Discussion Meeting Summary
April 28, 2010
Urinary Extracorporeal Shock Wave Lithotripsy

Present: Irma Lopez, *MDCH*; Brenda Rogers, *MDCH*; Sallie Flanders, *MDCH*; Kasi Hunziger, *MDCH*; Jessica Austin, *MDCH*; Jorgen Madsen, *Great Lakes Lithotripsy*; Melissa Cupp, *Wiener Associates*; Dennis McCafferty, *Economic Alliance of Michigan*; Amy Barkholz, *Michigan Health and Hospital Association*; Penny Crissman, *Crittenton*; Bill Finateri, *Beaumont*; Robert Meeker, *Spectrum*; Karen Kippen, *Henry Ford Health System*

The Department submitted its report and recommendation to deregulate Urinary Extracorporeal Shock Wave Lithotripsy services to the Certificate of Need Commission at the March 25, 2010. At the request of the CON Commission, the Department held a discussion group on April 28, 2010, for the purpose of gathering additional information from interested parties regarding whether to continue regulating lithotripsy or to deregulate this service. This summary reflects the discussion of April 28.

Several participants expressed concern that deregulating lithotripsy services would have a negative impact as the state has no other quality oversight mechanisms in place other than the CON standards. They further noted that CON regulation is a cost-effective way for the state to monitor quality, access, and cost.

One participant stated that low costs are maintained through high utilization of each existing unit; adding more units in the state would likely result in existing services losing procedures. If physicians are able to obtain equipment for use in their office costs may rise as lithotripsy is exempt from Stark's Regulation; and, as such, doctors may self-refer for the procedure.

Participants questioned why the Department would recommend deregulation to the Commission when this had not been identified as an issue for consideration. Department staff noted that whether or not a particular set of standards should continue to be regulated is always the first question that is considered as part of the regular cycle of review for each set of standards that is required by statute. The Department provided a recommendation to the Commission on this issue along with recommendations on issues that had been identified through public testimony. Lithotripsy has twice been considered for deregulation; in 2007 and in 2005.

The participants also expressed concern that there had been inadequate advance notice that the Commission might be discussing deregulation of lithotripsy services at their March meeting. However, the Department had presented a recommendation that the Commission consider deregulating Lithotripsy at the January Commission meeting. At its March meeting, the Commission asked that the Department's March report be posted on its website, and requested that a meeting be scheduled to gather comments which resulted in the April 28 meeting.

Several participants pointed out that the standards had been previously modified to address possible problems with access approximately ten years ago by eliminating the cap and by expanding the role of mobile units to assure broader geographic access. The consensus of the group was that these changes demonstrated a positive response to an

identified shortcoming in the standards and resulted in improved standards and justified the existing regulation.

One participant suggested reviewing the question of regulation vs. deregulation through addressing three questions:

- What has the impact of regulation been on cost, quality, and access?
- What are the potential consequences -positive and negative -of deregulation?
- Who is complaining about continued regulation?

Representatives of several medical groups, including Henry Ford, Sparrow, Oakwood, and St. John/Ascension voiced support for continued regulation to maintain quality, low cost, and access. All meeting attendees, with the exception of the Department representatives, support the continued regulation of lithotripsy.

Participants agreed to go through the Commission's document entitled "Guiding Principles for Determining Whether a Clinical Service Should Require Certificate of Need (CON) Review" point-by-point. Group consensus on whether lithotripsy meets these guidelines follows each statement in bold italics.

1. The clinical service has low capital costs. For purposes of this document, low capital costs are defined to mean the capital costs associated with developing and offering a service, including but not limited to buildings, equipment, etc., are less than the covered capital expenditure threshold (currently $2,942,500). YES: ***Capital costs for lithotripsy services are well below the existing threshold. The group notes that most current covered clinical services fall within the definition of low capital costs; e.g. MRI, CT, PET/CT.***

2. The clinical service has low operating costs. YES: C***urrent cost data is attached. The group expressed concern that the Guiding Principles do not provide a good measure for determining whether operating costs are high or low; therefore, it is not possible to answer this question as written. However, the consensus of the non-department staff is that mobiles can be operated more cost effectively and efficiently than fixed units and removing CON advantages for mobile services will result in increased operating costs. It was noted that operating costs primarily consist of costs related to the driver and the technician.***

3. The capital and operating costs associated with providing the service have decreased significantly during the 3 most recent years. NO: ***These costs have not significantly changed, either up or down, over the past 3 years.***

4. At the time a clinical service was included on the list, the service was new technology that was primarily provided by tertiary care centers and was not available widely in the community, and has since become an accepted standard of care provided in community settings. YES: ***Lithotripsy was a new service when first regulated, but now has become standard of care.***

5. Other organizations or mechanisms monitor the provision of the clinical service. For example, the service is licensed or certified by a state agency, or a voluntary accreditation program operated by a recognized private organization exists. NO:

The only other oversight is provided by MDCH Radiation Safety Section, which only regulates lead shielding in rooms where lithotripsy equipment is present.

6. The current CON review standards do not establish a methodology that quantifies how the need for the clinical service shall be demonstrated. NO: ***The current CON review standards establish a need methodology.***

7. The requirement to obtain a CON negatively affects geographic access to a clinical service that is considered a standard of care (No. 4) or a less costly alternative to other services. NO: ***The opinion of the non-departmental staff is that the requirement to obtain a CON positively affects access to lithotripsy service.***

8. The quality of a clinical service has not been linked, in scientific studies, to the volume of care provided. YES: ***There have been no scientific studies identified that have linked the number of lithotripsy procedures performed to quality of service. However, the group discussion suggests that there may be anecdotal information that would equate quality to the amount of experience and the proficiency gained by the specialized technicians performing a greater number of procedures. If the volume of procedures being performed by current providers was reduced, it could be argued that quality would be negatively impacted due to a decreased opportunity for the technicians in accruing experience and proficiency.***

9. Reimbursement policies, alone or in conjunction with quality assurance mechanisms, limit unnecessary or inappropriate utilization of the clinical service. NO: ***The service is reimbursed if provided and self-referral is possible. One area of concern previously raised was whether there were unnecessary re-treatments being carried out. The Department has a year of data that does not appear to show inappropriate levels of re-treatments; however, the group suggests looking at the data over a longer period of time before drawing conclusions and making final recommendations.***

Participants suggested several modifications to these review guidelines in regard to lithotripsy, including an assessment of the potential impact both "positively" and "negatively." Additionally, the group suggests adding a tenth item to the review guidelines that requires that we consider the potential consequences of deregulation; intended and unintended.

Participants also suggested weighing the experiences of other states that have deregulated lithotripsy services. These states include New Jersey, West Virginia, New Hampshire, Illinois, Mississippi, Kentucky, Alabama, and Georgia.

Some questions were raised as to whether it is actually possible to make fair comparisons between states for the following reasons:

1. States vary in how "regulate" is defined and carried out.

2. CON program operations vary from state to state; there is no single model.

3. States vary widely geographically and demographically.

While it may be possible to obtain anecdotal reports of experiences with regulating or deregulating lithotripsy from other states, it is not clear that those experiences can be completely translated to Michigan's experience.

In closing, the group suggests that the Commission and the Department place emphasis on quality and access issues in making its final determination regarding regulating or deregulating lithotripsy services. Cost certainly is an important factor in CON, but as noted above lithotripsy capital and operating costs are not excessive when compared to other CON regulated services or equipment. A concern expressed by participants is that deregulating lithotripsy will likely result in increased costs. This will be realized through the purchase of additional litho machines, resulting in lower volume per unit and, therefore, higher costs per procedures; and potential diminution of quality. This presumes that there are many providers ready to purchase the equipment if deregulation occurs, which could result in competition to existing services.

Participants believe that the impact of CON regulation of lithotripsy in Michigan has been greatly improved access (particularly geographic access) and lowered costs. Although there has been no demonstrable impact on quality, a limited number of highly qualified personnel accompanying the mobile equipment to perform procedures in locations throughout the state would seem to promote quality.

The consensus of meeting participants, excluding Department staff, was that lithotripsy should continue to be regulated under CON which they believe is strongly supported by the guiding principles analysis described above.

UESWL Service Cost Estimates - 2010
Unit Cost Comparison

	MOBILE	FIXED
Cost for 10 Mobile Sites versus 10 Fixed Sites over five year period.	2,491,980.00	18,799,800.00
	Monthly Per Mobile Unit Cost	Monthly Per Fixed Unit Cost
Total Personnel Expenses	13,250.00	8,000.00
Depr - Medical Equipment	8,333.00	8,333.00
Total Insurance Expenses	1,000.00	750.00
Service Contracts	4,000.00	4,000.00
Repairs & Maintenance	250.00	250.00
Total Vehicle Costs	2,500.00	-
Total Travel Expenses	2,000.00	-
Total Communications	200.00	-
Management Fees	8,000.00	8,000.00
Other Expenses	2,000.00	2,000.00
Estimated Monthly Cost	41,533.00	31,333.00
Estimated Annual Cost	498,396.00	375,996.00
# of Sites serviced	10	1
Estimated Annual Cost per Site	49,839.60	375,996.00
Estimated Cost per Site over 5 year project term	249,198.00	1,879,980.00
# of Sites	10	10
Cost for 10 Mobile Sites versus 10 Fixed Sites over five year period.	2,491,980.00	18,799,800.00