From: Pat Anderson <PatAnderson@Hcam.org>
Sent: Tuesday, May 02, 2017 7:48 AM
To: MDHHS-ConWebTeam
Subject: MRI Public Hearing Comment 2-4-16 through 2-11-16
Attachments: HCAM Testimony May 2 Hearing.pdf

Attached are the comments for the Nursing Home and Hospital LTC Unit Standards from the Health Care Association of Michigan.

Patricia E. Anderson
Exec VP of Reimbursement Services
Health Care Association of Michigan/Michigan Center for Assisted Living
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CON Public Hearing
Nursing Home and Hospital LTC Units
HCAM Testimony
May 2, 2017

The Health Care Association of Michigan welcomes the opportunity to participate in this public hearing regarding the Certificate of Need standards for Nursing Homes and Hospital LTC Units. HCAM did participate in the recent workgroup that reviewed the standards and recommended many of the changes being proposed. HCAM is supportive of all of the proposed changes to the CON standards and looks toward approval by the CON Commission. Once approved HCAM would recommend that the bed need for nursing homes be updated based on the changes to the methodology.

While HCAM is in agreement with the changes we continue to have a concern regarding the CON requirement and related fees for renewal of leases with no change to either party to the lease. Currently a lease renewal above the capital expenditure limit requires a new CON and payment of the related fees. HCAM questions whether or not a renewal lease between the same parties should be considered a change that requires CON. This issue was discussed extensively at the workgroup but the department with guidance from their attorney general did not agree. HCAM is reviewing their position and potential next steps which may include a legislative change.

The workgroup then approached the issue of the fee assessment based on the entire life of the lease arrangement. Some of these leases are for over 20 years and the value for that many years is great. This high multi-year value causes CON fees to be huge due to the length of the lease. Again the workgroup reviewed the fee issue but the department did not feel any change could be made and the workgroup did not come to a consensus on the issue. HCAM would like the department to consider for CON fee purposes to reducing multi-year leases to an annual year amount for the determination of the fee. This would continue the lease renewal but lower the fee substantially.

Thank you for the opportunity to provide input on these CON Standards. If you have any questions please contact me at patanderson@hcam.org or call 517-627-1561.

Patricia Anderson
Exec. VP of Reimbursement Services
Health Care Association of Michigan

From: Melissa Cupp <cuppm@rwca.com>
Sent: Tuesday, May 09, 2017 1:41 PM
To: MDHHS-ConWebTeam
Subject: UESWL Public Hearing Comment 5-2-17 through 5-9-17
Attachments: GLL Letter to Commission re Litho Standards 5-2-17.pdf

Good afternoon. I just realized that the subject line for my previous email referenced MRI and dates from last year instead of UESWL and the current dates. I didn't actually type in the subject line, so I'm guessing that's something that is auto-generated when I clicked on the email address in the public hearing notice. I apologize for not noticing it and changing it before sending. Wanted to make sure that you recognized that the attached letter is for the current public hearing on UESWL services ending today.

Thanks,
Melissa

Melissa D. Cupp
Partner
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RWC ADVOCACY
A Governmental Affairs Law Firm

From: Melissa Cupp
Sent: Tuesday, May 09, 2017 9:29 AM
To: MDHHS-ConWebTeam@michigan.gov
Subject: MRI Public Hearing Comment 2-4-16 through 2-11-16

Please find the attached written comments regarding the Certificate of Need Review Standards for UESWL Services, in response to the public hearing notice for May 2, 2017.

Please let me know if you have any trouble with the attachment.

Thanks,
Melissa

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RWC ADVOCACY
A Governmental Affairs Law Firm
[illegible]

From: Melissa Cupp <cuppm@rwca.com>
Sent: Tuesday, May 09, 2017 9:29 AM
To: MDHHS-ConWebTeam
Subject: MRI Public Hearing Comment 2-4-16 through 2-11-16
Attachments: GLL Letter to Commission re Litho Standards 5-2-17.pdf

Please find the attached written comments regarding the Certificate of Need Review Standards for UESWL Services, in response to the public hearing notice for May 2, 2017.

Please let me know if you have any trouble with the attachment.

Thanks,
Melissa

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UNITED MEDICAL SYSTEMS

May 2, 2017

Mr. Suresh Mukherji, MD
Chairman
Certificate of Need Commission
Michigan Department of Community Health
333 S. Grand Avenue
Lansing, Michigan 48933

Re: CON Standards for UESWL Services

Dear Chairman Mukherji,

Thank you for this opportunity to provide public comments regarding the proposed changes to the Certificate of Need Standards for Urinary Extracorporeal Shockwave Lithotripsy (UESWL) Services. As the managing partner of Great Lakes Lithotripsy and Michigan CON, LLC, two mobile UESWL provider in Michigan, we wanted to share our support for most of the proposed changes, but our concerns specifically regarding the language added at the March Commission meeting.

The changes proposed by the Department last year provide relevant updates to the standards and clarify some requirements that were often misunderstood by applicants. We continue to support those changes and would encourage you to move those forward for final action. However, we do have concerns with the language that was added at the last meeting.

As we have explained previously, the current UESWL CON standards greatly encourage a mobile system due to the relatively low volume of lithotripsy procedures by any single provider. By encouraging the use of mobile units, we have been able to provide very broad geographic access, while maintaining excellent quality and relatively low cost. Rather than individual facilities purchasing their own equipment to perform a relatively low number of procedures, we are able to concentrate procedures on 10 units across the State. In fact, looking at the data from our host sites, the average host site performs only 122 procedures per year. That is just 2.34 procedures per week.

The current system not only provides for efficient use of capital, but it also helps to ensure high quality. Unlike many procedures performed in the operating room, this procedure is overseen by a physician, but primarily performed by a technologist. If each host site instead purchased their own unit and hired their own technologist, that technologist would perform significantly less procedures than they do now. Under the current system, each technologist performs approximately 1,000 procedures per year. If the highest volume sites converted to fixed service, that number would decrease significantly. The fixed sites would not have enough volume to keep a technologist busy full-time, so they would likely use a tech that has other primary responsibilities. This would be exacerbated even further when you consider the need for coverage when techs are on vacation or ill – when techs with even less experience would be called in to cover. The mobile routes would also see a significant volume decrease and therefore even the technologists on the mobile routes would no longer have the benefit of the high volumes. In fact, technologist volumes would decrease as much as 57% on some routes.

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The current system has improved access to this service tremendously. Prior to the early 2000's when the current system was put into place, the only way to obtain UESWL service was to travel to one of the 4 fixed sites in the State. Those were all concentrated in Southeast Michigan, with the exception of one unit in Grand Rapids. Today we have 81 host sites providing this service all across the State, including the Upper Peninsula. However, this system relies upon a balance of high volume and lower volume sites. If you allow for high volume sites to convert to fixed service, and leave just the lower volume sites on the mobile routes, the current system becomes jeopardized.

We hold CONs for 4 mobile lithotripsy routes in Michigan, with a total of 7 units. 3 of the 4 routes have a host site that would qualify to convert to fixed service under the language proposed by Sparrow. Lithotripsy Network No. 147 would lose 57% of their current volume. One of the units on Lithotripsy Network No. 74 would lose 36%, and one of the units on Lithotripsy Network No. 23 would lose 40%. It is impossible to believe that a route/unit could sustain that kind of loss in volume and yet continue to maintain service at the same price. Fixed costs will either have to be absorbed by a fewer number of sites or routes will collapse, jeopardizing access to 45 sites across the State, severely limiting geographic access to this procedure.

Sparrow mentioned in their comments that they feel the costs paid for mobile lithotripsy service are excessive considering the cost of purchasing a unit themselves. However, the numbers they provided compared their annual payments to their mobile provider with just the cost of a lithotripsy unit itself. The fact of the matter is that the cost paid to the mobile provider include much more than just the unit. The mobile service provides the technologist to operate the unit (including all of the expenses associated with any employee), insurance, maintenance, service contracts, etc.

Sparrow also made the argument that adopting their proposed language would make the lithotripsy standards consistent with other standards. However, this just is not the case. First, there are only two sets of standards that currently allow for the conversion of a mobile host site to a fixed service, MRI and PET. The MRI standards require a host site to be meeting the minimum volume for a fixed unit in order to qualify to convert to fixed service. The PET standards require a host site to be meeting three times the minimum volume for a fixed service before qualifying to convert. The minimum volume for a lithotripsy unit is 1,000 procedures per year. Sparrow's proposal would only require the host site to be at ½ of the volume required for a fixed unit. Not only is this inconsistent with these other standards, but it sets the new fixed service up for failure. They would have to double their volume within the first 2 years of converting in order to be in compliance with their CON approval. If the demand existed for them to perform more procedures there is no reason why they would not add days of service currently to meet that demand. They are available. In order for this proposal to be consistent with the other standards that allow for this concept, the host site volume would need to reach 1,000 procedures per year to qualify.

Although we appreciate Sparrow's frustration with the fact that a Standards Advisory Committee could not be formed due to a lack of interest on the part of payers/purchasers and consumers, we are concerned with the idea of moving this language forward to final vote without a full discussion of the bigger picture and ramifications of this proposed change. For example, by

pulling existing routes below minimum volume requirements, existing providers will not be able to replace aged equipment. This means that not only are the routes in jeopardy from a financial perspective, but they would be unable to replace equipment and would eventually either be providing inferior quality and/or eventually have to shut down altogether, further exacerbating the risk to geographic access.

If the Commission is going to allow new entrants into this market, there should be serious consideration for adding accreditation/certification requirements. We believe that all lithotripsy technologists should be tested and credentialed by the CUI Board (Coalition of Urological Interests) every 3 years and all fixed sites accredited specifically for lithotripsy by the Healthcare Facilities Accreditation Program (HFAP) or another comparable organization. In addition, we have recently learned that Blue Cross Blue Shield of Michigan has partnered with Urologists across the state to create a program called MUSIC to help improve patient outcomes. It is our understanding that MUSIC will be adding UESWL treatments to their initiative and we would be very interested in learning how CON might be able to encourage participation in this program.

I do appreciate your time in considering these comments and would ask that you either remove the Sparrow proposal and move the original language forward with final action or at least consider a means to have a more meaningful dialogue.

Respectfully,

Jorgen Madsen
CEO

From: Robert Meeker <meekerbob48@gmail.com>
Sent: Tuesday, May 09, 2017 10:59 AM
To: MDHHS-ConWebTeam
Cc: Alan Buergenthal; Mark Drake
Subject: UESWL CON Standards
Attachments: Public_Hearing_Testimony 050917.pdf

Please find attached public testimony from Greater Michigan Lithotripsy about the proposed changes to the CON Standards for UESWL Services.
Feel free to contact me if you have any questions about the attached.
Bob Meeker

Greater Michigan Lithotripsy, LLC

May 8, 2017

Suresh Mukherji, M.D. Chairperson
Certificate of Need Commission
c/o Certificate of Need Policy Section
Michigan Department of Health and Human Services -
5th Floor South Grand Building,
333 S. Grand Ave.
Lansing, MI 48933

Dear Dr. Mukherji,

This letter is written as public testimony about the proposed changes to the CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services. Specifically, we would like to comment on the proposed language regarding converting from a mobile to a fixed lithotripsy service.

Greater Michigan Lithotripsy (GML) has been providing mobile lithotripsy services in Michigan for twelve (12) years. GML operates three (3) mobile routes covering much of the state. AKSM, Ltd., a national lithotripsy management company, has been the manager of GML since its inception.

The evolution of kidney stone treatment using lithotripsy is very different from the trends in other mobile technologies governed by CON. For all mobile services, the mobile units provide access to technology for health care facilities without fixed equipment. However, for other mobile modalities -- eg. MRI, PET -- mobile units provide access mostly to rural sites without the volume to justify a full-time machine. Mobile units are constrained by the dimensions of the trailer that houses them. As host site volume increases, there are CON paths to convert to fixed units, allowing access to state-of-the-art technology within the walls of the facility.

In the case of lithotripsy, this trend is reversed. Originally UESWL units were fixed at large teaching hospitals. The first generation machines were large and cumbersome, taking up a whole room. Over time, two things happened: 1) the technology evolved, becoming more effective and easily transportable, and 2) alternative kidney stone treatments were developed not requiring lithotripsy. That is why, today, the national model for UESWL services is overwhelmingly mobile. Therefore, the lithotripsy units that come to the approved host sites across Michigan are no different from those used at large academic kidney stone centers across the country. In Michigan, state-of-the-art equipment is wheeled into the operating rooms of host hospitals and surgery centers. In this way, practicing urologists at each site have access to the best technology available. Hence there is no technological advantage to having a "fixed" UESWL unit. The technology is the same for fixed and mobile.

A UESWL service is more than just a lithotripsy machine. Mobile host sites receive a comprehensive service package from their central service provider. Not only does this comprehensive mobile lithotripsy service include state-of-the-art equipment with

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constant upgrades, but it also provides trained, experienced, and certified technologists; at least quarterly preventive maintenance; local and national quality assurance and review; appropriate insurance; compliance oversight; non-OEM proprietary upgrades; and annual certification. The value of these important support functions is more than half a million dollars a year for each mobile machine. Hence, the cost of the lithotripter is simply a component of the cost of operating a full-service lithotripsy service.

Originally, the CON requirement for initiating a fixed lithotripsy in Michigan was the projection of least 1,000 procedures per year. The current standard for mobile lithotripters is still 1,000 procedures per year. In all CON Standards allowing both fixed and mobile services, mobile units have lower required volumes for initiation than do fixed units. This makes sense, since the fixed machine is available at its designated location all the time, whereas mobile units have down time for transport between authorized locations. However, the proposed language for converting from mobile to fixed requires that the host site demonstrate only 500 per year. To be consistent with other CON Standards, the volume requirement for converting to a fixed lithotripsy service should be at least as high as that for mobile.

The existing mobile routes for lithotripsy in Michigan include combinations of large, medium and small sized hospitals. There are nine (9) host sites, including Sparrow, performing more than 300 procedures a year in the state. However, even the highest volume host site at 755 annual procedures (200 higher than Sparrow), would perform only 3-4 procedures daily, if they had fulltime access to the machine. This volume represents only about 30% of the optimum capacity of equipment that can easily perform ten (10) or more procedures in a normal day. Thus, allowing fixed lithotripters, even in the highest volume facilities, would result in greatly underutilized lithotripters.

The higher volume sites on mobile routes are analogous to "anchor stores" in a shopping mall. By providing the highest percentage of the volume performed by the mobile unit, they enable the route to serve smaller facilities, permitting access for patients in more remote communities. If the "anchor" sites leave the route, the other sites would be unable to sustain the machine, causing the route to fall below CON minimum volumes and increasing costs for the other sites, which then would have to cover the fixed costs over fewer procedures. Costs for the remaining host sites on a route losing a high-volume host site would only increase. In the extreme case, existing routes would have to consolidate, in order to keep the machines sufficiently well utilized and the routes viable. With more host sites served on fewer routes, machine time conceivably would be less available, resulting in reduced service for existing host sites. Ironically, allowing fixed lithotripters at a few high-volume centers could decrease access to lithotripsy services across the state.

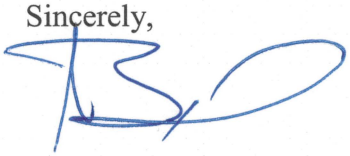
In consideration of the CON values of cost, quality and access, the proposed changes to the UESWL CON Standards allowing conversion to fixed lithotripsy with lower projected volume would be counter-productive. By diluting existing volume over more machines, costs would increase for existing host sites. Moreover, technologist proficiency and quality would be compromised with the proliferation of machines, because fixed site lithotripsy technologists will perform fewer procedures than those currently employed by the mobile providers. Likely, this effect would cascade to

technologists on the mobile routes as well, due to anticipated lower volumes. Additionally, access could be constrained if existing providers need to consolidate the existing mobile routes in response to reduced volumes resulting from the loss of high-volume host sites. Hence, from the standpoint of cost, quality and access, adoption of the proposed changes to the Standards, which would allow establishment of fixed lithotripsy services with lower projected volumes than the mobile routes, just doesn't make sense.

Based on these concerns, GML requests that the CON Commission not give final approval to the proposed language which would allow conversion from mobile to fixed lithotripsy with the reduced volume of only 500 procedures per year. If you feel that this topic may still have merit, we request a delay in final approval while a mechanism (eg. a work group) is implemented to permit more meaningful dialogue on the subject.

Thank you for the opportunity to comment on the proposed changes to the CON Review Standards for Lithotripsy Services. I intend to attend the CON Commission meeting on June 15, 2017, at which time I will be happy to discuss this matter in more depth, if desired.

Sincerely,



Alan Buergenthal,
Chief Executive Officer

From: Carrie Linderoth <clinderoth@kelley-cawthorne.com>
Sent: Monday, May 08, 2017 4:41 PM
To: MDHHS-ConWebTeam
Cc: Nagel, Elizabeth (DHHS); Shaski, John
Subject: Lithotripsy Public Hearing Testimony for Sparrow Health System
Attachments: Lithotripsy Public Hearing Testimony.pdf

Good afternoon,

Attached is public hearing testimony from Sparrow Health System with regard to Lithotripsy Services.

Please contact me if there are any questions or concerns with this testimony.

Carrie

Carrie A. Linderoth

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clinderoth@kelley-cawthorne.com

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Sparrow

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May 8, 2017

Dr. Suresh Mukherji
Chair, Certificate of Need Commission
Department of Health & Human Services
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing, MI 48933

Re: Lithotripsy Standards

Dear Dr. Mukherji:

Sparrow Health System ("Sparrow") would like to thank the Commission and the Department for their deliberation on the on the UESWL / Lithotripsy Standards.

Per the Commission's request, attached is a breakdown comparing what the anticipated costs will be for the next three years under a fixed or mobile scenario. The fixed unit's cost is $575,000 plus $60,000 annually for a service contract – contrasted with annual mobile lease costs of at least $750,000.

As you can see, approving language allowing for conversion from a mobile to a fixed unit will provide significant financial relief to our organization and other hospitals with consistently high patient need. Our patients will appreciate having readily available access to a pain-relieving equipment that can address a diagnosis that simply cannot wait weeks for treatment.

As always, Sparrow supports the Certificate of Need process and is grateful for the opportunity to work through this issue to a constructive outcome.

We appreciate your time and consideration.

Sincerely,

John A. Shaski

John A. Shaski
Government Relations Officer

Attachment
cc: CON Commission members
Beth Nagel

1200 E. Michigan Avenue
Lansing, Michigan 48912

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Sparrow Hospital
Lithotripsy Fixed versus Mobile

Volume Projections	Year 1	Year 2	Year 3
Volume - year 1 = 2016 volume	583	550	550
Fixed Unit Annual Projected Expense*	$248,376	$319,804	$321,223
Mobile Unit Annual Projected Expense	$ 778,305	$ 756,278	$ 756,278
Annual Savings	$ 529,929	$ 436,474	$ 435,055
Three year cumulative savings	$ 1,401,458		
One time cost to purchase	$575,000		

*Includes service contract of $60,000 annually