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August 1, 2016

Via Email to DHSR.CON.Comments@dhhs.nc.gov and
Tanya.Rupp@dhhs.nc.gov

North Carolina Division of Health Service Regulations
Attention: Tanya Rupp, Project Analyst
Healthcare Planning and Certificate of Need Section
Edgerton Building
809 Ruggles Drive
Raleigh, NC 27603

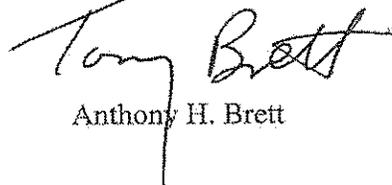
Re: Comments regarding CON application for a mobile lithotripter filed by
Eastern Carolina Lithotripsy, Inc.

Dear Ms. Rupp:

Attached are Comments submitted on behalf of our firm's clients Carolina Lithotripsy, a Limited Partnership, Fayetteville Lithotripters Limited Partnership – South Carolina II, and Fayetteville Lithotripters Limited Partnership – Virginia I in the above-referenced matter.

If there are any questions, please let me know at your earliest convenience.

Sincerely yours,

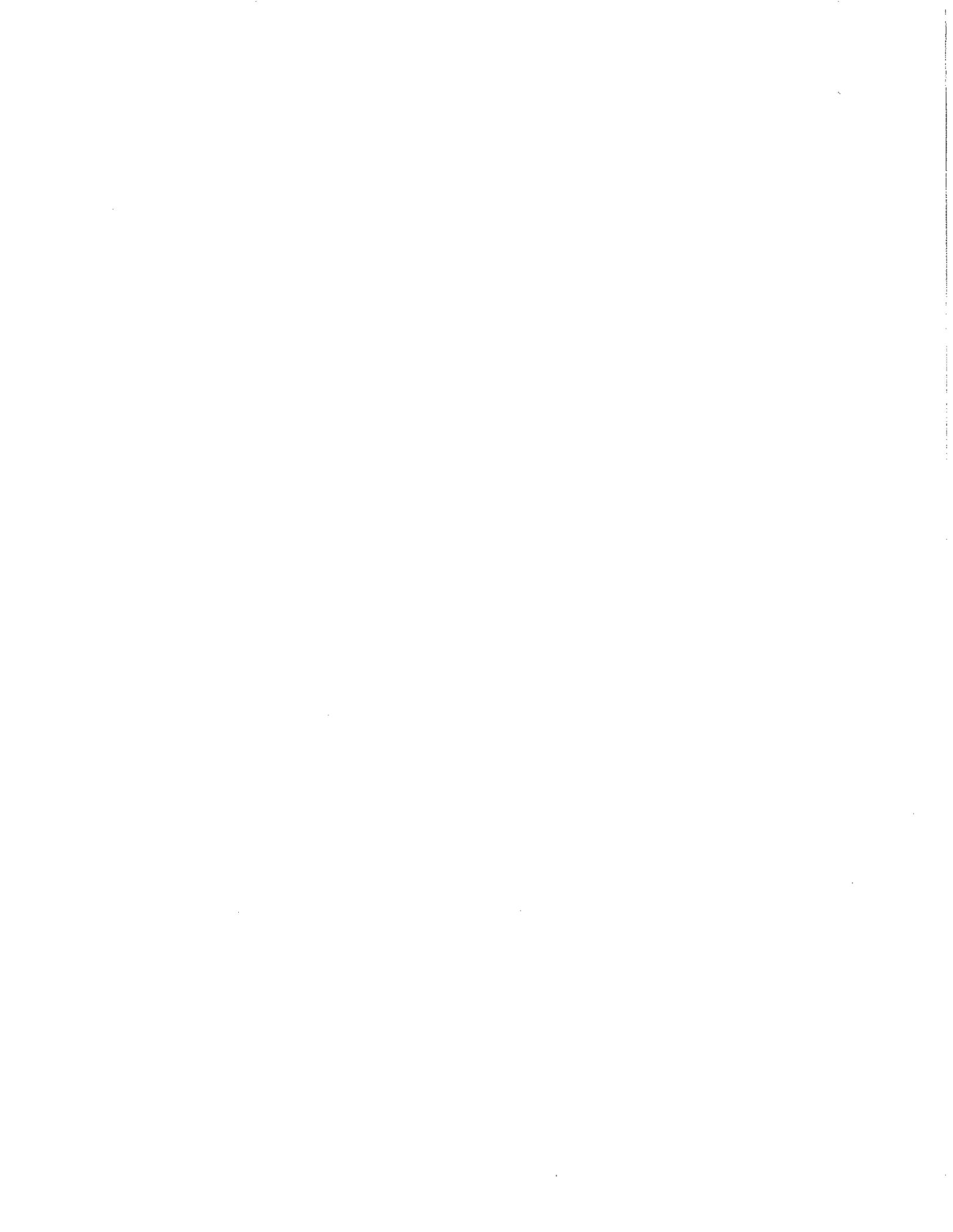


Anthony H. Brett

AHB/mib

Enclosures

cc: Debbie Scott



COMMENTS REGARDING

CON application for a mobile lithotripter filed by Eastern Carolina Lithotripsy, Inc. ("ECL")

Commenters: Carolina Lithotripsy, a Limited Partnership ("Carolina Lithotripsy")
Fayetteville Lithotripters Limited Partnership – South Carolina II ("South
Carolina II")
Fayetteville Lithotripters Limited Partnership – Virginia I ("Virginia I")

Through their general partners, ESL, Inc. and Lithotripters, Inc.

Contact: Debbie Scott
Vice President – Customer Relations
HealthTronics, Inc.
9825 Spectrum Drive, Building 3
Austin, TX 78717
(512) 721-4779 (office)
(800) 706-6502 (fax)
debbie.scott@healthtronics.com

On behalf of the three above-named Commenters, ESL, Inc. as general partner of Carolina Lithotripsy, and Lithotripters, Inc. as general partner of South Carolina II and Virginia I, provide the following comments concerning the above-referenced Certificate of Need Application. In short, the ECL Application is based upon the false premise that ECL would improve access for a medically-underserved population in eastern North Carolina, among other deficiencies.

Eastern North Carolina is not Underserved

As ECL notes at various places in its Application (pages 35, 63-64, and 73¹), Carolina Lithotripsy and Virginia I, which serve eastern North Carolina, operate at low volumes. Since both Carolina Lithotripsy and Virginia I focus on providing service throughout eastern North Carolina, this fact alone is strongly suggestive that there are not unmet needs (page 62). The suggestion by ECL that Carolina Lithotripsy and Virginia I are, for some unexplained and illogical reason, disinterested in providing service in this area is simply false. Instead, Carolina Lithotripsy and Virginia I are meeting the existing needs in this area, and both would relish the opportunity to provide services to additional patients at current host sites and at any additional host sites to serve any patients who have needs; combined, they provide service at over 30 host sites in eastern North Carolina (page 37).

Illustrative of these facts is ECL's focus on Craven County in which the CarolinaEast Health System ("CarolinaEast") is located in New Bern. Carolina Lithotripsy currently provides service for CarolinaEast. In the event that ECL were to provide service there, the number of patients available for treatment would not change even if Carolina Lithotripsy were completely displaced by ECL. As shown by the 2015 reporting of cases performed, Carolina Lithotripsy treated 89 patients (page 43). The number of patients treated in 2015 by Carolina Lithotripsy

¹ All page references are to ECL's Application.

represents a decrease from prior years (page 43). Despite these facts, ECL projects performing a volume of services at CarolinaEast of mythological proportions without explanation concerning where these additional patients would come from.

ECL suggests that Carolina Lithotripsy's current volume of service at CarolinaEast is a result of Carolina Lithotripsy not providing adequate availability to treat patients. However, as shown by **Exhibit A**, that is not a problem; for the year 2016 to date, the service provided by Carolina Lithotripsy at CarolinaEast has provided more available slots than were used for every month. As **Exhibit A** shows, Carolina Lithotripsy scheduled 30 weeks with 90 service slots, but CarolinaEast only used 38 service slots during 21 weeks. Also, as shown by the attached letters/emails from the following urologists contained in **Exhibit B**, the urologists who provide services at CarolinaEast are of the opinion that the Carolina Lithotripsy service meets the needs of their patients and does so providing quality services: Dr. Doak, Dr. Doyle, Dr. Holland, Dr. Stewart, Dr. Underhill,² and Dr. Walsh.²

As ECL's "Craven County" argument that needs are going unmet in eastern North Carolina is clearly false, then the remainder of ECL's "eastern North Carolina" argument should be met with a healthy degree of Missouri (the "Show Me" state) skepticism.

For example, ECL suggests that it will be "bringing lithotripsy" to Cumberland County area as if that would be a new thing (page 43). Well, that would be a good argument if it were true, but it is not. Carolina Lithotripsy performed 143 procedures in 2015 at Cape Fear Valley Medical Center (at its Highsmith-Rainey Specialty Hospital campus), which is located in Fayetteville (which is located in Cumberland County). Carolina Lithotripsy has provided these services at this host site for decades.

Another example that ECL's arguments are false is its proposal to provide services in Sampson County. South Carolina II provided services at Sampson Regional Medical Center in the past, and the volume levels were low. ECL incorrectly listed that in 2011 (South Carolina II's last year of service at this host site) that 54 procedures were performed (page 44); instead, 24 procedures were performed. Since the service at this host site was changed from South Carolina II to Triangle Lithotripsy Corp., there has been even lower volume at this site. Only 7 procedures are listed as having been performed in 2015, and only 61 total procedures are reported by Triangle Lithotripsy Corp. for the years 2011 through 2015 inclusive (page 44). These facts are not suggestive that ECL will be performing a meaningful volume of procedures at Sampson Regional Medical Center.

Another example of ECL misinterpreting facts relates to service in Onslow County. While only 6 days of service were provided in 2015 by Carolina Lithotripsy (to treat 7 patients at Onslow Memorial Hospital), 12 days were scheduled, but 6 days were not used because there were no patients to be served. Carolina Lithotripsy tries to coordinate a "special stop" service at that hospital when a urologist identifies that there is need for a patient's treatment. Again, the issue is not the lack of service from a lithotripsy provider; instead, the issue is the lack of need for the service.

² Both of these urologists are listed among the three urologists at CarolinaEast on page 104.

ECL's Application makes a series of general statements suggestive that there might be a need in eastern North Carolina for additional lithotripsy services, but then does not provide analysis as to why that would be the case. For example, pointing out that there are counties in eastern North Carolina in which lithotripsy service is not offered (page 39) does not mean that the area is underserved. A county that does not have a urologist or a host hospital site is not going to be able to offer the service. Also, these counties are located near the many sites in eastern North Carolina in which Carolina Lithotripsy and/or Virginia I provide services. **Exhibit C** contains letters from the following urologists addressing this very point: Dr. Hamilton, Dr. Murphy, Dr. Reeves, and Dr. Taylor.

In essence, the principal premise for ECL's Application is a false one given that it has presented no factual basis to support that there is an access issue that it would serve in eastern North Carolina or to support the alleged volumes of procedures that it would perform in eastern North Carolina. Therefore, ECL's Application is clearly deficient.

Other Points to Consider

Beyond the "eastern North Carolina" deficiency in ECL's argument in support of its Application, it also has a similar problem concerning its proposed host site at Rex Surgery Center located in Cary (Wake County), North Carolina. Rex Surgery Center is already served by Carolina Lithotripsy (page 44). As is the case at CarolinaEast, the slots provided for service at Rex Surgery Center for 2016 consistently exceed their use as shown in **Exhibit D**. As **Exhibit D** shows, Carolina Lithotripsy scheduled 14 weeks with 56 service slots, but Rex Surgery Center only used 28 service slots during 11 weeks.

Unrelated to locations of services, ECL, which has no track record, asserts that it will be a provider of quality services and suggests that, perhaps, some existing providers are not. However, ECL will not be providing a nurse in conjunction with its provision of service (pages 24 and 102), but Carolina Lithotripsy and Virginia I do. Also, even providing the nurse that ECL will not provide, these Commenters provide services at their host sites at comparable or lower prices than those proposed by ECL in its Application (see page 101).

Also, these Commenters can provide reliable mobile lithotripsy services on an ongoing basis for their host sites as they share (i) a field service engineer based in North Carolina to minimize equipment down time, (ii) a lead mechanic, and (iii) full array of parts and supplies located in Aberdeen, North Carolina. ECL does not address how its maintenance services would be provided, but it is doubtful that the services available to ECL would be superior to those already available for these Commenters' lithotripters.

ECL also claims that a key to its program is that a patient can locate its services within 24 hours (page 22). While this may intuitively sound good, it actually makes no sense. Would a patient (and the patient's urologist) in New Bern go to Cary for "next day" service (or the reverse)? Would the patient's urologist who has privileges at CarolinaEast also have privileges at Rex Surgery Center (or the reverse)? As Dr. Doak explains in his letter contained in **Exhibit B**, next day treatment does not make clinical sense and is not consistent with the national standard of care.

EXHIBIT A

CarolinaEast Medical Center, New Bern

Month	Weeks	Weeks used	Slots allotted	Slots filled
Jan	5	4	15	8
Feb	4	3	12	5
Mar	4	2	12	2
Apr	5	4	15	8
May	4	1	12	1
Jun	4	4	12	6
Jul	5 (4)	3	15 (12)	8

½ day every Friday – Mornings 7:30/9:00/10:30

EXHIBIT B

July 27, 2016

To whom it may concern:

It has come to my attention that a business known as Eastern Carolina Lithotripsy (ECL) has submitted an application to the state alleging that the urologists of Craven County are frustrated by the services of the existing lithotripsy provider, Carolina Lithotripsy. As one of only seven urologists operating in Craven County, I was surprised to hear about this. To my knowledge, the owners of ECL did not solicit the opinions of any Craven County urologists aside from their colleague, Dr. Robert Whitmore. I can speak only for myself, but since I began working at CarolinaEast two years ago, I have not had a single patient who has been turned away from lithotripsy, or had their lithotripsy procedure delayed because of a lack of access. Actually, I have had many days that I was scheduled to perform lithotripsy but had no patients who needed the service.

It has been suggested that with increased access to extracorporeal shock wave lithotripsy (ESWL), CarolinaEast will be performing 30 procedures per month by 2020, up from a supposed 10 per month at the current time. Reasonable people may disagree about the utility of increasing lithotripsy availability, but to suggest that the number of ESWL procedures could reach that level over the next 4 years betrays a basic lack of understanding of current surgical stone management.

Ureteroscopy is the principal procedure that competes with ESWL for management of renal and ureteral stones. Over the last 10-15 years, the performance of the technology used for ureteroscopy has undergone revolutionary improvement. Put simply, ureteroscopy is safer and more effective than ESWL for a greater number of kidney stones every year. This is reflected in recent guidelines by the American Urological Association. Note that it is not the *availability* of ureteroscopy that makes it superior for many kidney stones, but rather improved efficacy for stones at many locations within the urinary tract. For this reason referrals to lithotripsy have been in decline nationally over the last few years. They have been in decline at CarolinaEast for the same reason. In the last 6 months we have performed only 33 lithotripsies in Craven County, despite having 93 slots available. Note also that this is just over 5 procedures/month, rather than the 10 reported in support of the ECL Certificate of Need. Tripling the populations of Craven, Pamlico, and Jones Counties could probably produce a demand for 15 ESWLs per month, but opening up another half day on the schedule for ESWL most certainly will not.

Most major medical centers in this country share their lithotripters with other hospitals, and offer ESWL one day per week. I would consider this a national standard of care. ESWL is not an emergency procedure, and patients usually need to wait 5-7 days after discontinuing their NSAIDs and anti-platelet medications before having the procedure. For this reason, I would not expect to refer any more patients to ESWL even if it became available two days per week or five days per week. ESWL is an excellent treatment for a small and select group of patients, and I believe that our current lithotripsy capacity is more than adequate to cover CarolinaEast's current and future patients, Center of Excellence or not.

I applaud any investment in the medical infrastructure of eastern North Carolina. I can only wish ECL the best with what appears to be an audacious investment decision. Please take note, however, that the demand for ESWL in Craven County is not accurately represented by their Certificate of Need application.

If you have any additional questions on this matter, please feel free to contact me.

Sincerely,



Hoyt B. Doak, MD
CarolinaEast Urology Center
705 Newman Rd.
New Bern, NC 28562
252-633-2712

July 27, 2016

George Mark Doyle, MD
Carolina East Urology
705 Newman Rd
New Bern, NC 28562

To Whom It May Concern:

I was recently informed that a Certificate of Need application was submitted for another lithotripter in Eastern North Carolina. At no point was the application discussed with the majority of physicians who actually take care of these patients and perform lithotripsy. The physician who helped initiate this process has cut back significantly on his surgical care of stone patients over the past 6 months.

My patients have only experienced a delay of service on rare occasions due to the breakdown of equipment. Our current utilization is less than 50% of the designated ESWL slots at Carolina East Health Care Systems. Current treatment recommendations for stones are moving towards ureteroscopy and away from ESWL. Our hospital is currently developing a "Center of Excellence" for stone management. One of the primary goals of this effort is to reduce stone formation by non-surgical alternatives. Given these facts, I do not anticipate a significant increase in need for ESWL availability.

In addition, I am concerned that the LithoGold lithotripter does not provide a registered nurse during treatments. I believe this has the potential to increase patient risk if there is an unanticipated event.

I hope this helps in your decision process.

Sincerely,



George Mark Doyle, MD

Debbie Scott

From: Ryan Holland <ryan.holland@gmail.com>
Sent: Friday, July 29, 2016 6:46 AM
To: Debbie Scott
Subject: Re: Carolina Lithotripsy

Debbie,

It has been a crazy week. Please see my letter below.

To whom it may concern,

This remark is written to underscore the lack of need for another lithotripter to treat kidney stones at CarolinaEast Medical center.

As a urologic surgeon working at that particular hospital, I can say without any doubt that our current lithotripter service (Carolina Lithotripsy) is not running at full capacity. Said another way, if there were more patients with kidney stones that needed lithotripsy, they would get excellent and timely treatment at our medical center.

It is well known that the incidence of kidney stones is rising nationally. The number of lithotripsies being performed nationally, however, has been shown to be decreasing. This is due to advances in minimally invasive surgical techniques for kidney stone removal. I see a trend locally and nationally for the use of lithotripsy to remain stable or even continue to decrease.

The access to kidney stone care at CarolinaEast medical center is outstanding and will remain so without the addition of a CON for another lithotripter unit. Regardless, we will continue to provide the highest level of kidney stone care to Craven county and its surrounding region including all of Eastern North Carolina.

Ryan Holland

On Thursday, July 28, 2016, Debbie Scott <debbie.scott@healthtronics.com> wrote:

Dr. Holland,

Will you able to respond to my email below so that I can include it in our comment response regarding Eastern Carolina Lithotripsy's CON application? I need the responses by tonight if possible.

Thanks,

Debbie

Debbie Scott

Vice President – Customer Relations

HealthTronics, Inc | 9825 Spectrum Dr, Bldg 3 | Austin, TX 78717

debbie.scott@healthtronics.com



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From: Debbie Scott
Sent: Monday, July 25, 2016 3:48 PM
To: 'ryan.holland@gmail.com' <ryan.holland@gmail.com>
Subject: Carolina Lithotripsy
Importance: High

Dr. Holland,

I wanted to bring a matter to your attention regarding our service at Carolina East Medical Center. Triangle Lithotripsy (under the name of Eastern Carolina Lithotripsy) has filed an application with the State Planning Board to be granted a new CON for lithotripsy that is going to be awarded this year. In their application, they have targeted 4 host sites for their new lithotripter; one of those sites is Carolina East Medical Center in New Bern. In exhibits to their applications, they have provided support letters from Mr. Raymond Leggett and Dr. Robert Whitmore.

Among their reasons for requesting the new CON are:

- 1) The lack of available ESWL services in eastern North Carolina;
- 2) The need for developing a Kidney Stone Center of Excellence for all residents of eastern North Carolina;
- 3) Patients who are candidates for ESWL treatment often wait one to two weeks for services with some sites getting as little as one day per month.
- 4) They state that urologists in Pitt and Craven counties reflect frustration with Carolina Lithotripsy's responsiveness to their accessibility concerns.

Their application proposes:

- 1) They will provide service 1 day per week at Carolina East Medical Center with a LithoGold lithotripter.
- 2) They do not provide the use of a registered nurse.
- 3) Their proposed pricing would be \$2900 for commercial patients and \$1900 for government patients. (Carolina Lithotripsy's pricing at Carolina East is \$██████ for all patients regardless of insurance type.)

The links for the application filed by Triangle for Eastern Carolina Lithotripsy are below. The first link is to the application with their proposal and intent. The second link contains the exhibits and supporting documents. Note that the letter from Mr. Leggett is in Exhibit 5 and the letter from Dr. Whitmore is in Exhibit 15.

<https://drive.google.com/file/d/0B8TGpk2NINk6dkpQQVUxTFR0OVk/view?usp=sharing>

<https://drive.google.com/file/d/0B8TGpk2NINk6ZjhGbkhIOEJXY2s/view?usp=sharing>

Carolina Lithotripsy has provided ESWL service to Craven County and eastern North Carolina for over 25 years. We have recently within the past 2 years purchased new lithotripters to continue to provide patients with excellent service and quality outcomes. In addition, the staff of Carolina Lithotripsy has extensive experience providing lithotripsy service.

Please let me know your thoughts to this. Carolina Lithotripsy will be filing a response to this application by the deadline of August 1st so I need your feedback rather quickly.

Thanks,

Debbie

Debbie Scott

Vice President – Customer Relations

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July 26, 2016

Thomas S. Stewart, MD, MBA, FACS
CarolinaEast Urology
705 Newman Rd.
New Bern, NC 28562

To Whom it may Concern:

I recently learned that a Certificate of Need application was submitted for additional lithotripsy services in eastern North Carolina, and Carolina East was one of the hospitals listed in the application. This application was submitted without the support or even the knowledge of the majority of urologists at this hospital. In fact, to my understanding only one of seven urologists was even aware of the application. Dr. Robert Whitmore, the lone urologist to send a letter of support from our group, is actually scaling back his practice such that he no longer takes call, no longer performs lithotripsy, and has curtailed most of his operative practice including a majority of his operative stone cases.

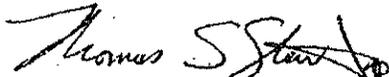
Currently Carolina East has 3 lithotripsy slots per week, on Friday morning. The day of the week and number of slots was dictated by the hospital. The urologists and Carolina Lithotripsy, the current supplier of lithotripsy services, have requested additional slots and options for different days of the week, and these have been refused by the hospital.

Currently the availability of lithotripsy services with our current provider exceed the our current need. If you look at the numbers from the beginning of the year, we have used 8 out of 15 slots in January, 5/12 in February, 2/12 in March, 8/15 in April, 1/12 in May, 6/12 in June, and although we filled 7/12 slots in July, we had 0/3 last week. If you total them up this is 37 out of 90 slots, or a utilization of 41%.

We have had times when patients had to wait additional time for lithotripsy services. This is rare, but when this has happened it occurred because of the hospital's unwillingness to allow us additional time, not lack of lithotripsy services. We have asked multiple times for more availability and have been refused. Addition of a fourth slot would likely have alleviated these delays, and the physicians and lithotripsy provider would have accommodated (and both strongly requested) if the hospital would have been willing to provide support for it. The hospital administration is well aware of this fact as we have discussed this in multiple meetings with the urologists and members of the administration.

I hope these facts will help you understand why a Certificate of Need is clearly not appropriate for this application, and should not be granted.

Respectfully yours,



Thomas S. Stewart, MD, MBA, FACS

Debbie Scott

From: reed underhill <reed_underhill@yahoo.com>
Sent: Wednesday, July 27, 2016 7:40 AM
To: Debbie Scott
Subject: Re: Carolina East Medical Center

I would like to say it false that Litho services are so busy that we in Eastern NC need another machine. The number of procedures has actually gone down significantly over the last number of years so there is no need for another machine. Also when we have tried to add on extra our pre and post op areas have said they cannot handle extra cases. I also noticed the cost of the extra machine is significantly higher for commercial payers. \$2,900 verse \$[REDACTED] I do not see any need for another machine. We are not under served in Eastern N. C.-- Reed Underhill MD
Sent from Yahoo Mail on Android

On Tue, Jul 26, 2016 at 5:53 PM, Debbie Scott <debbie.scott@healthtronics.com> wrote:

Dr. Underhill,

I wanted to bring a matter to your attention regarding our service at Carolina East Medical Center. Triangle Lithotripsy (under the name of Eastern Carolina Lithotripsy) has filed an application with the State Planning Board to be granted a new CON for lithotripsy that is going to be awarded this year. In their application, they have targeted 4 host sites for their new lithotripter; one of those sites is Carolina East Medical Center in New Bern. In exhibits to their applications, they have provided support letters from Mr. Raymond Leggett and Dr. Robert Whitmore.

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Carolina Lithotripsy has provided ESWL service to Craven County and eastern North Carolina for over 25 years. We have recently within the past 2 years purchased new lithotripters to continue to provide patients with excellent service and quality outcomes. In addition, the staff of Carolina Lithotripsy has extensive experience providing lithotripsy service.

Please let me know your thoughts to this. Carolina Lithotripsy will be filing a response to this application by the deadline of August 1st so I need your feedback rather quickly.

Thanks,

Debbie

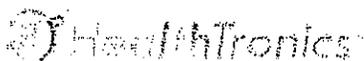
Debbie Scott

Vice President - Customer Relations

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debbie.scott@healthtronics.com

The logo for HealthTronics, featuring a stylized 'H' inside a circle followed by the word 'HealthTronics'.

July 28, 2016

RE: Eastern Carolina Lithotripsy CON Application

To Whom it may concern:

As the Clinical Director of CarolinaEast Urology I am strongly opposed to the requested CON application made by Eastern Carolina Lithotripsy, an Associate of Triangle Lithotripsy Corporation. I was very surprised to learn that anyone would believe that there is an unmet need for more Lithotripsy service in our area. I spent 6 years in Urologic training at Duke under one of the top leaders in the world for stone management before moving to New Bern 17 years ago. No one has treated more kidney stones in the CarolinaEast Health System than I have.

While Extracorporeal Shock Wave Lithotripsy (ESWL) has been a great option for patients in some situations, those select cases have become less and less over the years. The newer technologies for minimally invasive procedures can have better long term outcomes, require less retreatments and be much more precise and safer than previously. For these and other reasons, current Urologists are doing less ESWL procedures than previously. Our current ESWL usage reflects these changes. We are down to an average of 5 per month from 10-12 per month previously. The idea that calling our group a "Comprehensive Stone Center" will magically increase the need for a less relevant technology by 200-300% sounds to me like someone has been sold a bill of goods.

In reading through the CON application, much of the information appears to be based on potential business motivations for a corporation rather than the true needs for the patient. As a "man in the trenches" who has been managing stone patients for 17 years in the Craven, Pamlico, Jones, Carteret and Onslow counties, I can tell you another ESWL unit is NOT what our patients need.

Please respond negatively to the CON application made by Eastern Carolina Lithotripsy.

Sincerely,



Patrick J. Walsh, MD

Clinical Director of Urology

CarolinaEast Urology

705 Newman Road

New Bern, NC 28560

(252)633-2712

EXHIBIT C

Gregory E. Murphy, MD, FACS*
H. Mallory Reeves, MD, FACS*
Jonathan H. Taylor, MD, FACS*
Caroline D. Ryan, MD, FACS*
J. Nathaniel Hamilton, MD, FACS*
Matthew A. Collins, MD*
Steve Benson, PA-C
Wanda Hancock, PA-C

*Diplomate of the American Board of Urology



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www.easternurological.com

July 29, 2016

To whom it may concern,

I was very recently made aware of a CON application for an additional lithotripter in eastern North Carolina. As the regional representative for Carolina lithotripsy I am sending you this letter to express several concerns regarding the application and/or the claims made in this application.

First and foremost I would plainly state that the overall volume of lithotripsy in eastern North Carolina has been declining especially for the past several years. This has little to do with utilization but more to do with increased use of alternative modalities for treatment. A decision made by the attending surgeon and patient together in concert but very rarely made due to the equipment being unavailable for the procedure.

During this time of change Carolina lithotripsy has done their part to try to maximize utilization of their lithotripsy equipment. Continuous evaluation of how to make the process more efficient is undertaken to allow maximal patient access.

Furthermore neither my group nor I as an individual were contacted in anyway by the applicant regarding access to and/or availability of the equipment. There are claims that we have felt underserved and I can wholeheartedly tell you this is inaccurate.

I feel certain that you will hear echoing comments from both my partners in practice and multiple other providers in the community at large. Simply stated I feel that additional lithotripter services in eastern North Carolina are unlikely to provide any greater access and/or utilization of lithotripsy as a modality for treatment. Nor do I think the application which was submitted was fully accurate in its description of the overall situation.

In summary, I feel certain that upon your own review of the application for this CON you will come to the same conclusions as I.

J. Nathaniel Hamilton, MD, FACS

Eastern Urological Associates

Affiliate professor of surgery East Carolina University

Regional representative for Carolina Lithotripsy with Healthtronics

J. Richard Cavigan, MD, FACS*
Edward O. Jantosko, MD, FACS*
Benjamin G. Hines, Jr., MD, FACS*
Gregory F. Murphy, MD, FACS*
Dieter Bruno, MD

*Diplomate of the American Board of Urology



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Greenville, NC 27834
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RE: Eastern Carolina Lithotripsy CON Application

July 28, 2016

To Whom it may concern:

As Chief of Urology at Vidant Medical Center as well as President of Eastern Urological Associates, I write you to adamantly opposed the requested CON application made by Eastern Carolina Lithotripsy. As leader of the busiest urology practice in eastern NC, I was taken by great surprise to hear that a group 90 miles to our west made an application for services we provide without even the slightest consultation.

There are several blatant inaccuracies in their application not the least of which is the claim that the Urologists in Pitt County, which are comprised of my group, have expressed frustration with the present situation of Lithotripsy in eastern NC. This is an outright misrepresentation of the facts. We have NEVER stated such a claim. In reality we have seen a marked decrease in the demand for lithotripsy services over the last few years. Simply put there is NO 'unmet need' in eastern NC as is erroneously contended in the application. We have created a 'spoke and wheel' concept for health care in our 29 county catch basin and provide the full range of appropriate services for kidney stones for our patients.

Pointing out there is no lithotripsy service in 28 eastern NC counties merely states a fact that those of us in the east, who actually treat patients here, already know. The population density does not warrant a urologist to be in those counties, much less a specific service such as lithotripsy. Putting lithotripsy service in a county where there is no urologist defies logic much less common sense.

In summary this application is filled with clinical falsehoods and inaccurate suppositions. There is simply no need for an additional lithotripsy service in eastern NC. The lithotripsy company that has provided excellent quality service for over 30 years is totally fulfilling the present need as I see from someone who has lived and practiced in eastern NC for over 20 years. There is no need whatsoever for another lithotripsy company when the data would show the demand for lithotripsy has actually been decreasing rather than ~~decreasing~~ increasing.

I ask that you review the application with a negative judgment.

Sincerely,

Gregory F. Murphy, MD, FACS
Chief Division of Urology, Vidant Medical Center
President, Eastern Urological Associates, PA

July 28, 2016

Hugh M. Reeves, Jr., MD, FACS
Eastern Urological Associates
Greenville, NC 27834

To Whom It May Concern,

I became aware of the certificate of need application this week by Eastern Carolina Lithotripsy (ECL). I am writing to discourage awarding this certificate as it would duplicate services in our surrounding communities and unnecessarily waste healthcare resources. I feel that this application by ECL is motivated by monetary gain as the justifications for awarding the CON are exaggerated. The basis of the ECL application is that the stone disease population needs in eastern North Carolina from a lithotripsy standpoint are not met with the current provider and that many Urologists in the region are asking for additional provider services. Well, this is simply not true.

Lithotripsy utilization nationally and statewide has declined over the last 5-10 years. This is not a function of our current provider, Carolina Lithotripsy, not being able to keep pace with demand but rather a sign of a change in practice patterns by a younger generation of Urologists. Patient slots at each facility are dictated by demand and the demand for additional services has just not been there. There are instances when a patient may have to wait an additional week for treatment because a particular day may be full but that is exceedingly rare. At any rate, shockwave lithotripsy (SWL) is not the treatment of choice for the patient with the acute stone episode. SWL patients are typically minimally to moderately symptomatic and are stable. If these standard of care guideline are followed and our current utilization patterns persist then there is no need for additional lithotripsy services in eastern North Carolina. Thank you for your consideration.

Sincerely,



Hugh Mallory Reeves, Jr., MD, FACS

Vice President, Eastern Urological Associates, PA

Affiliate Clinical Professor of Surgery

East Carolina University, Brody School of Medicine



RE: Eastern Carolina Lithotripsy CON Application

July 28, 2016

To Whom It May Concern:

I have been practicing Urology in Eastern North Carolina since 2007 and am appalled at the misrepresentations made in the CON application referenced above. As a native of this area growing up in a small farming community in Craven County, I am proud of the Lithotripsy services that are currently in place and servicing this area of the state. I hope that those with a vote in this issue do not vote in favor of granting this CON as it would actually be detrimental to our area.

There are more issues than can be completely covered in this letter but I would like to highlight a few items. First, quality has been of utmost importance to us and I believe our group monitors and provides follow up on quality measures far beyond most groups in this state let alone the country. Secondly, access to care in our area is always an issue but Lithotripsy services are one of the few areas where there are very little in the way of wait times and it is quite convenient for the public. Contrary to the what the application implies, patients often choose Lithotripsy instead of surgery because Lithotripsy is more readily available than surgical options. Volumes for Lithotripsy across the country are down significantly over the past decade so making the argument that we need more companies providing that service is quite ridiculous. Furthermore, we have made efforts to provide this service to those who lack insurance which shows the commitment to our patients in this area of the state.

Without laboring through a host of other details that I believe are either false or misleading in the application, I again encourage those with a vote to deny the CON as I believe the citizens of Eastern North Carolina have been well served by this group for over 30 years and hopefully for a long term to come. If there are any questions or concerns please feel free to call or contact me.

Sincerely,

Jonathan H. Taylor, MD FACS
Associate Clinical Instructor
East Carolina School of Medicine
Department of Surgery
Eastern Urological Associates

EXHIBIT D

Rex Surgery Center Of Cary

Month	Weeks	Weeks used	Slots allotted	Slots filled
Jan	2	2	8	3
Feb	3	1	12	3
Mar	2	1	8	3
Apr	2	2	8	7
May	2	2	8	2
Jun	2	2	8	7
Jul	<i>4th July</i> 1	1	4	3

Every other Monday (4 slots) – 13:00 / 14:00 / 15:00 / 16:00

Rotates w/WakeMed on Monday afternoons

