

August 10, 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 Surgical Services

Dear Chairman Mukherji,

I understand that the Certificate of Need Commission is in the middle of reviewing potential changes to the Certificate of Need Standards for Surgical Services and that this is an opportunity to provide public comments regarding these standards. Although my comments are not directly regarding the proposed changes approved by the Commission at the June meeting, I am reaching out regarding a concern with the Surgical Services Standards.

The Centers for Medicare and Medicaid Services ("CMS") is implementing policy changes to address serious concerns about the fragmented system of care for individuals with End-Stage Renal Disease ("ESRD"), including the optimal type of vascular access for dialysis and preferred care settings. The type of vascular access is a major contributor to morbidity, mortality and cost associated with dialysis. Specifically, CMS has sponsored the Comprehensive ESRD Care Initiative and supports the creation of alternative payment models through a new concept known as "ESRD Seamless Care Organizations" ("ESCOs"). ESCOs seek to address:

- Poor health outcomes for ESRD patients due to underlying disease complications and co-morbidities; and
- High rates of hospital admission and readmission, as well as a mortality rate that is higher than that of the general Medicare population for patients with ESRD.

Although for cost and quality reasons, a renal-focused ambulatory surgery center ("ASC") is optimal, the current CON Standards for Surgical Services impose an insurmountable barrier to implementation of a renal-focused ASC and the CMS coordinated care model.



We recently met with the Michigan Department of Health and Human Services. The Department encouraged us to submit this letter and request an opportunity to present more detailed information about this complex issue and the access and quality issues for ESRD beneficiaries. We recognize that we are raising this issue late in the process for the review and proposed revisions to these CON Standards. We are not looking to delay action on the changes to these Standards already under way, but would very much appreciate an opportunity to share with you the challenges we are facing and work to find a mutually beneficial solution that would enhance care and outcomes for ESRD beneficiaries in Michigan.

Thank you for your time in considering these comments. Please feel free to contact me directly with questions and for further discussion at 717-515-4048 or <a href="mailto:greege.miller@azuracare.com">greege.miller@azuracare.com</a>.

Respectfully,

Gregg Miller, MD

Vice President Operations

Azura Vascular Care

August 3, 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 the proposed changes adopted by the Commission at your meeting June 15, 2017, including specifically, the amendment to increase the volume requirement for converting a host site to a fixed service from the previously proposed 500 to 1,000 as recommended by the Department.

Based on the discussion at the June meeting, I wanted to take this opportunity to provide more specific data referenced during that meeting. There were a lot of questions regarding Sparrow's volume and their ability to meet the 1,000 minimum volume for a lithotripsy unit on their own. Sparrow made the assumption that they would have the demand to fill a unit full-time if they own their own unit and have it available full-time. I have several concerns with this assumption.

First, this assumption speaks to the very reason Certificate of Need exists. The concept of "if we build it they will come" or often referred to as "a built bed is a filled bed" has been a concern in health care for a very long time. We have certificate of need to try to balance this concern so that a facility must demonstrate the need for equipment or a service BEFORE they purchase it not rely on assumptions that they will double their volume simply because they have more equipment/beds.

Second, if Sparrow's assumptions were true, they would have a backlog of patients now and/or demand more days of service. The opposite is true. Because of Sparrow's proposal we have been tracking days of service to their facility. Over the past 5 months, with 31 days of service scheduled, they have canceled 5 days. That is nearly 20%. (See attached log.) If there were a backlog of patients or demand for more service they most certainly would not be canceling days.

Finally, kidney stone volume is not increasing and therefore lithotripsy volumes have been steady but not increasing. Without an increase in volume or a significant change in treatment guidelines, there is no reason to expect that Sparrow's volume would increase at all, let alone double. In fact, Sparrow's volume has consistently been decreasing for the past 7 years as shown in the table below.

Year	2010	2011	2012	2013	2014	2015	2016
Lithotripsy Procedures	850	772	781	653	635	594	584
Days of Service	77	76	75	71	74	70	72
Avg. Cases/Day	11	10	10	9	9	8	8

As you can see, they hit their highest volume in 2010 and have been decreasing significantly ever since. Based on their volumes to date, they are trending to hit only 465 cases in 2017. And it is not because they have had fewer days of service. You can see that their number of patients per day have also been decreasing consistently. The fact is that lithotripsy procedures are moving away from the inpatient/hospital setting into ambulatory surgical centers generally. As was pointed out by Commissioner Hughes at the June meeting, the cost to payers is double when this procedure is performed at Sparrow versus at a local ASC. With more patients moving to high deductible insurance plans, they are driving their care to the least costly setting. We expect this trend to continue and would anticipate Sparrow's volumes continuing to decrease.

As we have elaborated on in the past, we believe that the current system in place has provided broad access to high quality lithotripsy services at a competitive cost. Although we stand by our support for the existing lithotripsy standards, we do support final action on the language adopted by the Commission at the June meeting. We strongly believe that if a provision is going to exist to allow for the conversion of a host site to fixed service, the host site needs to be meeting the minimum volume of 1,000 procedures per year in order to show that they will be able to meet that minimum volume once approved for the fixed service. Allowing for an assumed volume increase of 100% over 2 years merely sets the applicant facility up for failure and increases the demand for compliance action on the Department and Commission.

Thank you for your time in considering these comments. Please feel free to contact me directly with questions and for further discussion at (508) 870-6565 or imadsen@ums-usa.com.

Respectfully,

Jorgen Madsen

CEO

Day	Date	Facility	Status	Equipment	Support Engineer	Technologist	# cases
Wednesday	3/1/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	8
Thursday	3/2/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	4
Tuesday	3/14/2017	Edward W. Sparrow Hospital	Cancelled	Wolf 743	Ed Wolverton	Eric Matlock	0
Wednesday	3/15/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	8
Thursday	3/16/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	8
Tuesday	3/28/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	14
Wednesday	3/29/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	11
Thursday	3/30/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	7
Tuesday	4/11/2017	Edward W. Sparrow Hospital	Cancelled	Wolf 743	Ed Wolverton	Eric Matlock	0
Wednesday	4/12/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	8
Thursday	4/13/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	6
Tuesday	4/25/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	13
Wednesday	4/26/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	9
Thursday	4/27/2017	Edward W. Sparrow Hospital	Cancelled	Wolf 743	Ed Wolverton	Eric Matlock	0
Tuesday	5/9/2017	Edward W. Sparrow Hospital	Cancelled	Wolf 743	Ed Wolverton	Eric Matlock	0
Wednesday	5/10/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	6
Thursday	5/11/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	8
Tuesday	5/23/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	11
Wednesday	5/24/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	9
Thursday	5/25/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	4
Tuesday	6/6/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	4
Wednesday	6/7/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	7
Thursday	6/8/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	2
Tuesday	6/20/2017	Edward W. Sparrow Hospital	Cancelled	Wolf 743	Ed Wolverton	Eric Matlock	0
Wednesday	6/21/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	12
Thursday	6/22/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	2
Wednesday	7/5/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	10
Thursday	7/6/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	3
Tuesday	7/18/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Deb Eckert	4
Wednesday	7/19/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Ryan Reseigh	15
Thursday	7/20/2017	Edward W. Sparrow Hospital	Normal	Wolf 743	Ed Wolverton	Eric Matlock	1

## Greater Michigan Lithotripsy, LLC

August 10, 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 most recent proposed changes to the CON Review Standards for Urinary Extracorporeal Shock Wave Lithotripsy (UESWL) Services. Specifically, Greater Michigan Lithotripsy would like to comment on the proposed language regarding converting from a mobile to a fixed lithotripsy service.

As we have testified previously, the trend nationwide is away from fixed lithotripters, in favor of mobile machines which can serve patients in hospitals and surgical centers across the state. In that regard, due to optimal accessibility and state-of-the art delivery of lithotripsy services, we do not believe that language providing a path from mobile to fixed lithotripsy is necessary. However, if the Commission decides to include such language in the CON Review Standards, we support the current proposal to require a mobile site to have performed an average of 1,000 procedures annually over the last three (3) years. This language would be consistent with the existing standards that require lithotripsy applicants to demonstrate in advance their ability to meet the current minimum volume standards for all lithotripsy machines, both mobile and fixed.

In our previous testimony, we have described in detail how we believe that the current system is serving the patients of Michigan well. Using the existing system of mobile lithotripters, access is assured to all areas of the state, including some of the smaller rural communities. Also, quality is assured through higher volumes, which enable lithotripsy technologists to continuously exercise their skills and maintain them at the highest level. It should also be noted that the service agreements between the lithotripsy companies and the host facilities In Michigan are among the most reasonably priced in the nation. As a result, the mobile lithotripsy system currently in place allows affordable access to both large and small facilities across the state. Based on the values of cost, quality and access, the existing CON Review Standards for Lithotripsy Services are a success in the state of Michigan.

Therefore, while we maintain our support for the existing lithotripsy standards, we urge the Commission to take final action on the language adopted at the June meeting.

Thank you for the opportunity to comment on the most recent proposed changes to the CON Review Standards for Lithotripsy Services. If you have any questions about this topic, please feel free to contact me directly.

Managed By:
American Kidney Stone
Management, Ltd.
100 West 3<sup>rd</sup> Avenue
Suite350
Columbus, Ohio 43201

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Sincerely,

Alan Buergentinal President



Henry Ford Health System One Ford Place – Suite 4A Detroit, MI 48202

August 9, 2017

Dear Commissioner Mukherji,

At the January Commission meeting the Commission directed the Department to draft changes to the surgical services standards based on a request brought forward by University of Michigan. UofM's request was to either allow existing surgical services to commit their own excess volume toward the initiation of a new surgical service rather than having to collect physician commitments or to allow the expansion of an existing surgical service and relocation of the expanded ORs to create a new site.

At the June Commission meeting, the Department provided language that would allow existing surgical services to commit their own excess volume toward the initiation of a new surgical service as long as they were also the applicant for the new service. The Department clarified during the June meeting that the applicant would still be required to provide the surgical case data required and would still need to identify which physicians and their respective case volume that would be committed to the proposed new service. Given the need to have the physician's case volume included, we believe we should also be having the physician sign a commitment form thereby signing their acknowledgement and agreement of the respective case volume. With the clarity provided by the Department at the June meeting, Henry Ford Health System does not believe this is a substantive enough change to warrant adopting the proposed language.

However, if the Commission is inclined to adopt language that would allow the facility applicant to commit their excess volume to a proposed new service, hence creating a facility to facility commitment, without the identification of specific physicians and cases, then Henry Ford Health System would support this proposal. We believe this could be accomplished by excluding these applicants from Section 11(2)(a) and (b) in addition to what the Department already suggested. This proposed change would allow an existing surgical service to commit their own excess volume toward the initiation or expansion of a surgical service.

Respectfully,

Barbara Bressack

Henry Ford Health System

Director, Planning & CON Strategy

One Ford Place, 4A Detroit, MI 48202 Dr. Suresh Mukherji
Chair, CON Commission
Department of Health and Human Services
Certificate of Need Policy Section
5th Floor South Grand Building, 333 S. Grand Ave.
Lansing, MI 48933

Re: CON Commission activity regarding Lithotripsy

Dear Dr. Mukherji

I am deeply concerned regarding the CON Commission's recent decision to set an unreasonably high volume threshold to convert from a mobile to fixed Lithotripter. As a patient routinely in need of lithotripsy services I want to share my experiences to explain why access is a problem in Michigan and allowing more facilities to provide full time service is in the best interest of patients.

I got my first kidney stone in March of 2007. Not long after, in the Spring of 2012 - I was living in Alpena and was diagnosed with another 7mm stone. I had to go to Petoskey to see a doctor and was told that it would be 6 weeks before there was an opening on the litho schedule. The doctor first tried to get the stone by going on a "fishing" exposition with a "basket". He was unable to catch it so he put in a stint and told me to come back in two weeks and he would laser blast it. A stint in the ureter and kidney is one of the most painful experiences I have ever encountered.

In April of 2014 - I went to a Muskegon area Urologist for an 8mm stone and was told I could get litho on June 28 (first available date on schedule in Muskegon). I was given Norco for pain and was told that is all he could do for me. After two weeks I called back to see if there were any cancellations on the schedule and told the doctor that I was available if there was any cancellations. I was told the machine only comes around every two weeks and the schedule is full until the end of June. I asked if there was any other procedure that could be done to relieve the pain and was told no just take your meds and wait. After another two weeks I called again and requested an office visit. I met with the PA at the office and was told again that there was no way to get moved up on the schedule and I really needed to just wait my turn. I was getting to the point that the Norco was really was not working for me so I was told to take 10 mg to manage the pain. In the middle of May I was talking to a friend in the medical profession and he suggested that I present myself to ER at Spectrum in Grand Rapids (I had found out that the litho machine would be there the next day) and report that I was in so much pain I really needed something done and tell the staff that I was at a pain level of 10 and continue to report that pain level until they put me on the schedule for litho. I was told the schedule was full for

the next day but I could call the next morning to see if anyone cancelled. I prepared for the procedure not knowing I would be able to get it done by not eating after midnight. I called around 11 am the day the machine was being used at Spectrum and was told that I could come to the hospital around 2 pm and they would add me to the schedule at 5 pm, after the last scheduled appointment.

In July of 2016 - I was diagnosed with another 7mm stone and was told I could get it blasted at the end of August so again I waited six weeks on pain meds for an opening on the litho schedule at Metro Hospital in Grand Rapids.

In June 207 - I was in St. Ignace for a wrestling camp with Fruitport High School team. On the last night of the camp I was again in pain and knew that it was another kidney stone so the coach took me to the hospital and dropped me off. After a c-scan I was told it was another 7mm stone and they were going to transport me to McLaren Northern Michigan Hospital in Petoskey (54 miles away) where I would meet with a urologist to determine next steps. I was told that it would be three weeks before the machine would be available in Petoskey and maybe I could get litho done there. I called my Urologist in Grand Rapids to see if I could get in sooner there but was told the schedule was full until the end of August. I chose to have a procedure done in Petoskey where the doctor would try to "fish" for the stone but if he could not get it he would laser blast it and put in a stint (ouch, again). He was able to blast the stone and I was discharged the next day.

I get between 3 to 7 kidney stones a year since I had esophageal cancer in 2007 that required an esophagostomy. My body is unable to process and break down food the way most other people's body does because my food goes directly to my intestines. I never know what foods will agree with my body on a daily basis and there are many foods and supplements I cannot tolerate.

I am sure I'm not the only patient that has suffered through these painful wait times. My experience demonstrates that the availability of time is an issue state wide. I urge you to reconsider the volume threshold and allow more facilities to provide full time fixed lithotripsy services so that more patients don't have to go through the pain that I have wait for an extended period of time or seek painful and sometimes unsuccessful surgical outcomes.

Sincerely,

David Clark 231.740.4702

David W. Clark



August 10, 2017

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

Dear Chairman Mukherji:

The incidence of urolithiasis ranges from 10-15% with a recurrence rate of approximately 70% (1,2). These occurrences are very painful requiring narcotic analgesia in most cases until the stone has passed. If the stone does not pass or is too large to pass, lithotripsy is required. The sooner lithotripsy can be done the more likely the patient will achieve analgesia without the need for opioids. In this era of increase opioid addiction, a delay in appropriate care (lithotripsy) may serve to exacerbate the present crisis. The other scenario is that practitioners may be less likely to adequately treat the pain associated with urolithiasis. According to the National Institute on Drug Abuse, the economic burden of opioid prescription misuse cost 78.5 billion dollars per year and results in 90 deaths per day attributed to opioid overdose. (3)

When a narcotic analgesic is prescribed for acute pain, the best approach is the least amount needed for adequate pain relief and the shortest duration. The longer a patient is on a narcotic analgesic, the more likely they are to develop tolerance and addiction. Besides increased risk for addiction, the patients are at risk for side effects to opioids including more time off work, increased risk of drug seeking behavior and death.

There is growing evidence that those patients who suffer with urolithiasis and recurrent urolithiasis are at higher risk for opioid dependency with prevalence rates as high as 34.8% in one study (4). In addition, another recent study revealed a higher risk of opioid dependence and overdose with urological surgery (5).

In situations where Patients cannot obtain lithotripsy promptly there is a much higher likelihood that we as providers will either under-treat the patient due to fear of opioid addiction or prescribe opioids longer than we would like due to the present excessive wait



times to treatment. As an internist, I am asking you to reconsider the CON standards thereby decreasing the likelihood of opioid addiction and delivering the best possible care to our patients in the Mid-Michigan area.

Sincerely,

Paul Entler, DO

Medical Director, Physician Performance

cc:

**CON Commission Members** 

Beth Nagel, MDHHS Brenda Rogers, MDHHS



August 10, 2017

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

Dear Chairman Mukherji:

Thank you for the opportunity to provide public comments regarding the proposed changes to the Certificate of Need Standards for Urinary Extracorporeal Shockwave Lithotripsy (UESWL) Services. As the Chief Financial Officer for Sparrow Health System, we are disappointed in the Commission's decision to reverse the unanimous recommendation made at the March meeting to reduce the conversion threshold for a fixed lithotripter unit to 500 equivalents from 1,000.

Sparrow Health System respects and supports the tenets of the CON regulations which are in place to "balance cost, quality and access issues and ensure that only needed services are developed in Michigan." Each day Sparrow and other healthcare providers are being asked by Federal and State Government, Commercial insurers, employers and patients to improve access and become more affordable. Sparrow Health System is the region's only Level 1 Trauma center and treats over 120,000 patients in our Emergency Department each year. This is an issue about access, not the number of lithotripsy procedures. Patients do not present on a "set schedule" based on when the mobile unit is present. Sparrow believes that it should be able to invest in a lithotripsy service to provide 24/7/365 access to patients without incurring a significant financial burden.

I would like to respond to several issues raised by United Medical Systems (UMS), LLC based in Westborough, MA and Greater Michigan Lithotripsy, LLC based in Columbus, OH:

1) In previous public comment sessions, our mobile provider indicated that we had not requested additional days and at times cancel a day when we have no cases as an illustration that we do not need a fixed unit to support patient care. Additional days wouldn't guarantee patients present on these days any more than they do now, just raise the cost. Sparrow's contract with Great Lakes Lithotripsy, LLC provides three days coverage every other week, a minimum charge of three procedures per day at \$1,334



per procedure and allows one no charge cancellation per quarter. If Sparrow were to request coverage 7 days per week on annual basis the cost would be \$1,460,730, versus a one-time lithotripter purchase of \$575,000 and an annual ongoing operating cost of just over \$300,000.

In 2016, Sparrow paid Great Lakes Lithotripsy, LLC a total of \$732,915 for an average of 6 days of coverage per month. The one-time equipment investment plus operating costs, would be paid for in less than a year of service and be available for patient treatment 24/7/365, for multiple years.

- 2) The acquisition cost of approximately \$575,000 is far less than other CON regulated equipment and comparable to other non-regulated equipment that health systems routinely purchase, such as Digital X-Ray, Digital Mammography, Ultrasound, Cardiac Echo technology and many others. As incorrectly stated by UMS, the numbers we provided included not just the cost of the equipment but the staff and supplies required as well.
- 3) Sparrow has multiple accreditations and "Center of Excellence" designations from both BCBSM and The Joint Commission, we encourage and pay for employees who have requirements for licensure and certifications. We support the position that all technologists should be certified and tested, all sites be accredited by HFAP or another organization and participate in BCBSM's program to improve patient outcomes. Sparrow has capability to recruit, hire and train employees to operate a Lithotripsy service, as demonstrated by our ability to employ highly skilled employees to operate surgical robots, cardiac catherization labs, and many other types of complex equipment. These issues would neither present a challenge nor a barrier to Sparrow's capability to operate a fixed unit.
- 4) Unlike the other mobile routes located at the Michigan Surgical Center and Genesis Surgery Center, Sparrow is open 24/7/365 to patients regardless of ability to pay and subject to EMTALA regulations. If the service is not available, the options for patients are to travel to another site, wait for the mobile to arrive, receive an alternate more invasive procedure or manage pain with opiates until a procedure can be scheduled.

Sparrow strongly believes that the Commission should uphold their original decision to reduce the conversion threshold to 500 equivalents or alternately support that Lithotripsy should no longer be a covered service.



Included you will find letters from Paul Entler, DO and David Clark, a frequent patient, further illustrating some of the issues raised in my comments. Thank you for your consideration.

Sincerely,

Paula M. Reichle

Senior Vice President and CFO

Sparrow Health System

cc:

**CON Commission Members** 

Beth Nagel, MDHHS Brenda Rogers, MDHHS



August 10, 2017

Suresh Mukherji, M.D., Chairperson

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

Re: CON Standards for Surgical Services

Dear Chairperson Mukherji:

Thank you for this opportunity to provide public comment regarding the proposed changes to the CON Review Standards for Surgical Services. Specifically, Spectrum Health would like to comment on the proposed language regarding initiating a new surgical service under common ownership.

Spectrum Health appreciates the Department's proposed changes to the surgical services review standards and supports the underlying intent of the changes. We believe that the goal of the proposed language is to ease the administrative burden imposed on health systems while ensuring access to quality care.

However, Spectrum Health is concerned with the need to identify specific physicians and cases to commit to a new facility. The proposed language in essence commits those specific physicians to moving their cases to the new site. If done without the physician's knowledge, this could damage the health system's credibility. In attempt to prevent this, the facility may create an internal process to discuss the commitment plans and have the physician sign an internal document allowing their cases to be committed. In the end, this will not ease the administrative burden on health systems.

Rather, Spectrum Health believes that the facility should simply demonstrate that it has the required excess cases to initiate a new service and commit to ensuring that the requisite volume will move over to the new site to meet the CON volume requirements. Our concern can easily be alleviated by exempting applicants from sections 11(2)(a) and 11(2)(b) in addition to section (11)(2)(e).

Again, thank you for the opportunity to provide feedback on the proposed changes to the CON Review Standards for Surgical Services. Spectrum Health appreciates the Department's work on this proposal and is eager to work with the Commission to modify it to ensure that it really does ease the administrative burdens placed on health care systems.

Sincerely,

John C. Shull

Vice President Surgical Services

Spectrum Health