary and tertiary procedures, a CKSTC may preferentially treat more patients with these other modalities than a uni-dimensional lithotripsy service performing more routine procedures. As a result, volume counts should be based upon the total volume of stones treated, regardless of the particular treatment modality employed. We would propose that -- a procedural count of a total of 500 stones treated on an annual basis, including all modalities of treatment, as the criterion for lithotripter replacement for a CKSTC under these Standards." And it's signed "James E. Montie, M.D., Chairman, Department of Urology, Valassis Professor of Urologic Oncology." Thank you.

MS. ROGERS: Thank you. When you come up to provide testimony, would you please print your name? Thank you. Forgive me if I mispronounce this. David Terhune with Lakeside Urology. Also, for those of you just coming in for the lithotripsy, if you do wish to provide testimony, please fill out a card and bring that up to me. Thank you.

DR. TERHUNE: Good morning. My name is David Terhune. I'm a urologist in Southwest Michigan. My partners and I serve the southwest corner of the state, including Niles, St. Joseph, Watervliet and South Haven. Our appeal is on the behalf of the patients in our region, who have restricted access to lithotripsy services and for the physicians taking care of them who need greater flexibility in managing stone disease. As you know, urinary stone disease is highly prevalent, and the risks of managing urinary stone disease has been historically highly morbid and even mortal, so much so that the Hippocratic Oath specifically addresses this disease by requiring physicians of almost 3,000 years ago to promise not to cut for stone, but to leave it to practitioners of that art. So the management of stone disease has been a recognized problem for almost 3,000 years. In 1985, with the advent of extracorporeal shock wave lithotripsy to the

United States, we experienced a major medical miracle, one of the many of the 20th century, with a drastic reduction in mortality and morbidity, a drastic reduction in loss of patient productivity. Today, for the most part, extracorporeal shock wave lithotripsy is considered to be the standard of care for upper tract stones, certainly not in all but in many cases. However, for our patients of Southwest Michigan, they are placed at an increased risk due to the lack of access.

Since 1985, we have traveled at least 85 miles each way to use the lithotripsy unit in Grand Rapids, Michigan. Time does not permit all the anecdotes of both patients and physicians encountering major travel challenges en route to or from Grand River, with accidents, complications from either the surgery or the anesthetic en route with diversions to hospital ER's en route. But this lack of access has given rise to long waits and inconvenient and risky travel. So the patients from -- the patients have demanded from us more invasive procedures, due to the improved convenience. These are not unnecessary procedures, necessarily, but they are -- these are cases that could be done at less risk with a completely non-invasive modality. So from the patient's point of view, the current arrangement with Certificate of Need restricts access, increases patient inconvenience, increases wait times, and increases the risk by pressuring patients to opt for a more invasive procedure. From the physician's point of view, we also experience diminished access, increased travel risk and inconvenience, and increased medicolegal risk, as we undertake in some cases more invasive procedures. Also, we have encountered decreased flexibility. Not all extracorporeal shock wave machines are the same. In the same way that the B-52 works, but there have been improvements since the 1950's, similarly, the extracorporeal shock wave lithotripter of the 1980's is not as user-friendly or patient-friendly as that of today. It requires immersion, intubation, lifting the patient as dead weight onto an awkward gantry. And new units are far more convenient and less painful for the patient. There are stones for which the older units are more preferable, but we, as surgeons, need the flexibility to make that choice. We do not have that at this time.

Since the mid-1990's, we in Southwest Michigan decided to ask our patients to -- to stop asking our patients to make such a distant travel, and we look to Indiana where lithotripsy companies are free to compete for lithotripsy services. Obvious challenges for us included the Indiana State license requirements, liability insurance requirements, and reimbursement challenges. Despite these challenges, we pursue this option, and since that time, we have pursued ESWL out of state. We believe this is suboptimal. We would ask that this Certificate of Need law be relaxed to allow competition of lithotripsy services within Southwest Michigan.

MS. ROGERS: Thank you. Mark Lucas, M.D., Healthcare Midwest Urology.

DR. LUCAS: Good morning, and thank you for allowing me this opportunity to address the group. I am a urologist in practice in Kalamazoo, Michigan. I'm part of a five-member group of urologists there, and I'm speaking for the other urologists in my group, and I'm speaking on behalf of our patients with stone disease. Our patients currently are enduring unnecessary suffering because of our very limited access to lithotripsy in Kalamazoo. Our current situation is that we have a mobile unit, which comes to Kalamazoo once every three weeks. There is a chronic backlog of available time slots to use this machine. So the current scenario is that if I or any one of my colleagues were to see a patient in our office or in the emergency room next week, that patient would have to wait over five weeks to obtain lithotripsy in Kalamazoo. Our safety valve is an outlet in Grand Rapids, but as Dr. Terhune has already commented, that sort of travel can be very inconvenient for patients as well as treating physicians. I would like to describe to you what a patient goes through during that prolonged period of waiting. Many of these patients are in pain. They're requiring extra procedures, such as stent placements, ureteroscopies of mid or lower ureteral stones, which could otherwise be treated with the

modern mobile units. These patients then also often have to undergo stent removals, which is another procedure. The mobile unit that does visit Kalamazoo requires only sedation for most of the cases. When a patient has to go up to Grand Rapids it invariably requires general anesthesia to use that machine. So these patients are enduring extra risk, extra procedures, not to mention the fact that many of them continue to suffer throughout this whole period while they're waiting to have their lithotripsy performed. Many of them need to be on narcotics. They lose work. Many of them are never free of pain until they can get their treatment done. The bottom line is that we need better access to lithotripsy services in Kalamazoo. And, as Dr. Terhune has already requested, I would also propose that the Certificate of Need requirements be relaxed to allow a mobile unit to visit Kalamazoo on a more timely basis. I would think that a once-a-week rather than a once-every-three-week trip of a mobile unit to Kalamazoo would serve our patients far better. Thank you very much.

MS. ROGERS: Thank you. Phillip G. Wise, M.D.

DR. WISE: Thank you for the opportunity, for allowing me to speak here. I have a bit of a different perspective. I moved up here from California for personal reasons, and in California, there was no Certificate of Need law. We had as many lithotriptors as we wanted, and it was actually sort of a supply and demand. It was whatever the market would bear. I believe we had one that made the rotation around. It replaced a fixed unit that was at the University, and the University folks participated in the treatment of the kidney stones as well. It worked out extremely well. People were happy; in fact, so happy that they bought another unit and it was also busy and has remained so to this day. The patients were -- I believe there was not more than perhaps a week waiting list to get to be treated in the San Diego County area. Many of the urologists who had not had training for lithotripsy previously were trained on the machine. They brought six patients in, they trained them. So the training for the lithotripsy nowadays is not as difficult as it was in the old days when you had to bring 26 or so and get treated, in order to get your training. The machine, itself -- not as expensive as it was back ten years ago. It used to be \$2,000,000, you could pick up a machine. Now they're 350,000 or 300,000 or maybe even less.

I think that it's kind of a shame that Michigan has only one machine in the western area to service that whole area. I think that the need you're talking about isn't the need of the patients that you're looking at, perhaps the need of something else. But I think that if you're looking at the needs of the patient, that you should relax the standards and allow more lithotriptors to come in, be allowed to be able to treat more patients at their homes instead of having to go. If you've ever had a stent before -- if you've never had a stent before, I can tell you from personal experience, it's not fun. They are painful. They migrate. They can cause bladder irritation. You have to go to the bathroom frequently, with blood, and sometimes they leave altogether, and then you're stuck with the stone again, and you have to have another stent put in. So I would urge you to relax the standards, allow more lithotriptors to come in and make your patients and my patients happier. Thank you.

MS. ROGERS: Thank you. Joseph Mashni, Lansing Institute of Urology.

DR. MASHNI: I represent four urologists -- one semi-retired, but four urologists in the local area here. And I'll present some data for you to explain to you. We have two mobile units that come in, one every three weeks, and one every other week. So we don't really have a long-term wait, but there's still enough of a problem. Between the five-member group that I have, about 550 patients in the year 2003 were treated with lithotripsy. 150 of them required intervention with stenting and secondary procedures to do that. That's a lot of numbers, if you were that patient. Even though -- with two mobile lithotripsies, we're getting those kind of numbers that require

secondary procedures. You've got to relax those rules to do that. And these are actual numbers I just pulled out yesterday. Thanks.

MS. ROGERS: Thank you. Robert Meeker, Spectrum Health.

MR. MEEKER: I'm Bob Meeker from Spectrum Health in Grand Rapids. I'd like to briefly comment on three aspects of the CON review standards for lithotripsy services, and I will follow up with written comments later in the week. First of all, I would like to strongly urge the Commission to retain CON coverage for lithotripsy. We've heard many people comment on the need to relax those standards, and indeed that may be true, but I would urge the Commission not to eliminate coverage altogether. Stone disease is a finite disease. As my friend Mark Mailloux said, there are a lot of different ways to treat it, and if the only thing you've got is a hammer or a lithotripter, that may be the only modality you use. And so I think that the proliferation of too many lithotriptors could result in unnecessary procedures. Related to the Comprehensive Kidney Stone Treatment Center, I was interested in some of the comments of Mr. Mailloux, and I hope to work with him between now and the Commission meeting. Certainly, we're very open to modifying the definition of a stone center. I know that there have been other comments -- I don't know that there have been any today -- that the number of lithotripsy procedures themselves might be too low, and certainly we would be willing to negotiate that. Perhaps Mr. Mailloux's approach of not having specific subdivisions, but rather having a total number of stone procedures might be a way to address that. So we think that the concept of a comprehensive kidney stone treatment center is important, especially with a number of mobile lithotriptors around the state, that ultimately, as we've already heard this morning, there are some procedures that -- I'm sorry -- there are some stones that are best taken care of with a fixed lithotripter when other machines or other modalities fail.

Finally -- and this may get to the concern about opening the standards a little bit -- we would strongly urge that the Commission reconsider the formula by which additional machines are justified under the need methodology. We acknowledge that the use of inpatient data, being the only data we have, may be a necessary evil, but it clearly is sort of a strange situation that we're justifying an outpatient procedure with inpatient data. If in fact we continue to use that formula, however, I think that the factor applied to inpatient discharges related to stone disease needs to be increased dramatically. I think that the number of inpatient discharges related to stone disease actually is going down. It certainly isn't increasing dramatically, whereas the number of outpatient procedures is increasing.

Earlier, folks from United Medical Systems demonstrated data that they had from their sites that show that that formula -- that that factor should be increased considerably. Data from the physicians who visit the West Michigan Stone Center at Spectrum Health, which until recently was the only provider of stone services in West Michigan, would also indicate that it needs to be increased. The current factor is .7. The proposed increase is .8. Our data would increase it at least -- it needs to be at least 1.2, and the data from United Medical Systems would indicate even higher than that. So we would strongly urge that that formula be reconsidered.

MS. ROGERS: Thank you. Brian Drabik, Cadillac Urology.

DR. DRABIK: My name is Brian Drabik, and I drove from Cadillac Urology today, because I feel so strongly about this. My partner, Steve Reznicek -- and the two of us work very hard to take care of a lot of patients in an underserved area. We do not have access to even a fixed mobile unit. The closest unit we have is Grand Rapids, and our patients are traveling an hour and a

half or even more. We're only allowed one day a month to take care of our patients in the lithotripter unit, and we're very busy. The two of us together have treated over 80 patients a year. That's double the national average. As most urologists, I would disagree with Mr. Meeker in that about 90 percent of our patients are actually treated on an outpatient basis, not inpatient basis, for stone disease. And some of the urologists who have spoken already have talked about the pain that patients go through. I don't know if everyone here understands, when we talk about kidney stone pain, what that really means. I know of no urologist -- in fact I almost want to ask questions and have people raise hands. But people here who have had a kidney stone know the kind of pain we're talking about. People who have children have either seen their wives deliver babies, or have delivered babies themselves. I know of no person who would rather have a kidney stone than deliver a baby. Our patients wait four or six weeks before they're treated for a kidney stone. Try to be in labor for four to six weeks. That's the kind of problem we're dealing with. That's how long our patients are waiting. That is very important to us. Our patients travel long distances, and they are going under very -- much more procedure than necessary by stenting. I've also had patients come to me, who I've put a stent in, and they've begged to have it out, because it was worse than the stone pain. I wouldn't significantly -- I feel very strongly that I would like the Commission to relax the needs and allow more lithotriptors, especially mobile units in Cadillac, where we can serve more people more quickly. I think that's unreasonable to have a patient wait that long. Thank you.

MS. ROGERS: Thank you. John Kopchick.

DR. KOPCHICK: Yes. My name's John Kopchick. Thank you for the opportunity to speak. I am a urologist at Spectrum Health in Grand Rapids, and as I look at the CON position, I want to basically come out against it.

There are pros and cons to the CON and to the lithotriptors. One of the pros is that you have a unit where lots of people can come in. In fact, there are about 55 doctors who are on staff at the lithotripsy center, and you have lots of different kinds of cases, lots of different people, so the support staff there do develop a good expertise. And the CON system is very good at trying to prevent duplication of services, so you have the same thing going on at all of the different hospitals around town.

However, as we've heard today, there are already market pressures at work that are causing lots of other services to be utilized for lithotripsy; going out of state, having lithotriptors travel from Detroit to Western Michigan to provide services that are otherwise not available. It seems to me as though the CON technique is an antiquated system. It's time to move into the next century. The CON system permits formation of a monopoly. The CON system has given Spectrum Health, Butterworth campus, a monopoly on lithotripsy. And I believe that you should let market forces, which are already at work, determine how people can best be served. Thank you.

MS. ROGERS: Thank you. Joseph Salisz, West Shore Urology, a Muskegon urologist.

DR. SALISZ: Dr. Joe Salisz. Thanks for allowing me the opportunity to speak. I trained at the time the lithotripsy business advented, and I was at Beaumont Hospital in Detroit. It quickly became the busiest urology program in the state. When the lithotripter that we had became outdated by machines that did not require immersion in water, the Beaumont Hospital system bought a new lithotripter, and it was readily apparent that it was better at treating ureteral stones than the previous machine.

And, therefore, the Big Three auto industries came to Beaumont and asked them to do a quick study to determine whether treating stones in the ureters from patients coming directly out of the emergency room would lessen their time off from work and improve their productivity and decrease their pain and suffering. Indeed, the studies showed that rapidly, that if you took a patient with ureteral stone up to the lithotripsy unit and had availability of the anesthesia, which obviously had changed from a general anesthetic to a regional or a sedation type of anesthesia, you could get that patient back out of the hospital and on the road back to work faster and more productive and with less pain and suffering. The problem was that there were multiple urologists using that machine, and because of that, because of scheduling conflicts and problems with the lithotripsy unit being completely consumed by patients that were scheduled weeks in advance, the study failed because we couldn't get times for those patients to come out of the emergency room and go directly up to the unit for lithotripsy. I'm now in an environment that's completely different than that. I'm in Muskegon, which is a rural community. It's 40 miles from the closest fixed lithotripter. Butterworth patients have had to wait -- we have block time for my urology group and for the other five urologists from Muskegon so that we can get patients in typically a month to six weeks, sometimes two months in the busy summer months when stones are more prevalent, so that patients are waiting typically four to six weeks for lithotripsy.

In the last six months, we had a machine now that comes from Henry Ford to come up and do lithotripsy in Muskegon, which has changed the convenience for the patients so that now they don't have to drive. I, personally, have had two patients involved in car-deer accidents on their way to Grand Rapids for lithotripsy, Kent County being the greatest car-deer accident county in the state. But, anyway, they prefer to stay in Muskegon for the lithotripsy, but the machine only comes once a month because of how busy it is. And typically the patients wait one to two months now for their lithotripsy, and so if you average it out, it's probably six weeks still for the lithotripsy. I encourage the state to drop the CON requirements so that lithotripsy is more available in the rural communities. Thank you.

MS. ROGERS: Thank you. John Arema (pronouncing). This is just a reminder. As you come up and speak, please sign your name. Thank you.

DR. ANEMA: For the record -- and pardon my handwriting. It's Anema (pronouncing) but no one can pronounce it anyway.

DR. ANEMA: I am a urologist practicing in Grand Rapids, and I also spend some time in a rural community near to Grand Rapids, Greenville. I'm sensitive to some of the concerns that have already been addressed today about rural access. And I think really the bottom line is that the current CON does limit access. Now, if you happen to live in a large metropolitan area like Detroit, where there are multiple institutions that have multiple lithotriptors, this is not really a concern -- or is not as big a concern. But for an area that's geographically located -- such as the western part of the state or all the rural communities in Michigan, this is a significant factor. Now, Dr. Wise has also mentioned earlier the economics of this have changed dramatically. When lithotriptors first became available, they were about \$2,000,000, and now the costs are much lower than that. They're much less expensive. And we are all concerned about the health of our rural hospitals, but up to this point, those hospitals are mostly completely X'd out of this type of treatment. These patients have to be sent to a referral center, and we've already heard about all the problems associated with that, if you happen to be unfortunate enough to live in a small community.

Now, we heard a comment that lowering the standard for CON would encourage physicians to do unnecessary treatments and I am a little offended by that. Our judgments are based on what's the best interest for our patients. If we were unscrupulous, we could still treat them

extra. We could still make extra money for those procedures if we so chose to do that. But that's not why, I don't think, anyone in this room went into medicine, and that's not how we help people. There was a comment earlier made about restricting the comprehensive stone centers to connections with residency programs. This is a problem. All of the residency programs are near the Detroit area. I'm sorry. There are a couple of D.O. -- it shows my bias -- D.O. residencies in other parts of the state. But by and large this would exclude the western part of Michigan from access to this type of care and service. So for all these reasons, we must relax the standards on the Certificate of Need for the benefit of all of the residents of Michigan. Thank you very much.

MS. ROGERS: Thank you. Don Pietruk.

MR. PIETRUK: Good morning. Thank you. My name is Don Pietruk. I'm here representing United Medical Systems today, which manages the lithotripter operated by Henry Ford Harper and Harper Hospital. We wish to support the changes proposed in the CON standard that the Commission approved at their last meeting. I've heard a lot of the concerns about access today. We obviously share that. The machine that we're operating

is so busy we cannot give access to any more hospitals at this point. But the changes proposed by the Commission, by removing comparative review, which effectively limits the number of machines that were operated in the state, goes a long way toward giving that -- starting that alleviation. I was a few minutes late, so I didn't hear the comments by Mr. Mailloux from U of M, but I did hear those from Mr. Meeker, and probably, you know, the data we have at our -- the data we have submitted previously indicates that the formula for deriving how much inpatient data can be used is -- we would agree needs to be tweaked. Our data suggests 2.0. Bob suggested 1.2. I think we could probably sit down and reach some sort of -- between now and the Commission meeting, we can probably sit down and reach some sort of factor, maybe working with the Department, to come up with a number that is reasonable in that regard. But certainly discounting the number of MIDV procedures makes no sense probably at this point. And, you know, I think the other thing I just wanted to add is that, you know, the -- clearly, what we've seen with our mobile and with the other mobiles that are operating around the state is that getting access to the community and rural hospitals is the critical thing here, and I think that doing it under the guise of CON seems to make sense, and the changes promulgated -- or proposed changes I think would do this in an orderly fashion. And so we wish to support continuing the CON process for litho, but making changes which make access -- which increase access to patients and to health facilities and to physicians. We'll submit some comments in writing to the Department also. Thank you.

MS. ROGERS: Thank you. Do we have any other speakers that would like to provide testimony regarding the lithotripsy standards today? Okay. Hearing none, it is 10:10, and this hearing is adjourned.

(Proceedings concluded at approximately 10:10 a.m.)