

**Michigan Department of Community Health (MDCH or Department)**  
**Report to Certificate of Need (CON) Commission**  
**Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Standards**  
**March 25, 2010**

On January 28, 2010, the Michigan Department of Community Health made a recommendation to the CON Commission that it consider these standards for deregulation. The department utilized the Commission's "Guiding Principles for Determining Whether a Clinical Service should Require Certificate of Need Review" in evaluating whether the UESWL standards should continue to be regulated. After further deliberation, the Department recommends that this service be deregulated. The Department bases its recommendation on the points listed below. If the Commission chooses to pursue deregulation of UESWL, then the process would be to move to Public Hearing and back to the Commission for final action.

- This is a well established service with Michigan CON standards in place for the past 25 years. It is no longer a new technology. The first approval of a lithotripter device in the United States was in 1984.
- This is a low-cost service. In 2007, Great Lakes Lithotripsy, which has 4 (four) mobile sites in Michigan, provided estimated annual cost data for what both a mobile and fixed unit would cost. Those estimates were that for one fixed site lithotripter unit it would cost \$369,996.00 annually whereas a mobile unit serving 10 sites annually would cost \$49,239.60 annually per site. The key point is that it is more cost effective to run a mobile route for lithotripsy than it is to have one fixed unit. No significant cost increase has been shown.
- Access does not appear to be an issue, and no access concerns have been brought to our attention through the processes of public hearing or public testimony.
- Currently, Michigan has 9 lithotripters and all of them are mobile units.
- There has been no evidence of proliferation presented. This procedure must be performed in an operating room and under the guidance of an anesthesiologist and is a treatment procedure rather than a diagnostic or exploratory procedure.
- UESWL is a non-invasive medical procedure and patients are most commonly treated as outpatients rather than inpatients.
- Currently, Michigan does not regulate other forms of this procedure such as laser treatments or using lithotripters for biliary procedures. Other states were found to regulate for biliary and not for renal (urinary). This raises the question of whether the intent of the Michigan standards is to regulate the medical procedure rather than the equipment.

- In 2007, the department considered recommending deregulation of the UESWL standards; however, questions were raised by a 2006 Mayo Clinic study<sup>1</sup> that hypothesized a link between UESWL and some chronic health conditions (diabetes mellitus and hypertension). Subsequently, studies in 2008<sup>2</sup> and 2009<sup>3</sup> have refuted the finding of the 2006 study eliminating the department’s concern of moving too quickly.
- Some questions/concerns have been raised in regard to the number of re-treatments. Re-treatment data is collected as part of the annual survey process, and currently, the available data does not show increases or unusual numbers of re-treatments.
- Research also shows that expulsive therapy or drug treatment to relax the urinary system muscles to facilitate the passage is a more common treatment than is lithotripsy.
- Only 17 other states regulate Lithotripsy; however, no other states in the mid-west except for Michigan do so. See list below.

CON States w/Lithotripsy Coverage	CON States w/o Lithotripsy Coverage	Non-CON States
Alaska	Alabama	Arizona
Connecticut	Arkansas	California
Delaware	Florida	Colorado
Dist. Of Columbia	Illinois	Idaho
Georgia	Iowa	Indiana
Hawaii	Louisiana	Kansas
Kentucky*	Maryland	Minnesota
Maine	Mississippi	New Mexico
Massachusetts	Montana	North Dakota
Michigan	Nebraska	Pennsylvania
Missouri	Nevada	South Dakota
New York	New Hampshire	Texas
North Carolina	New Jersey	Utah
South Carolina	Ohio	Wyoming
Tennessee	Oklahoma	<b>14 States Total</b>
Vermont	Oregon	Source: American Health Planning Assoc. 2009 National Directory State Certificate of Need Programs Health Planning Agencies
Virginia	Rhode Island	
<b>17 States Total</b>	Washington	
*Coverage for mobile units only.	West Virginia	
	Wisconsin	
	<b>20 States Total</b>	

<sup>1</sup> Krambeck, A.E., Gettman, M.T., Rohlinger, A.L., Lohse, C.M., Patterson, D.E., & Segura, J.W. (2006). Diabetes mellitus and hypertension associated with shock wave lithotripsy of renal and proximal ureteral stones at 19 years of followup. *The Journal of Urology*, 175(5): 1742-1747.

<sup>2</sup> Sato, Y., Tanda, H., Kato, S., Ohnishi, S., Nakajima, H., Nanbu, A., et al. (2008). Shock wave lithotripsy for renal stones is not associated with hypertension and diabetes mellitus. *Urology*, 71(4): 586-591.

<sup>3</sup> Makhoulf, A.A., Thorner, D., Ugarte, R., & Monga, M. (2009). Shock wave lithotripsy not associated with development of diabetes mellitus at 6 years of follow-up. *Urology*, 73(1): 4-8.

- The following three states are a sample of how other states regulate Lithotripsy under CON:
  - Massachusetts:
    - The website for the Massachusetts Department of Need (DON) lists “that any addition or expansion of, or development of innovative services and new technology, non-acute care services, or freestanding ambulatory surgery centers” are regulated under DON. These new technology services include the use of ESWL for gallstones. Lithotripsy, in general, is regulated under DON but to what extent it is not clear. Additional research found that the MA regulations for Lithotripsy only included the following three categories in which applicants must meet: physical environment requirements, anesthesia requirements, and agreements for inpatient services.
  - Missouri:
    - According to the Missouri Certificate of Need website they regulate Lithotripsy under the major medical equipment acquired over the period of 12 months with an aggregate operating cost of over one million dollars or more. Therefore, they regulate based on a dollar amount threshold. Within the standards, they have a need methodology formula that is applied for lithotripsy when the cost is one million or more in which applicants must then meet to both initiate and expand.
  - New York:
    - According to the New York state laws and regulations contained on their website, they regulate lithotripters for use in renal and biliary (gallstones) procedures. In New York’s standards they do list an annual volume capacity for each lithotripter is 600 patients per year which includes both biliary and renal patients.
- On February 22, 2010, MDCH staff met with a Lithotripsy provider to gain input on their thoughts of the current UESWL CON standards in Michigan. Jorgen Madsen from the United Medical Systems presented the Department information regarding their involvement with UESWL being the largest mobile route provider in Michigan.