



Certification

The undersigned applicant(s) hereby assures (assure) and certifies (certify) that the information included in this application and all attachments is correct to the best of my (their) knowledge and belief and that it is my (their) intent to develop and offer the proposed new institutional health service as described.


LEGAL NAME OF APPLICANT: Eastern Carolina Lithotripsy, Inc.

NAME OF RESPONSIBLE OFFICER: David B. Driggs

TITLE OF OFFICER: President

ADDRESS: 440 Savannah Way

Franklin, TN 37067

SIGNATURE OF OFFICER: 

DATE: June 15, 2016

LEGAL NAME OF APPLICANT: _____

NAME OF RESPONSIBLE OFFICER: _____

TITLE OF OFFICER: _____

ADDRESS: _____

SIGNATURE OF OFFICER: _____

DATE: _____

**Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT
State of North Carolina, Department of Health and Human Services**

OFFICE USE ONLY

Project I. D. Number: _____ Batch Category: _____
Proposal Type: _____ Beginning of Review: _____

I. IDENTIFICATION

1. **Legal Name of the Applicant: The applicants are the legal entities (i.e., persons or organizations) that will own the facility and any other persons who will offer, develop or incur an obligation for a capital expenditure for the proposed new institutional health service.**

LEGAL APPLICANT

Eastern Carolina Lithotripsy, Inc.

(Name)

C/o American Diagnostics Inc., 8161 Highway 100, PMB 170

(Street & Number)

Nashville

(City)

TN

(State)

37221

(Zip)

2. **Name of Parent Company (if applicable):**

(Name)

(Street & Number)

(City)

(State)

(Zip)

Not applicable; there is no parent company.

3. Person to whom all correspondence and questions regarding this application should be directed:

David Driggs	President	
(Name)	(Title)	
440 Savannah Way		
(Street & Number)		
Franklin	TN	37067
(City)	(State)	(Zip)
615-308-2538		
(Telephone #, incl. area code and extension)		(Fax #)
d5205@aol.com		
(Email Address)		

4. Name of Lessor (If applicable):

(Name)		

(Street & Number)		
_____	_____	_____
(City)	(State)	(Zip)

Not applicable; there is no lessor

5. Name of Lessee: (If applicable) (Attach copy of lease agreement)

(Name)		

(Street & Number)		
_____	_____	_____
(City)	(State)	(Zip)

Not applicable; there is no lessee.

6. **Name of Management Company: (If applicable) (Attach copy of management contract)**

American Diagnostics, Inc.

(Name of Management Company)

8161 Highway 100 PMB 170

(Street & Number)

Nashville	TN	Davidson	37221
(City)	(State)	(County)	(Zip)

Please see Exhibit 1 for a copy of the proposed management agreement.

7. **Name of existing/proposed facility**

Eastern Carolina Lithotripsy is a mobile lithotripsy unit. It proposes to provide services at four to five North Carolina locations.

WakeMed Cary	Wake
(Name of Facility)	(County)

1900 Kildaire Farm Road

(Street & Number)

Cary	NC	27518
(City)	(State)	(Zip)

Rex Surgery Center	Wake
(Name of Facility)	(County)

1505 SW Cary Parkway

(Street & Number)

Cary	NC	27511
(City)	(State)	(Zip)

- (b) **List by name and location all health care facilities in North Carolina that are currently owned by the applicant identified in Section I.1. or I.2. How many health care facilities does the applicant own in other states?**

Eastern Carolina Lithotripsy has no other facilities or operations in North Carolina or other states.

- (c) **List by name and location all health care facilities in North Carolina currently managed/operated by the company or person(s) that will be managing this facility.**

American Diagnostics, Inc. of Nashville, TN manages Triangle Lithotripsy Corporation (TLC), which provides mobile lithotripsy service in Wake, Durham, Lee, Nash, Sampson and Wayne counties in North Carolina. American Diagnostics has managed this service for 25+ years and has previously managed mobile lithotripters in four other states.

- (d) **List by name, location, vendor, and serial number all similar medical equipment in North Carolina that are currently owned by the applicant identified in Section I.1. or I.2. What medical equipment of a similar nature does the applicant own in other states?**

Not applicable; ECL is a new company and owns no similar medical equipment.

(e) **Describe specific experience of the applicant in providing the proposed service(s).**

ECL is a new entity that has no previous operations. American Diagnostics, which will be contracted to manage the operations of ECL, has 27 years' experience managing mobile lithotripsy in North Carolina and in four other states (Florida, Kansas, Kentucky and Ohio). Key to ECL's efforts include:

David B. Driggs, Sr.

The President of ECL, Mr. Driggs has lengthy experience in healthcare, both in managing general acute hospitals and tertiary referral medical centers as well as in developing and managing service providers offering mobile clinical services (including lithotripsy, ultra-sound and MRI). He is President of Triangle Lithotripsy Corporation which has provided mobile lithotripsy in North Carolina for over 25 years.

Gordon L. Mathes, Jr., MD

Dr. Mathes will serve as the Medical Director of ECL. He is a Board Certified Urologist with over 35 years of experience, the last 33 as a community practitioner in Rocky Mount, NC. A graduate of Vanderbilt University and the University of Tennessee Center for Health Sciences he completed both General Surgery and Urology residencies. He is a member of the American Urological Association, the American Lithotripsy Society, the American Medical Association and the North Carolina and Nash County Medical Societies, among others. He is an international consult

IV. UTILIZATION

1. Using the format of Table IV below, provide annual utilization data for the following time periods:

- (a) **Historical annual utilization data for the two full fiscal years prior to the submission of the application for each service component included in this application. Provide the dates for the fiscal years in the following format: Month/Date/Year to Month/Date/Year.**

Not applicable; ECL does not currently operate any mobile lithotripters and proposes to begin operation October 1, 2017; therefore has no historical or partial years of operation data. See Table IV.1 below. For information purposes, Triangle Lithotripsy Corporation, a related company, provided the following procedures.

Table IV. 1 – TLC Total Annual Procedures, 2014, 2015

	2014	2015
# of Units	1	1
# of Procedures	1,125	1,057

Source: 2015 and 2016 Registration and Inventory Equipment Form

- (b) **Projected annual utilization data for each fiscal year from the time the application was submitted through the fiscal year the project is complete for each service component included in this application.**

Not applicable; ECL does not currently operate any mobile lithotripters and proposes to begin operation October 1, 2017; therefore has no historical or partial years of operation data. See Table IV.6 below.

- (c) **Projected annual utilization data for each service component in this application, for the first three full fiscal years after completion of the proposed project.**

See Table IV.6 below.

7. **Provide a copy of the current or proposed business office policies regarding the credit collection procedures that will be utilized by the facility.**

Host sites pay ECL directly on a per case basis. Therefore, the host site facility contract defines the credit and collection process. ECL will operate on the same business model as Triangle Lithotripsy Corporation – charging the host site a flat fee per patient, due within 30 days of billing. There is no separate billing by ECL to the patient. This straightforward process simplifies the billing process and minimizes overhead cost. This also allows the community facility to make determination as to any formal or informal adjustment to the charges based on lack of insurance or other factors. It also removes ECL from the role of being a gatekeeper for patients seeking needed services.

This process effectively eliminates bad debt and serves to keep costs as low as possible.

8. **The information provided below should be reflected on the pro formas in Section X.9.**

- (a) **What amount of charity care did the facility provide to patients during the last full fiscal year?**

_____ \$ **Charity Care**
_____ **% of Net Revenue**

Not applicable, applicant is not yet in operation.

- (b) **Does this amount include bad debt? If so, what amount is bad debt?**

_____ \$ **Bad Debt**
_____ **% of Net Revenue**

Not applicable, applicant is not yet in operation.

-
9. (a) **Indicate the means by which a person will have access to the project's services (e.g., physician referral, self admissions, etc.).**

ACCESS TO PROPOSED SERVICE

All patients, whether originating in Emergency Departments, primary care physician offices or urgent care facilities, must be seen by a urologist who determines that the case meets the criteria for using ESWL and schedules the actual procedure.

- (b) **Identify the specific facilities or agencies that have historically referred patients to your facility or service (e.g., hospitals, home health agencies, etc.).**

ECL is a new provider and therefore does not have a historical record. However, Triangle Lithotripsy Corporation which operates under common management has strong relationships with North Carolina urologists, especially in Wake County and including many urologists who are willing to extend their practices in Sampson and Harnett Counties. These community practitioners are utilizing TLC to treat their patients with kidney stones. These practitioners have indicated in support letters (Exhibit 15) a willingness to refer even more patients given the opportunity. This directly applicable experience supports the contention that ECL will have no difficulty in achieving the volume of cases projected in this application.

- (c) **Do you have established working agreements with each of these agencies? If yes, please describe.**

ECL has no CON for lithotripsy. Thus, it cannot have formal agreements. See letters of intent to refer patients from area urologists in Exhibit 15.

- (d) **If no working agreements have been established with the referring agencies, describe the efforts made by the applicant to establish them. For example, with whom and on what date did you meet.**

As indicated in V.3(a), ECL has met with Urologists, individually and in groups as well as with hospital administrators to discuss the provision of lithotripsy to meet the needs in Wake and surrounding counties and to serve significant populations in eastern North Carolina which are either not served or not adequately served. In addition to reinforcing understanding of need, these discussions have also led to an enhanced understanding of the evolution of practices developing comprehensive programs utilizing a patient-focused approach to treatment and prevention of kidney stones.

10. (a) **Describe any civil rights equal access complaints that have been filed against the applicant(s) or any facilities or services owned, managed or operated by the parent company of the applicant(s) in North Carolina in the last five years.**

ECL is a start-up entity with no experience relevant to this question. However, neither Triangle Lithotripsy Corporation (a provider with largely common ownership) nor American Diagnostics, which manages the TLC operation, has had any civil rights equal access complaints in the last five years.

- (b) **What is the current status of the resolution of these complaints, if any?**

Not applicable, neither the applicant nor any related entities has had any civil rights equal access claims filed against it.

11. **What public (federal, state or local) obligations does the applicant(s) have under applicable Federal regulations or agreements to provide uncompensated care, community service, or access to care by medically underserved, minorities and handicapped persons? If you have had such requirements in the past, please describe how they have been fulfilled and the amount provided for the last three years.**

The applicant has no obligations under Federal, state or local regulations to provide uncompensated care, community service, or access by minorities or persons with disabilities.

- (c) **Provide justification for the number of staff identified in the table for the proposed staff.**

For information purposes, the management company – American Diagnostics – has over 25 years of experience operating Triangle Lithotripsy Corporation (TLC). TLC operates nearly identical equipment in an adjacent service area. It operates on a lean staffing model that is adequate to meet the clinical responsibilities as well as transportation via a self-propelled mobile medical environment. The business model proposed will mirror that of TLC. The applicant expects to hire two Radiology Technologists with a Commercial Driver’s License, or the ability to obtain one. Hiring two technologists allows for a “one week on one week off” employee work schedule. This also allows more flexibility to allow for vacation, sick, and training time. Having the second technologist on board also gives ECL the opportunity to extend service to six days per week if demand is present.

3. (a) **State the number of FTE positions identified in Table VII.1 (completed for the proposed staff) that are new positions to be established for the proposed project.**

Both the Radiology Technologists (2.0 FTEs) and the Medical Director (contract) positions are new.

- (b) **Describe the research completed to determine the availability of the required additional personnel for this project.**

American Diagnostics has resumes for Radiology Technologists who can acquire a commercial driver’s license. ECL has an identified candidate who has accepted the Medical Director position.

4. **Describe the educational and special training requirements for the new positions to be established.**

TRAINING REQUIREMENTS

Once hired, the Radiology Technologists will require one week of applications training provided by the original equipment manufacturer (included in the cost of the equipment) as well as training conducted with an experienced Radiology Technologist. Training includes both technical and operational responsibilities. Each employee is required to obtain a valid NC commercial driver’s license. See the job description in Exhibit 20 for further detail.

EXHIBIT

B

STATE HEALTH COORDINATING COUNCIL

2017

PROPOSED
STATE
MEDICAL
FACILITIES
PLAN



Health Service Regulation
HEALTH AND HUMAN SERVICES

Chapter 9:

Technology & Equipment

- Lithotripsy
- Gamma Knife
- Linear Accelerators
- Positron Emission Tomography Scanner
- Magnetic Resonance Imaging
- Cardiac Catheterization Equipment

CHAPTER 9

TECHNOLOGY AND EQUIPMENT

Summary of Service Supply and Utilization

The number of lithotripsy procedures reported on lithotripters registered in North Carolina for 2014-2015 was 10,019. There were 14 lithotripsy units operated by eight providers and one lithotripter approved in the 2016 State Medical Facilities Plan, but not yet operational.

The present gamma knife located at North Carolina Baptist Hospital in Health Service Area (HSA) II serves the western portion of the state (HSAs I, II, and III). During 2014-2015, 439 gamma knife procedures were reported. Vidant Medical Center received a certificate of need pursuant to a need determination in the North Carolina 2003 State Medical Facilities Plan for one gamma knife to serve the eastern portion of the state (HSAs IV, V and VI). Vidant Medical Center began offering service as of October 2005, and reported 123 gamma knife procedures provided during 2014-2015. The two gamma knives assure that the western and eastern portions of the state have equal access to gamma knife services.

Linear accelerators provided 574,069 Equivalent Simple Treatment Visit procedures that are counted for need determination purposes in 2014-2015. The average number of procedures statewide per linear accelerator as shown in Table 9G is 4,520. There are 127 linear accelerators in North Carolina that are operational, have a certificate of need, or for which there is a prior year need determination.

Twenty-one hospitals and two outpatient facilities reported a total of 35,158 procedures for fixed Positron Emission Tomography (PET) Scanners that were operational in the reporting period. Thirty sites reported 6,505 procedures in total for mobile PET service.

In 1983, there were only two magnetic resonance imaging (MRI) programs in North Carolina, performing a total of 531 procedures. In 2014-2015, fixed and mobile scanners were reported as providing 843,768 procedures.

A total of 48 hospitals and cardiac diagnostic centers provided fixed cardiac catheterization services during fiscal year 2014-2015. Also, during fiscal year 2014-2015 mobile cardiac catheterization services were reported at 5 hospitals and cardiac diagnostic centers across the state.

Changes from the Previous Plan

No substantive changes in basic principles and methodologies have been incorporated into the Technology and Equipment Chapter in the North Carolina Proposed 2017 State Medical Facilities Plan. There is one new policy incorporated into Chapter 4 of the the North Carolina Proposed 2017 State Medical Facilities Plan for Technology and Equipment. *Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners* has been added by a recommendation of the State Health Coordinating Council. This policy will allow facilities that meet the outlined requirements to apply a fixed magnetic resonance scanner.

Throughout the chapter, data have been revised to reflect services provided during FY 2014-2015, and dates have been advanced by one year, where appropriate.

LITHOTRIPSY

Introduction

Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

Lithotripter Utilization

Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population¹. Not all cases of urinary stone disease would be appropriately treated by lithotripsy. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases.

The number of lithotripsy procedures reported in North Carolina for the period of 2014-2015 was 10,019 procedures. There were 14 lithotripsy units operated by eight providers and one lithotripter approved in the 2016 State Medical Facilities Plan, but not yet operational. Procedures were provided by a fixed unit at one facility, and by 13 mobile units operated by seven providers. Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2014-2015 fiscal year is 716.

Access

Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

Lithotripsy Need Determination Methodology

North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the estimate of urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL.

The standard methodology used for determining need for lithotripters is calculated as follows:

Step 1: Divide the July 1, 2017 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the estimated incidence of urinary stone disease per 10,000 population.

¹ Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In *Clinical Manual of Urology*, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

- Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.
- Step 3: Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.
- Step 4: Sum the number of existing lithotripters in the state, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.
- Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

Lithotripsy Services in North Carolina

There are eight providers that offer lithotripsy services in North Carolina. On the following pages, Table 9A and Table 9B provide information on the number of procedures as well as the location of the facilities served by these eight providers.

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Carolina Lithotripsy, 9825 Spectrum Drive Bldg 3, Austin, TX 78717-
 Machines 2; #1137 (11/15/2000); #01179 (12/15/2011)

Areas Generally Served: Eastern North Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Cape Fear Valley Medical Center, Fayetteville, NC	143
CarolinaEast Medical Center, New Bern, NC	89
Carteret General Hospital, Morehead City, NC	40
Columbus Regional Healthcare, Whiteville, NC	18
Duke Raleigh Hospital, Raleigh, NC	3
Firsthealth Moore Regional Hospital, Pinehurst, NC	173
Firsthealth Richmond Memorial, Rockingham, NC	15
Halifax Regional Medical, Roanoake Rapids, NC	48
Johnston Health, Smithfield, NC	86
Lenoir Memorial Hospital, Kinston, NC	25
New Hanover Regional Medical Center, Wilmington, NC	189
Novant Brunswick Medical Center, Bolivia, NC	31
Onslow Memorial Hospital, Jacksonville, NC	7
Rex Hospital, Raleigh, NC	27
Rex Surgery Center of Cary, Cary, NC	65
Southeastern Regional Medical Center, Lumberton, NC	47
Vidant Beaufort Hospital, Washington, NC	37
Vidant Medical Center, Greenville, NC	142
WakeMed Raleigh Campus, Raleigh, NC	64
Wayne Memorial Hospital, Goldsboro, NC	23
Wilson Medical Center, Wilson, NC	34
Total Procedures:	1,306
Average Number of Procedures per Lithotripter	653

Provider: Catawba Valley Medical Center, 810 Fairgrove Church Road, SE, Hickory, NC 28602-
 Machines 2; #1355 (11/2010); TC-2051 (03/2001)

Areas Generally Served: Western and Central North Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Catawba Valley Medical Center, Hickory, NC	221
Frye Regional Medical Center, Hickory, NC	57
Rutherford Regional Medical Center, Rutherfordton, NC	62
Scotland Memorial Hospital, Laurinburg, NC	66
Total Procedures:	406
Average Number of Procedures per Lithotripter	203

Proposed 2017 SMFP

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Fayetteville Lithotripters Limited Partnership-South Carolina II, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-197 (01/17/2011)

Areas Generally Served: Western North Carolina and South Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Charles George VA Medical Ctr, Asheville, NC	30
Harris Regional Hospital, Sylva, NC	114
Haywood Regional Medical Center, Clyde, NC	143
Margaret R Pardee Memorial Hospital, Hendersonville, NC	80
Park Ridge Health, Hendersonville, NC	61
St. Luke's Hospital, Columbus, NC	10
The McDowell Hospital, Marion, NC	23
Transylvania Regional Hospital, Brevard, NC	34
Oconee Medical Center, Seneca, SC	63
Total Procedures:	558
Average Number of Procedures per Lithotripter	558

Provider: Fayetteville Lithotripters Limited Partnership-Virginia I, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-519 (11/9/2013)

Areas Generally Served: Eastern North Carolina and Virginia

<i>Facility and Location</i>	<i>Procedures</i>
Sentara Albemarle Medical Center, Elizabeth City, NC	33
The Outer Banks Hospital, Nags Head, NC	7
Vidant Chowan Hospital, Edenton, NC	32
Mary Immaculate Hospital, Newport News, VA	159
Mary Washington Hospital, Portsmouth, VA	3
Rappahannock General Hospital, Kilmarnock, VA	3
Riverside Doctors Surgical, Williamsburg, VA	3
Riverside Tappahannock Hospital, Tappahannock, VA	10
Southside Community Hospital, Farmville, VA	2
Southside Regional Medical Center, Petersburg, VA	9
Spotsylvania Regional Medical Center, Fredricksburg, VA	3
Total Procedures:	264
Average Number of Procedures per Lithotripter	264

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider:	Piedmont Stone Center, PLLC, 1907 S Hawthorne Road, Winston-Salem, NC 27103-	
Machines	4; 01138 (03/26/2002); 01175 (04/10/2003); 01171 (04/24/2003); 1925 (12/26/2006)	
	<i>Areas Generally Served:</i> Western and Central North Carolina and Virginia	
	<i>Facility and Location</i>	<i>Procedures</i>
	Alamance Regional Medical Center, Burlington, NC	175
	Annie Penn Hospital, Reidsville, NC	33
	Carolinas HealthCare System-Blue Ridge, Valdese, NC	184
	Davis Regional Medical Center, Statesville, NC	54
	High Point Regional Health System, High Point, NC	417
	Hugh Chatham Memorial Hospital, Elkin, NC	149
	Iredell Memorial Hospital, Statesville, NC	118
	Lexington Medical Center, Lexington, NC	50
	Maria Parham Medical Center, Henderson, NC	64
	Morehead Memorial Hospital, Eden, NC	217
	Northern Hospital of Surry County, Mount Airy, NC	51
	Novant Health Forsyth Medical Center, Winston-Salem, NC	98
	Novant Health Rowan Medical Center, Salisbury, NC	220
	Novant Health Thomasville Medical Center, Thomasville, NC	49
	Piedmont Stone Center, Winston-Salem, NC	780
	Randolph Hospital, Asheboro, NC	138
	Wake Forest Baptist Medical Center, Winston-Salem, NC	81
	Watauga Medical Center, Boone, NC	132
	Wesley Long Hospital, Greensboro, NC	315
	Wilkes Regional Medical Center, North Wilkesboro, NC	89
	Yadkin Valley Community Hospital, Yadkinville, NC	20
	Carilion New River Valley Medical Center, Christiansburg,, VA	19
	Lynchburg General Hospital, Lynchburg, VA	251
	Martha Jefferson Hospital, Charlottesville, VA	203
	Memorial Hospital of Martinsville, Martinsville, VA	124
	Montgomery Regional Hospital, Blacksburg, VA	26
	Piedmont Day Surgery Center, Danville, VA	39
	Twin County Regional Hospital, Galax, VA	84
	Total Procedures:	4,180
	Average Number of Procedures per Lithotripter	1,045

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider:	Stone Institute of the Carolinas, LLC, 215 S Main Street, Suite 201, Davidson, NC 28036-	
Machines	2; 2053 (10/2006); 1048 & 01384 (01/2001)	
	<i>Areas Generally Served:</i> Western and Central North Carolina	
	<i>Facility and Location</i>	<i>Procedures</i>
	Carolinas HealthCare System - Cleveland, Shelby, NC	146
	Carolinas HealthCare System - Huntersville, Huntersville, NC	112
	Carolinas HealthCare System - Lincoln, Lincolnton, NC	59
	Carolinas HealthCare System - Northeast, Concord, NC	238
	Carolinas HealthCare System - Pineville, Charlotte, NC	199
	Carolinas HealthCare System - Union, Monroe, NC	106
	Carolinas HealthCare System - University, Charlotte, NC	225
	Carolinas Medical Center, Charlotte, NC	123
	Caromont Regional Medical Center, Gastonia, NC	160
	Lake Norman Regional Medical Center, Mooresville, NC	155
	Novant Health Matthews Medical Center, Matthews, NC	175
	Novant Health Presbyterian Medical Center, Charlotte, NC	96
	Piedmont Medical Center, Rock Hill, SC	195
	Total Procedures:	1,989
	Average Number of Procedures per Lithotripter	995
Provider:	Triangle Lithotripsy Corp, 7003 Chadwick Dr #321, Brentwood, TN 37027-	
Machines	1; 10142940 (04/01/2010)	
	<i>Areas Generally Served:</i> East Central North Carolina	
	<i>Facility and Location</i>	<i>Procedures</i>
	Central Carolina Hospital, Sanford, NC	54
	Durham Regional Hospital, Durham, NC	8
	James E Davis Ambulatory Surgery, Durham, NC	60
	Nash General Hospital, Rocky Mount, NC	122
	North Carolina Specialty Hospital, Durham, NC	68
	Rex Hospital, Raleigh, NC	219
	Rex Surgery Center, Cary, NC	306
	Sampson Regional Medical Center, Clinton, NC	7
	WakeMed, Raleigh, NC	154
	Wayne Memorial Hospital, Goldsboro, NC	59
	Total Procedures:	1,057
	Average Number of Procedures per Lithotripter	1,057
	Total Mobile Procedures:	9,760

Table 9B: Fixed Lithotripsy Providers and Locations Served

(From 2015 data as reported on the "2016 Hospital License Renewal Application")

Provider: Mission Hospital, Inc./Mission, 509 Biltmore Ave., Asheville, NC 28801

Machines: 1 08/2000

<i>Area Served:</i>	
<i>Facility and Location</i>	<i>Procedures</i>
WNC Stone Center, Asheville, NC	259
Total Number of Procedures:	259
<i>Average Number of Procedures per Lithotripter:</i>	259

Table 9C: Mobile and Fixed Lithotripsy

(Total Procedures/Units Reported)

Total Procedures Reported	Units Reported	Average Procedures Per Unit
10,019	14	716

2016 Need Determination for one lithotripter brings the state total to 15.

Table 9D: Lithotripter Need Determination
(Proposed for Certificate of Need Review Commencing in 2017)

It is determined that the service areas listed in the table below need additional lithotripters as specified.

Lithotripters	Lithotripter Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
It is determined that there is no need for additional lithotripters anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

STATE HEALTH COORDINATING COUNCIL

2016

STATE
MEDICAL
FACILITIES
PLAN

DHSR

N.C. Division of Health Service Regulation

NORTH CAROLINA 2016 STATE MEDICAL FACILITIES PLAN

Effective January 1, 2016

Prepared by the
North Carolina Department of Health and Human Services
Division of Health Service Regulation
Healthcare Planning and Certificate of Need Section

Under the direction of the
North Carolina State Health Coordinating Council

For information contact the
North Carolina Division of Health Service Regulation
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

www.ncdhhs.gov/dhsr/ncsmfp/index.html

(919) 855 - 3865 Telephone Number
(919) 715 - 4413 FAX Number

NOTE: Data used in the North Carolina 2016 State Medical
Facilities Plan was last updated October 9, 2015.



The North Carolina Department of Health and Human Services does not discriminate on the basis of race, color, national origin, sex, religion, age or disability in employment or the provision of services.

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Chapter 2:

Amendments and Revisions to the State Medical Facilities Plan

CHAPTER 2

AMENDMENTS AND REVISIONS TO THE STATE MEDICAL FACILITIES PLAN

Amendment of Approved Plans

After the North Carolina State Medical Facilities Plan has been signed by the Governor, it will be amended only as necessary to correct errors or to respond to statutory changes, amounts of legislative appropriations or judicial decisions. The North Carolina State Health Coordinating Council will conduct a public hearing on proposed amendments and will recommend changes it deems appropriate for the Governor's approval.

NOTE: Need determinations as shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (*See Chapter 4*).

Petitions to Revise the Next State Medical Facilities Plan

Anyone who finds that the North Carolina State Medical Facilities Plan policies or methodologies, or the results of their application, are inappropriate may petition for changes or revisions. Such petitions are of two general types: those requesting changes in basic policies and methodologies, and those requesting adjustments to the need projections.

Petitions for Changes in Basic Policies and Methodologies

People who wish to recommend changes that may have a statewide effect are asked to contact Healthcare Planning and Certificate of Need Section staff as early in the year as possible, and to submit petitions no later than March 2, 2016. Changes with the potential for a statewide effect are the addition, deletion, and revision of policies or projection methodologies. These types of changes will need to be considered in the first four months of the calendar year as the "Proposed North Carolina State Medical Facilities Plan" (explained below) is being developed.

Instructions for Writing Petitions for Changes in Basic Policies and Methodologies

At a minimum, each written petition requesting a change in basic policies and methodologies used in the North Carolina State Medical Facilities Plan should contain:

1. Name, address, email address and phone number of petitioner.
2. Statement of the requested change, citing the policy or planning methodology in the North Carolina State Medical Facilities Plan for which the change is proposed.
3. Reasons for the proposed change to include:
 - a. A statement of the adverse effects on the providers or consumers of health services that are likely to ensue if the change is not made, and
 - b. A statement of alternatives to the proposed change that were considered and found not feasible.

4. Evidence that the proposed change would not result in unnecessary duplication of health resources in the area.
5. Evidence that the requested change is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access, and Value.

Each written petition must be clearly labeled "Petition" and one copy of each petition must be received by the North Carolina Division of Health Service Regulation, Healthcare Planning by 5:00 p.m. on March 2, 2016. Petitions must be submitted by e-mail, fax, mail or hand delivery.

E-Mail: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

Fax: 919-715-4413

Mail: North Carolina Division of Health Service Regulation
Healthcare Planning
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

The office location and address for hand delivery and use of delivery services:

809 Ruggles Drive
Raleigh, North Carolina 27603

Response to Petitions for Changes in Basic Policies and Methodologies

The process for response to such petitions is as follows:

1. Staff, in reviewing the proposed change, may request additional information and opinions from the petitioner or any other people or organizations who may be affected by the proposed change.
2. The petition and other information will be made available to the members of the appropriate committee of the North Carolina State Health Coordinating Council.
3. The petition will be considered by the appropriate committee of the North Carolina State Health Coordinating Council and the committee will make recommendations to the North Carolina State Health Coordinating Council regarding disposition of the petition.
4. The North Carolina State Health Coordinating Council will consider the committee's recommendations and make decisions regarding whether or not to incorporate the changes into the Proposed North Carolina State Medical Facilities Plan.

Petitioners will receive written notification of times and places of meetings at which their petitions will be discussed. Disposition of all petitions for changes in basic policies and methodologies in the North Carolina State Medical Facilities Plan will be made no later than the final Council meeting of the calendar year.

Petitions for Adjustments to Need Determinations

A North Carolina Proposed State Medical Facilities Plan is adopted annually by the North Carolina State Health Coordinating Council, and is made available for review by interested parties during an annual "Public Review and Comment Period." During this period, regional public hearings are held to receive oral/written comments and written petitions. The Public Review and Comment Period for consideration of each North Carolina Proposed State Medical Facilities Plan is determined annually and dates are available from Healthcare Planning and published in the North Carolina State Medical Facilities Plan.

People who believe that unique or special attributes of a particular geographic area or institution give rise to resource requirements that differ from those provided by application of the standard planning procedures and policies may submit a written petition requesting an adjustment be made to the need determination given in the North Carolina Proposed State Medical Facilities Plan. These petitions should be delivered to Healthcare Planning as early in the Public Review and Comment Period as possible, but no later than the last day of this period. Requirements for petitions to change need determinations in the North Carolina Proposed State Medical Facilities Plan are given below.

Instructions for Writing Petitions for Adjustments to Need Determinations

At a minimum, each written petition requesting an adjustment to a need determination in the Proposed State Medical Facilities Plan should contain:

1. Name, address, email address and phone number of petitioner.
2. A statement of the requested adjustment, citing the provision or need determination in the Proposed State Medical Facilities Plan for which the adjustment is proposed.
3. Reasons for the proposed adjustment, including:
 - a. Statement of the adverse effects on the population of the affected area that are likely to ensue if the adjustment is not made, and
 - b. A statement of alternatives to the proposed adjustment that were considered and found not feasible.
4. Evidence that health service development permitted by the proposed adjustment would not result in unnecessary duplication of health resources in the area.
5. Evidence that the requested adjustment is consistent with the three Basic Principles governing the development of the North Carolina State Medical Facilities Plan: Safety and Quality, Access and Value.

Petitioners should use the same service area definitions as provided in the program chapters of the North Carolina Proposed State Medical Facilities Plan.

Petitioners should also be aware that Healthcare Planning staff, in reviewing the proposed adjustment, may request additional information and opinions from the petitioner or any other people and organizations who may be affected by the proposed adjustment.

Each written petition must be clearly labeled "Petition" and one copy of each petition must be received by Healthcare Planning by 5:00 p.m. on July 28, 2016. Petitions must be submitted by e-mail, fax, mail or hand delivery.

E-Mail: DHSR.SMFP.Petitions-Comments@dhhs.nc.gov

Fax: 919-715-4413

Mail: North Carolina Division of Health Service Regulation
Healthcare Planning
2704 Mail Service Center
Raleigh, North Carolina 27699-2704

The office location and address for hand delivery and use of delivery services:

809 Ruggles Drive
Raleigh, North Carolina 27603

Response to Petitions for Adjustments to Need Determinations

The process for response to these petitions by the North Carolina Division of Health Service Regulation and the North Carolina State Health Coordinating Council is as follows:

1. Preparation of an agency report. Staff may request additional information from the petitioner.
2. Consideration of the petition and the agency report by the appropriate committee of the North Carolina State Health Coordinating Council.
3. Committee submits its recommendations to the North Carolina State Health Coordinating Council regarding disposition of the petition.
4. Consideration of the committee recommendations by the North Carolina State Health Coordinating Council and decisions regarding whether or not to incorporate the recommended adjustments in the final draft of the North Carolina State Medical Facilities Plan to be forwarded to the Governor.

Petitioners will receive written notification of times and places of meetings at which their petitions will be discussed. Disposition of all petitions for adjustments to need determinations in the North Carolina State Medical Facilities Plan will be made no later than the date of the final Council meeting of the calendar year.

Scheduled State Health Coordinating Council Meetings and Committee Meetings
Any changes to Council, Committee, Work Group and Public Hearing meeting dates, times and locations will be posted on the meeting information web page at:

<http://www2.ncdhhs.gov/dhsr/mfp/meetings.html>

North Carolina State Health Coordinating Council
(All meetings begin at 10:00 a.m.)

March 2, 2016	Dorothea Dix Campus 801 Biggs Drive – Raleigh NC Brown Building Room 104
May 25, 2016	Dorothea Dix Campus 801 Biggs Drive – Raleigh NC Brown Building Room 104
September 7, 2016	Dorothea Dix Campus 801 Biggs Drive – Raleigh NC Brown Building Room 104
October 5, 2016	Dorothea Dix Campus 801 Biggs Drive – Raleigh NC Brown Building Room 104

Directions to the Brown Building can be found at:

<http://www2.ncdhhs.gov/dhsr/brown.html>

The Council will conduct a public hearing on statewide issues related to development of the North Carolina Proposed 2017 State Medical Facilities Plan immediately following the business meeting on March 2, 2016.

Committee Meetings for 2016
(All meetings begin at 10:00 a.m.)

Acute Care Services Committee

April 12, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

May 3, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

September 13, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

Long-Term and Behavioral Health Committee

April 8, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

May 6, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

September 9, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

Technology and Equipment Committee

March 30, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

April 27, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

September 14, 2016

Dorothea Dix Campus
801 Biggs Drive – Raleigh, N.C.
Brown Building – Room 104

Deadlines for Petitions and Comments, and Public Hearing Schedule

The deadline for receipt by Healthcare Planning of petitions, written comments and written comments on petitions and comments is 5:00 p.m. on dates listed below.

- March 2, 2016 The Council will conduct a Public Hearing on statewide issues related to Development of the North Carolina Proposed 2017 State Medical Facilities Plan (SMFP) immediately following the business meeting.
- March 18, 2016 Deadline for receipt by Healthcare Planning of any written comments regarding petitions or comments submitted by the March 2nd deadline on statewide issues related to development of the North Carolina Proposed 2017 State Medical Facilities Plan.

2016 Schedule for Public Hearings on the N.C. Proposed 2017 SMFP

(All hearings begin at 1:30 p.m.)

- | | | |
|---------------|------------|---------------------------------------|
| July 12, 2016 | Greensboro | The Women's Hospital |
| July 15, 2016 | Asheville | Mountain Area Health Education Center |
| July 19, 2016 | Greenville | Pitt County Office Building |
| July 22, 2016 | Wilmington | New Hanover County - Main Library |
| July 25, 2016 | Concord | CMC - NorthEast |
| July 28, 2016 | Raleigh | Dorothea Dix Campus – Brown Building |
- July 28, 2016 Deadline for receipt by Healthcare Planning of petitions for adjustments to need determinations and other written comments regarding the North Carolina Proposed 2017 State Medical Facilities Plan.
- August 12, 2016 Deadline for receipt by the Healthcare Planning of any written comments on petitions or comments submitted by the July 28th deadline regarding adjusted need determinations or other issues arising from the North Carolina Proposed 2017 State Medical Facilities Plan.

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Chapter 9:

Technology & Equipment

- Lithotripsy
- Gamma Knife
- Linear Accelerators
- Positron Emission Tomography Scanner
- Magnetic Resonance Imaging
- Cardiac Catheterization Equipment

CHAPTER 9

TECHNOLOGY AND EQUIPMENT

Summary of Service Supply and Utilization

The number of lithotripsy procedures reported on lithotripters registered in North Carolina for 2013-2014 was 10,459. There were 14 lithotripsy units operated by eight providers.

The present gamma knife located at North Carolina Baptist Hospital in Health Service Area (HSA) II serves the western portion of the state (HSAs I, II, and III). During 2013-2014, 375 gamma knife procedures were reported. Vidant Medical Center received a certificate of need pursuant to a need determination in the North Carolina 2003 State Medical Facilities Plan for one gamma knife to serve the eastern portion of the state (HSAs IV, V and VI). Vidant Medical Center began offering service as of October 2005, and reported 133 gamma knife procedures provided during 2013-2014. The two gamma knives assure that the western and eastern portions of the state have equal access to gamma knife services.

Linear accelerators provided 584,630 Equivalent Simple Treatment Visit procedures that are counted for need determination purposes in 2013-2014. The average number of procedures statewide per linear accelerator as shown in Table 9G is 4,677. There are 125 linear accelerators in North Carolina that are operational, have a certificate of need, or for which there is a prior year need determination.

Twenty-one hospitals and two outpatient facilities reported a total of 32,381 procedures for fixed Positron Emission Tomography (PET) Scanners that were operational in the reporting period. Thirty sites reported 5,870 procedures in total for mobile PET service.

In 1983, there were only two magnetic resonance imaging (MRI) programs in North Carolina, performing a total of 531 procedures. In 2013-2014, fixed and mobile scanners were reported as providing 800,182 procedures.

A total of 49 hospitals and cardiac diagnostic centers provided fixed cardiac catheterization services during fiscal year 2013-2014. Also, during fiscal year 2013-2014 mobile cardiac catheterization services were reported at 5 hospitals and cardiac diagnostic centers across the state.

Changes from the Previous Plan

No substantive changes in basic principles and methodologies have been incorporated into the Technology and Equipment Chapter in the North Carolina 2016 State Medical Facilities Plan. There is one new policy incorporated into Chapter 4 of the the North Carolina 2016 State Medical Facilities Plan for Technology and Equipment. Policy TE-2-Intraoperative Magnetic Resonance Scanners has been added by a recommendation of the State Health Coordinating Council. This policy will allow facilities that meet the outlined requirements to apply for an intraoperative magnetic resonance scanner (iMRI). Language has been added to Chapter 9: MRI section which clarifies that equipment obtained through Policy TE-2 will not be counted in the inventory and the CPT procedures will be excluded from the need determination calculation.

Throughout the chapter, data have been revised to reflect services provided during FY 2013-2014, and dates have been advanced by one year, where appropriate.

LITHOTRIPSY

Introduction

Lithotripsy is defined as the pulverization of urinary stones by means of a lithotripter. Extracorporeal lithotripsy is lithotripsy that occurs outside the body. Extracorporeal shock wave lithotripsy (ESWL) is the non-invasive procedure with which this section will concern itself.

A lithotripter is a device that uses shock waves to pulverize urinary stones, which can then be expelled in the urine. An emitter is placed in contact with the patient's abdomen and the shock waves are focused on the stone, which is shattered by the force.

A lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.

Lithotripter Utilization

Lithotripter utilization can be reasonably estimated by the incidence of urinary stone disease. Urinary stone disease, or urolithiasis, is a disease in which urinary tract stones or calculi are formed. The annual incidence of urinary stone disease is approximately 16 per 10,000 population¹. Not all cases of urinary stone disease would be appropriately treated by lithotripsy. It has been estimated that 85 to 90 percent of kidney stone patients, when surgery is indicated, can be treated successfully by ESWL treatment. The annual treatment capacity of a lithotripter has been estimated to be 1,000 to 1,500 cases.

The number of lithotripsy procedures reported in North Carolina for the period of 2013-2014 was 10,459 procedures. There were 14 lithotripsy units operated by eight providers. Procedures were provided by a fixed unit at one facility, and by 13 mobile units operated by seven providers. Given the 14 lithotripsy units, the average number of procedures per lithotripter for the 2013-2014 fiscal year is 747.

Access

Due to the mobility of lithotripter services, and the subsequent number of sites from which the service is provided, it may be concluded that geographic access is available to the maximum economically feasible extent.

Lithotripsy Need Determination Methodology

North Carolina uses a methodology based on the incidence of urinary stone disease. The need is linked to the estimate of urinary stone disease cases and is based on the assumption that 90 percent could be treated by ESWL.

The standard methodology used for determining need for lithotripters is calculated as follows:

- Step 1: Divide the July 1, 2016 estimated population of the state, available from the North Carolina Office of State Budget and Management, by 10,000 and multiply the result by 16, which is the estimated incidence of urinary stone disease per 10,000 population.

¹ Pahiri, J.J. & Razack, A.A. (2001) "Chapter 9: Nephrolithiasis". In Clinical Manual of Urology, by Philip M. Hanno, Alan J. Wein, S. Bruce Malkowicz. McGraw-Hill Professional Publisher.

- Step 2: Multiply the result from Step 1 by 90 percent to get the number of patients in the state who have the potential to be treated by lithotripsy in one year.
- Step 3: Divide the result of Step 2 by 1,000, which is the low range of the annual treatment capacity of a lithotripter, and round to the nearest whole number.
- Step 4: Sum the number of existing lithotripters in the state, lithotripters not yet operational but for which a certificate of need has been awarded, and lithotripter need determinations from previous years for which a certificate of need has yet to be awarded.
- Step 5: Subtract the result of Step 4 from the result of Step 3 to calculate the number of additional lithotripters needed in the state.

Lithotripsy Services in North Carolina

There are eight providers that offer lithotripsy services in North Carolina. On the following pages, Table 9A and Table 9B provide information on the number of procedures as well as the location of the facilities served by these eight providers.

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Carolina Lithotripsy, LTD, 2014 Litho Place, Fayetteville, NC 28304-

Machines 2; #1137 (11/15/2000); #01179 (12/15/2011)

Areas Generally Served: Eastern North Carolina

<i>Facility and Location</i>	<i>Procedures</i>
CarolinaEast Medical Center, New Bern, NC	103
Carteret General Hospital, Morehead City, NC	53
Columbus Regional Healthcare System, Whiteville, NC	12
Duke Raleigh Hospital, Raleigh, NC	10
FirstHealth Moore Regional Hospital, Pinehurst, NC	162
FirstHealth Richmond Memorial Hospital, Rockingham, NC	25
Halifax Regional Medical Center, Roanoke Rapids, NC	30
Highsmith-Rainey Specialty Hospital, Fayetteville, NC	177
Johnston Health, Smithfield, NC	81
Lenoir Memorial Hospital, Kinston, NC	21
New Hanover Regional Medical Center, Wilmington, NC	201
Novant Health Brunswick Medical Center, Supply, NC	12
Onslow Memorial Hospital, Jacksonville, NC	4
Rex Hospital, Raleigh, NC	125
Southeastern Regional Medical Center, Lumberton, NC	73
Vidant Beaufort Hospital, Washington, NC	28
Vidant Medical Center, Greenville, NC	138
WakeMed, Raleigh, NC	50
Wayne Memorial Hospital, Goldsboro, NC	17
Wilson Medical Center, Wilson, NC	38
Total Procedures:	1,360
Average Number of Procedures per Lithotripter:	680

Provider: Catawba Valley Medical Center, 810 Fairgrove Church Road, SE, Hickory, NC 28602-

Machines 2; #1355 (11/2010); TC-2051 (03/2001)

Areas Generally Served: Western and Central North Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Carolinas HealthCare System- Blue Ridge, Morganton, NC	39
Catawba Valley Medical Center, Hickory, NC	321
Rutherford Regional Medical Center, Rutherfordton, NC	68
Scotland Memorial Hospital, Laurinburg, NC	135
Total Procedures:	563
Average Number of Procedures per Lithotripter:	282

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Fayetteville Lithotripters Limited Partnership-South Carolina II, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-197 (01/17/2011)

<i>Areas Generally Served:</i> Western North Carolina and South Carolina	
<i>Facility and Location</i>	<i>Procedures</i>
Charles George VA Medical Ctr, Asheville, NC	25
Harris Regional Hospital, Sylva, NC	118
Haywood Regional Medical Center, Clyde, NC	112
Margaret R Pardee Memorial Hospital, Hendersonville, NC	93
Park Ridge Health, Hendersonville, NC	60
St. Luke's Hospital, Columbus, NC	7
The McDowell Hospital, Marion, NC	32
Transylvania Regional Hospital, Brevard, NC	46
Oconee Medical Center, Seneca, SC	100
Total Procedures:	593
Average Number of Procedures per Lithotripter:	593

Provider: Fayetteville Lithotripters Limited Partnership-Virginia I, 9825 Spectrum Drive, Bldg 3, Austin, TX 78717-

Machines 1; SID OR-519 (11/9/2013) replaced SID 1147

<i>Areas Generally Served:</i> Eastern North Carolina and Virginia	
<i>Facility and Location</i>	<i>Procedures</i>
Sentara Albemarle Medical Center, Elizabeth City, NC	24
The Outer Banks Hospital, Nags Head, NC	17
Vidant Chowan Hospital, Edenton, NC	51
Harborview Medical Center, Suffolk, VA	20
Louise Obici Memorial Hospital, Suffolk, VA	2
Mary Immaculate Hospital, Newport News, VA	157
Maryview Medical Center, Portsmouth, VA	8
Riverside Tappahannock Hospital, Tappahannock, VA	9
Riverside Walter Reed Hospital, Newport News, VA	4
Southside Community Hospital, Farmville, VA	19
Spotsylvania Regional Medical Center, Fredricksburg, VA	1
Total Procedures:	312
Average Number of Procedures per Lithotripter:	312

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Piedmont Stone Center, PLLC, 1907 S Hawthorne Road, Winston-Salem, NC 27103-
 Machines 4; 01138 (03/26/2002); 01175 (04/10/2003); 01171 (04/24/2003); 1925 (12/26/2006)

Areas Generally Served: Western and Central North Carolina and Virginia

<i>Facility and Location</i>	<i>Procedures</i>
Carolinas HealthCare System-Blue Ridge, Valdese,	94
Davis Regional Medical Center, Statesville,	45
High Point Regional Health System, High Point,	498
Hugh Chatham Memorial Hospital, Elkin,	182
Iredell Memorial Hospital, Statesville,	144
Lexington Medical Center, Lexington,	64
Maria Parham Medical Center, Henderson,	60
Morehead Memorial Hospital, Eden,	172
Northern Hospital of Surry County, Mount Airy,	50
Novant Health Forsyth Medical Center, Winston-Salem,	116
Novant Health Rowan Medical Center, Salisbury,	213
Novant Health Thomasville Medical Center, Thomasville,	41
Randolph Hospital, Asheboro,	115
Wake Forest Baptist Medical Center, Winston-Salem,	103
Watauga Medical Center, Boone,	144
Wesley Long Hospital, Greensboro,	326
Wilkes Regional Medical Center, North Wilkesboro,	75
Alamance Regional Medical Center, Burlington, NC	186
Annie Penn Hospital, Reidsville, NC	14
Piedmont Stone Center, Winston-Salem, NC	799
Yadkin Valley Community Hospital, Yadkinville, NC	9
Lynchburg General Hospital, Lynchburg, VA	254
Martha Jefferson Hospital, Charlottesville, VA	204
Memorial Hospital of Martinsville, Martinsville, VA	110
Montgomery Regional Hospital, Blacksburg, VA	131
Piedmont Day Surgery Center, Danville, VA	43
Twin County Regional Hospital, Galax, VA	74
Total Procedures:	4,266
Average Number of Procedures per Lithotripter:	1,067

Table 9A: Mobile Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Lithotripsy Registration and Inventory Form for Mobile Equipment")

Provider: Stone Institute of the Carolinas, LLC, 215 S Main Street, Suite 201, Davidson, NC 28036-
Machines 2; 2053 (10/2006); 1048 & 01384 (01/2001)

Areas Generally Served: Western and Central North Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Carolinas HealthCare System-Lincoln, Lincolnton, NC	60
Carolinas Medical Center, Charlotte, NC	153
Carolinas Medical Center-Huntersville, Charlotte, NC	72
Carolinas Medical Center-Northeast, Concord, NC	220
Carolinas Medical Center-Pineville, Charlotte, NC	217
Carolinas Medical Center-Union, Monroe, NC	115
Carolinas Medical Center-University, Charlotte, NC	211
Caromont Regional Medical Center, Gastonia, NC	126
Cleveland Regional Medical Center, Shelby, NC	108
Lake Norman Regional Medical Center, Mooresville, NC	184
Novant Health Matthews Medical Center, Matthews, NC	197
Novant Health Presbyterian Medical Center, Charlotte, NC	87
Piedmont Medical Center, Rock Hill, SC	161
Surgery Center at Edgewater, Fort Mill, SC	34
Total Procedures:	1,945
Average Number of Procedures per Lithotripter:	973

Provider: Triangle Lithotripsy Corp, 7003 Chadwick Dr #321, Brentwood, TN 37027-
Machines 1; 10142940 (04/01/2010)

Areas Generally Served: East Central North Carolina

<i>Facility and Location</i>	<i>Procedures</i>
Central Carolina Hospital, Sanford, NC	126
Duke Regional Hospital, Durham, NC	28
Durham Ambulatory Surgical Center, Durham, NC	104
Nash General Hospital, Rocky Mount, NC	127
North Carolina Speciality, Durham, NC	13
Rex Hospital, Raleigh, NC	168
Rex Surgery Center, Cary, NC	15
Sampson Regional Medical Center, Clinton, NC	253
WakeMed, Raleigh, NC	74
Wayne Memorial Hospital, Goldsboro, NC	
Total Procedures:	1,125
Average Number of Procedures per Lithotripter:	1,125

Total Mobile Procedures: 10,164

Table 9B: Fixed Lithotripsy Providers and Locations Served

(From 2014 data as reported on the "2015 Hospital License Renewal Application")

Provider: Mission Hospital, Inc./Mission, 509 Biltmore Ave., Asheville, NC 28801

Machines: 1 08/2000

<i>Area Served:</i>	
<i>Facility and Location</i>	<i>Procedures</i>
WNC Stone Center, Asheville, NC	295
Total Number of Procedures:	295
<i>Average Number of Procedures per Lithotripter:</i>	295

Table 9C: Mobile and Fixed Lithotripsy

(Total Procedures/Units Reported)

Total Procedures Reported	Units Reported	Average Procedures Per Unit
10,459	14	747

Need Determination

Application of the standard methodology for the North Carolina 2016 State Medical Facilities Plan determined the need for one lithotripter as shown in Table 9D. There is no need anywhere else in the state and no other reviews are scheduled.

Table 9D: Lithotripter Need Determination
(Scheduled for Certificate of Need Review Commencing in 2016)

It is determined that the service areas listed in the table below need additional lithotripters as specified.

Lithotripters	Lithotripter Need Determination*	Certificate of Need Application Due Date**	Certificate of Need Beginning Review Date
Statewide	1	June 15, 2016	July 1, 2016
It is determined that there is no need for additional lithotripters anywhere else in the state and no other reviews are scheduled.			

* Need determinations shown in this document may be increased or decreased during the year pursuant to Policy GEN-2 (see Chapter 4).

** Application due dates are absolute deadlines. The filing deadline is 5:30 p.m. on the application due date. The filing deadline is absolute (see Chapter 3).

**Comments on Petition to the State Health Coordinating Council
Regarding New Technology and Equipment Policy TE-3
2017 State Medical Facilities Plan**

March 18, 2016

Commenter:	Contact:
Name: Triangle Lithotripsy Corporation	Name: David B. Driggs; William Pinna; Nancy Lane
Address: 2601 Oberlin Road, #100 Raleigh, NC 27608	E-mail: D5205@aol.com ; bpinna@pjb-law.com ; nlane@pda-inc.net
	Phone: 919-755-1317, 919-754-0303

SUMMARY OF REQUESTED ADJUSTMENT

Hampton Roads Lithotripsy, LLC, a Virginia company based in Norfolk, filed a petition requesting a new Policy TE-3 for the 2017 State Medical Facilities Plan.

The petition's stated intent is to permit applicants who own mobile lithotripsy equipment to increase access to rural areas in North Carolina. The proposed policy would:

- Benefit only companies that operate outside the state of North Carolina, in contiguous states including states as far away as Georgia;
- By-pass the Need Methodology for Lithotripsy in Chapter 9 of the *State Medical Facilities Plan*;
- Not require the applicant to be serving North Carolina at the time it applies for a Certificate of Need under the proposed policy; and
- Permit operation only at hospital sites.

We appreciate the state's consideration of our comments on the petition and welcome any questions.

COMMENTS

UNFRIENDLY TO NORTH CAROLINA

Petition Policy Elements 1 and 2 would prohibit a mobile lithotripsy company that serves only North Carolina from applying. Specifically the petition requires the following:

... has regulatory approval if needed, to operate in a state contiguous to North Carolina

..currently provides services to at least one host site in one of the states that is contiguous to North Carolina

The petition had no letters of support from North Carolina and the petitioner chose not to exercise the opportunity to make a case in person before the State Health Coordinating Council at its meeting in March 2016.

UNFRIENDLY TO RURAL NORTH CAROLINA

The petition's third Policy Element requires that a Certificate of Need application filed under the proposed new policy TE-3 to serve only rural hospital sites.

Will serve only hospital sites in areas defined as rural...

Several North Carolina counties do not have a hospital; Alexander, Graham, and Warren are a few examples. The petition actually notes that these counties would not be appropriate for mobile lithotripsy (page 9 of 12).

INSIGHTFUL CONSIDERATIONS

The petition raises good questions about access to lithotripsy in rural North Carolina. However, the petition favors only the solution that benefits this one out-of-state company. The petition would give Hampton Roads Lithotripsy, and other out-of-state companies, unrestricted access to grow business in North Carolina at the expense of companies that are in North Carolina and serve North Carolina. A North Carolina company that operates at full capacity could not apply for a CON under the policy as written, but an out of state company with no track record, would have permission to create a case and that applicant would not be subject to the standard performance requirement. It would only need to serve an area defined as rural. It could compete where others could not. The proposed policy would create two classes of lithotripsy providers.

The petition's arguments that the 1994 use rates merit re-examination are valid, but the petition falls short of resolution on alternatives. However, it appropriately opens the door for additional discussion. The petition makes an excellent case that service to out of state locations should be discounted in the state methodology, even noting without so saying that the out-of-state cases exceed the state threshold for an additional lithotripter. However, the petition makes a blanket assumption that no provider could serve rural areas, instead proposes a solution that serves the petitioner's interest in Northeastern North Carolina. It appropriately notes the planning obstacles associated with the state's missing patient origin data, but only generally references its own data on service to North Carolina residents. It notes that patients of urologists in the Hampton Roads area could be served by lithotripters in rural North Carolina, but fails to discuss whether those urologists would go to the rural North Carolina lithotripter.

The proposed policy is incomplete with regard to the narrative. The narrative suggests using a placeholder to count service to counties the out of state unit would serve, but does not apply the same to North Carolina units that go out of state. Over time, this will create an imbalance that favors the out of state unit.

INAPPROPRIATE TIMING

As the petitioner notes, the 2016 SMFP shows a statewide need for one additional lithotripter. Applications are due mid-year and the review may not finish before the end of the year. Consideration of the policy now, before filing the batch applications, would put the state in an untenable position. Certificate of Need staff would be constrained in their comments because of a review in progress.

STATEMENT OF ADVERSE EFFECTS ON PROVIDERS AND CONSUMERS IF THE ADJUSTMENT IS MADE

The petition would permit duplication of resources. For example, it could permit location in a county, at the border of very urban county. Thoughtful review and consideration could eliminate such unintended consequences.

REMEDY

The petitioner clearly raises issues that merit consideration by a group that understands the full spectrum of lithotripsy treatment, disease indicators, cost of operations and quality program requirements. A work group could be appointed and could convene in late fall, to provide recommendations to the Technology Committee in spring 2017.

The petition correctly notes that the development of the current methodology occurred in 2001. Now, fifteen years later, it is appropriate to revisit the methodology and its research foundations.

A new methodology could include more current nephrolithiasis disease incidence and kidney stone prevalence information, as well as utilization patterns and underserved areas. It could make adjustments for fixed and mobile unit status, as is the case with MRI. The methodology could exclude counts of procedures provided outside the state by adding one extra step to the current methodology.

As a first step, in 2016, the SHCC could remedy the problem of missing patient origin data, by asking DHSR Planning to add one table to the required Registration and Inventory of Equipment forms. When the SHCC expanded the MRI methodology, a similar panel looked at underserved areas and adjusted thresholds to favor redistribution of resources. A study group could look at that.

CONCLUSION

The petition raises important questions about the methodology for calculating need for lithotripter capacity and the best ways to serve rural communities in North Carolina. The Hampton Roads Lithotripsy petition should be tabled until the conclusion of the 2016 Lithotripsy CON review cycle. A work group should then be created to review the petition and make recommendations to the SHCC. This allows the work group to account for the 2016 application decision and yield the best recommendations.



EXECUTIVE SUMMARY

Medical Equipment

Eastern Carolina Lithotripsy, Inc.

Certificate of Need Application for
Acquisition of Mobile Lithotripter
Statewide

Eastern Carolina Lithotripsy, Inc. is applying for Certificate of Need approval to establish mobile lithotripter services in three eastern North Carolina counties by purchasing and operating a mobile lithotripter in Health Service Areas IV, V, and VI.

Scheduled to begin operations in October 2017, the completed project will provide additional days of service to host sites serving patients in Orange, Durham, Wake, Johnston, Nash, Harnett, Cumberland, Sampson, Duplin, Lenoir, Jones, Onslow, Carteret, Craven, Beaufort, Hyde, and Pamlico counties.

Funding in the amount of \$1,150,000 for the proposed project included capital expenditures and start-up expenditures and will be funded by a bank loan.

The project is a response to the statewide need for additional mobile lithotripsy services. It directly responds to the substantial unmet need for mobile lithotripsy services, in the underserved counties of Health Service Areas IV, V, and VI.

Certificate of Need Application
**ACUTE CARE FACILITY/
MEDICAL EQUIPMENT**
State of North Carolina, Department of Health and Human Services

OFFICE USE ONLY

Project I. D. Number: _____ Batch Category: _____
Proposal Type: _____ Beginning of Review: _____

I. IDENTIFICATION

1. **Legal Name of the Applicant:** The applicants are the legal entities (i.e., persons or organizations) that will own the facility and any other persons who will offer, develop or incur an obligation for a capital expenditure for the proposed new institutional health service.

LEGAL APPLICANT

Eastern Carolina Lithotripsy, Inc.
(Name)

C/o American Diagnostics Inc., 8161 Highway 100, PMB 170
(Street & Number)

Nashville TN 37221
(City) (State) (Zip)

2. **Name of Parent Company (if applicable):**

(Name)

(Street & Number)

(City) (State) (Zip)

Not applicable; there is no parent company.

II. SCOPE OF SERVICES/QUALITY OF CARE

1. (a) Describe each service component included in the proposed project (e.g., acute care beds, Emergency Department, Radiology, Laboratory, MRI scanner, CT scanner, operating rooms, etc.).

SERVICE COMPONENT DESCRIPTION

Overview

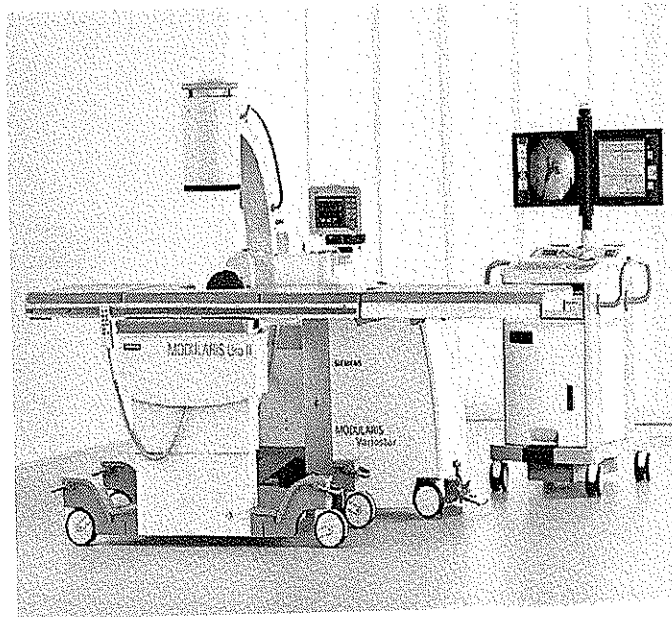
The applicant proposes to acquire a complete lithotripsy system consisting of LithoGold shockwave generator, Siemens C-arm fluoroscopy system, patient treatment table and all other equipment required to perform lithotripsy on a mobile basis. All equipment will be installed on a custom designed mobile coach from Medical Coaches of Oneonta, NY, built on an International 4300 Chassis Cab, and taken to sites in three service clusters in eastern North Carolina. Those clusters are:

- Wake County – served through host sites at WakeMed Cary and Rex Surgery Center Cary;
- Craven County – served through a host site at CarolinaEast Medical Center in New Bern; and
- Sampson / Harnett Counties – served by a site at Sampson Regional Medical Center in Clinton and / or at Harnett Health Betsy Johnson Hospital in Dunn.

Eastern Carolina Lithotripsy will:

- Purchase the Lithotripter System as described above, see brochure in Exhibit 4;
- Install the lithotripter on a mobile coach, see mobile coach specifications in Exhibit 4;
- Serve three geographical clusters with high need / inadequate access; and,
- Contract with host sites to operate the mobile lithotripter at the site defined on the schedule.

Figure II. 1 - Lithotripter System



Host sites will:

- Schedule patients;
- Provide service support; and
- Bill and collect payment from patients and insurance.

Local urologists will:

- Diagnose and refer appropriate patients; and
- Supervise all procedures.

American Diagnostics will:

- Provide technical staff;
- Maintain the coach and equipment; and
- Maintain the service schedule.

Design of this service model allows the applicant to deliver a quality service to communities through:

- Service provided at community hospitals or surgery centers;
- Focus on high need / low access communities; and
- Planning and coordination with community providers, physicians and facilities.

Planning for the service included physicians and hospitals / health systems, and with a narrowing primary focus to locations with high need, access to providers, and optimal access for both patients and providers. ECL will support an existing stone center and two developing Eastern North Carolina Stone Centers (Center of Excellence). These centers will:

- Have a patient-centered focus;
- Involve primary care physicians, urologists and nephrologists; and,
- Focus on patient needs versus episode of care, with an emphasis in holistic approach to care for persons who have kidney stones.
- Organize a schedule that responds to population need: quality versus quantity.

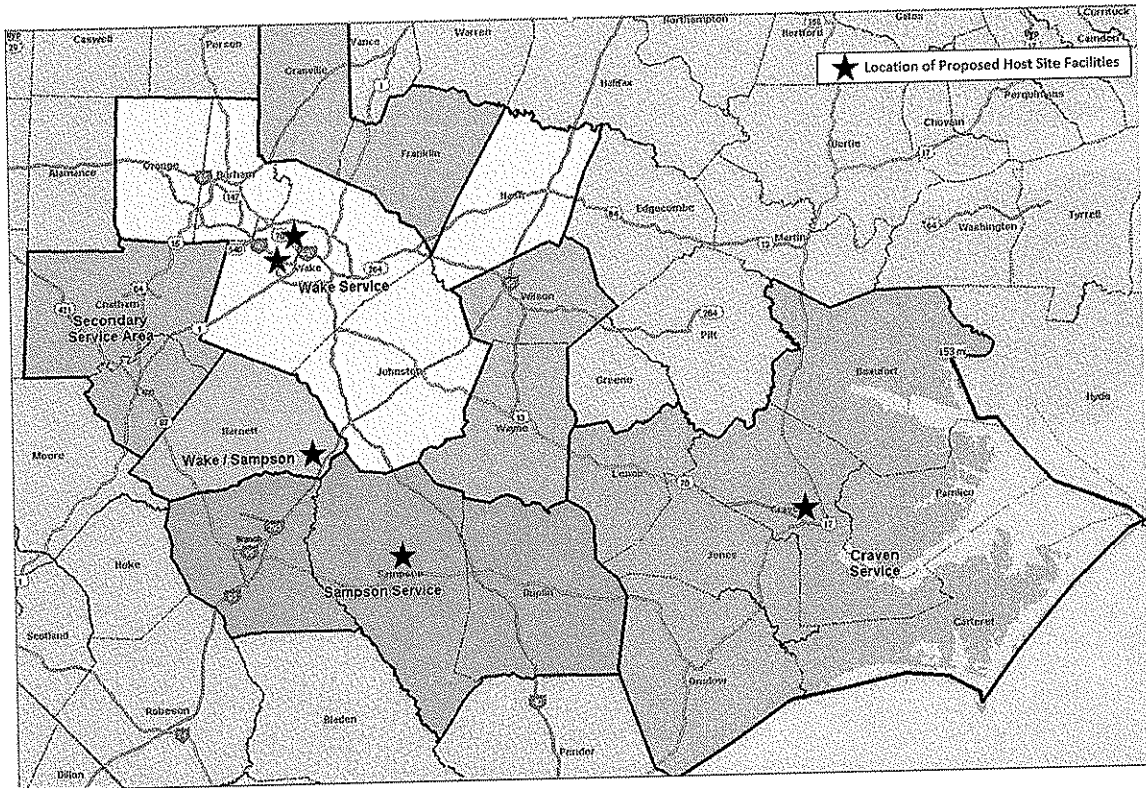
Host sites are positioned to reach the maximum number of underserved populations and assure predictability for patients.

Table II. 1 – Proposed Service Clusters

Host Site County	Host Site Facility	Counties Served
Wake	WakeMed Cary	Wake Orange Durham Harnett
	Rex Surgery Center	Johnston Nash
Sampson / Harnett	Sampson Regional Medical Center	Sampson Duplin Harnett
	Harnett Health Betsy Johnson Hospital	Cumberland
Craven	CarolinaEast Medical Center	Craven Onslow Beaufort Lenoir Carteret Pamlico Jones

ECL will assure that every host site knows the location of the lithotripter at any time. This will remove uncertainty for patients and emergency rooms. Host sites will promote access. The map in Figure II.2 shows each county by service cluster; the stars indicate locations of actual host site facilities by city from Table II.1.

Figure II. 2 – Proposed Service Clusters by County and Host Site Facility Locations by City



Proposed host site facilities correspond to those in Table II.1.

In fact, some patients in adjacent counties like Wayne, Franklin, and Granville, may also use the service as the program gains recognition.

Key to the program is predictability, so that a patient in pain with a kidney stone can call a regional center and locate service within 24-hours.

4. Provide the regularly scheduled hours of operation for each service component included in the proposed project.

ECL will provide services to a host site location from 7:00 am to 5:00 pm on its schedule day of service. ECL will offer lithotripsy on a regular basis at sites selected and on a schedule to maximize access to lithotripsy in communities with significant unmet need. ECL will schedule at the following host sites:

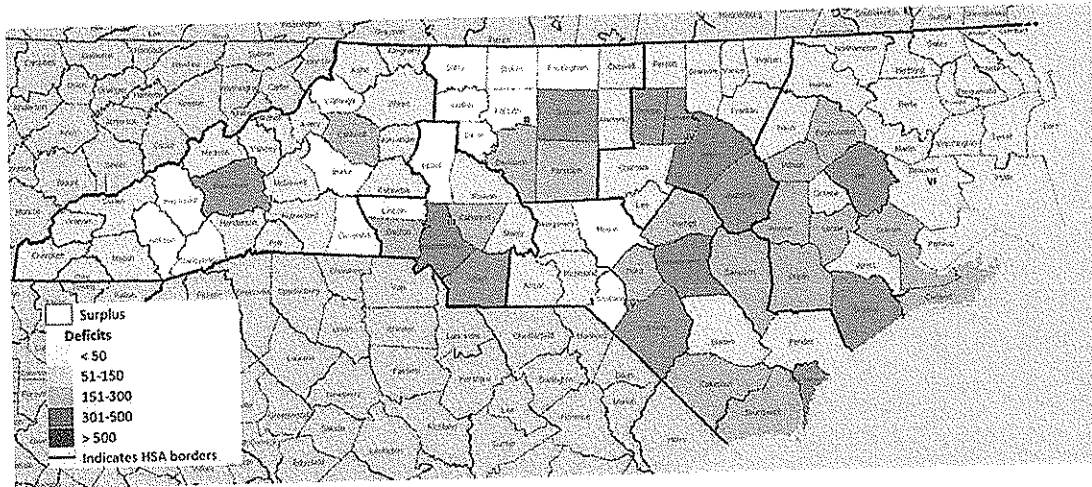
Table II. 4 – Proposed Schedule for ECL Host Site Facilities Upon Opening

Host Site Facility	Location	Days per Week
Western Wake Medical Center	Cary, Wake County	2
Rex Surgery Center	Cary, Wake County	1
Sampson Regional Medical Center	Clinton, Sampson County	1 (a)
Harnett Health	Dunn, Harnett County	
CarolinaEast Medical Center	New Bern, Craven County	1

Notes: a. Sampson Regional Medical Center and Harnett Health may share a day of service, and / or alternate one day per week at each site.

Community urologists schedule patients based on availability of time slots prior to the day the lithotripter is on site. Per operations staff of American Diagnostics, ECL will see as many patients as the facility is willing to schedule – usually up to 10 on a given day. If a physician wishes to treat a patient on a scheduled site visit, they are not turned away based on the need of the ECL staff. While this typically will include procedures performed between its established operating hours, 7:00 am to 5:00 pm, ECL will adjust according to provider needs.

Figure III. 1 – 2015 Surplus / Deficit of Estimated Procedures versus Expected Procedures by County at 2016 SMFP Use Rate



Notes: a. Estimated Patients Served – Expected Procedures at State Use Rate, 2016 SMFP
c. See Section III.1(b), for further detail regarding determination of each county's surplus / (deficit)
c. Health Service Areas as determined by 2016 SMFP

Eastern North Carolina

Unfortunately, access to ESWL service, especially in eastern North Carolina, is limited at best. The mobile units travel significant distances and some sites get as little as one day per month of service. As a result, patients who are candidates for ESWL treatment are often left with the option of waiting one to two weeks for services, or having surgery. Increased access, even in a limited area, means more patients are able to choose a non-invasive treatment with in-home recovery, versus a more expensive, surgical treatment that includes a hospital stay.⁵ Figure III.2 shows the providers by host city for HSAs IV, V, and VI. As shown, seven of the 15 units serve eastern North Carolina. But, the three units of Carolina Lithotripsy, LTD and Triangle Lithotripsy Corporation (TLC) provide the majority of service.⁶ Tables III.1 and III.2 summarize this.

⁵ <http://urology.wustl.edu/en/Patient-Care/Kidney-Stones/Surgery-for-Kidney-Stones>

⁶ 2016 Lithotripsy Registration and Inventory Form for Mobile Equipment; 2015 data collected from October 1, 2014 through September 30, 2015

- (c) **Document that the facility is needed at the proposed site as opposed to another area of the service area.**

As shown in Step 8 of III.1.(b), ECL is proposing a target service area of 16 North Carolina counties. Within those counties, ECL has identified four to five host site locations in which to provide service:

Table III. 12 – Proposed Counties Served by Host Site County

Host Site County	Host Site Facility	Counties Served
Wake	WakeMed Cary	Wake Orange Durham Harnett
	Rex Surgery Center	Johnston Nash
Sampson / Harnett (a)	Sampson Regional Medical Center	Sampson Duplin
	Harnett Health – Betsy Johnson Hospital	Harnett Cumberland
Craven	CarolinaEast Medical Center	Craven Onslow Beaufort Lenoir Carteret Pamlico Jones

Notes: a. As of the application date ECL has identified two potential service sites in the Sampson / Harnett cluster, at Sampson Regional Medical Center in Clinton and at Harnett Health – Betsy Johnson Hospital in Dunn. ECL will serve one day per week at this site, in whatever combination is most effective at meeting the needs of patients in those

See Exhibit 5 for letters from these facilities attesting to interest in serving as host sites.

The applicant chose the listed counties because of a demonstrated high-unmet need. ECL considered other places in the state, but as shown in Figures III.5 and III.6 above, eastern North Carolina, specifically HSAs IV, V, and VI, is the most underserved. Furthermore, significant portions of western counties, those in HSAs I, II, and III, actually have an estimated annual surplus of ESWL procedures.

Although it is tempting to be distracted by deficits in Mecklenburg and Union counties, as demonstrated in Exhibit 10, the total calculated deficit in 2015 in these counties is 1,027 procedures compared to a deficit of 2,682 in the proposed ECL service area. Moreover, the two mobile units serving this area, operated by Stone Institute of the Carolinas, have elected to serve South Carolina sites, Exhibit 7. This suggests that some other factor in these two counties is reducing demand.

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PARTNERSHIP

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Anthony H. Brett
Direct Dial: 336-721-3620
Direct Fax: 336-733-8331
E-mail: ABrett@wcsr.com

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

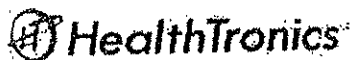
Debbie Scott

Vice President – Customer Relations

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

512.721.4779 office 512.470.5263 mobile 800.706.6502 fax

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/0B8TGpk2NINk6dkpOOVUxTFR0OVk/view?usp=sharing>

<https://drive.google.com/file/d/0B8TGpk2NINk6ZihGbkhIOEJXY2s/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

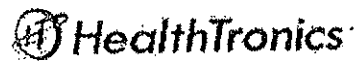
Debbie Scott

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.

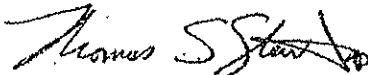
Currently Carolina East has 3 lithotripsy slots per week, on Friday morning. The day of the week and number of slots was dictated by the hospital. The urologists and Carolina Lithotripsy, the current supplier of lithotripsy services, have requested additional slots and options for different days of the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

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 \$[REDACTED] 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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debbie.scott@healthtronics.com

 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

JUL. 29. 2016 8:45AM

EASTERN URO LAB 2

NO. 164 P. 2/2

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



275 Bethesda Drive
Greenville, NC 27834
252-752-5077
Toll Free: 1-888-752-5077
Fax: 252-752-9544
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 Gavigan, MD, FACS*
Edward O. Janosko, MD, FACS*
Benjamin C. Hines, Jr., MD, FACS*
Gregory F. Murphy, MD, FACS*
Dieter Bruno, MD

*Diplomate of the American Board of Urology



275 Bethesda Drive
Greenville, NC 27834
252-752-5077
Toll Free: 1-888-752-5077
Fax: 252-752-9544

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

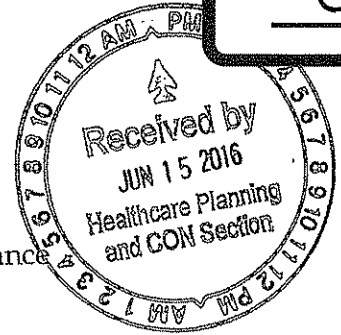
Month	Weeks	Weeks used	Slots allotted	Slots filled
Jan	2	2	8	3
Feb	3	1	12	3
Mar	2	1	8	3
Apr	2	2	8	7
May	2	2	8	2
Jun	2	2	8	7
Jul	<i>4th July</i> 1	1	4	3

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

Rotates w/WakeMed on Monday afternoons

CERTIFICATION

The undersigned hereby assures and certifies that:



- (a) the work on the proposed project will be initiated in accordance with the timetable set forth on the certificate of need;
- (b) completion of the proposed project will be pursued with reasonable diligence;
- (c) the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances;
- (d) the applicant will materially comply with the representations made in its application in the development of the project and the offering of the service pursuant to G.S. 131E-181 (b); and,
- (e) that the information included in this application and all attachments is correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

Legal Name of Applicant or Co-Applicants: Piedmont Stone Center, PLLC

Name of Responsible Officer: Charles H. Hauser

Title of Officer: Chief Executive Officer

Address: 3825 Forrestdge Drive, Winston-Salem, NC 27103

Signature Of Officer: *Charles H. Hauser*

Date: 6/1/16



Piedmont Stone Center, PLLC

Clinical Office
(336) 765-6373
Fax (336) 765-6436

PO Box 25866 • Winston Salem, NC 27114-5866

Business Office
(336) 714-1258
(888) 373-6328
Fax (336) 714-2554



Ms. Martha Frisone, Assistant Chief
Healthcare Planning & Certificate of Need Section
Division of Health Service Regulation
N.C. Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27626-0530

June 1, 2016

RE: Letter of Intent -- CON Application for Additional Lithotripter/Statewide Need Determination

Dear Ms. Frisone:

Piedmont Stone Center, PLLC (PSC) intends to file a Certificate of Need application for acquisition of one (1) additional lithotripter to be utilized for providing extracorporeal shock wave lithotripsy (ESWL) services at various host site locations in the central piedmont area of North Carolina. PSC proposes the project in response to the growing demand for high quality and cost-effective ESWL services in North Carolina.

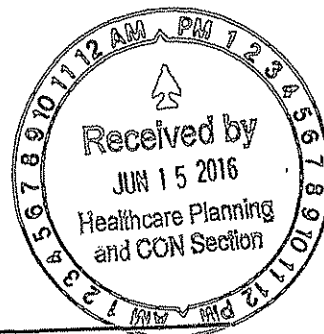
PSC will fund the project capital cost primarily via a bank line of credit. PSC will file the CON Application as a Category J, on the June 15, 2016 due date, as specified in the 2016 SMFP.

Please let me know if you have any questions about our intent to file this application. Thank you for your time and attention.

Sincerely,

Charles H. Hauser
Chief Executive Officer
Piedmont Stone Center, PLLC

Certificate of Need Application
ACUTE CARE FACILITY/
MEDICAL EQUIPMENT PROJECT
State of North Carolina
Department of Health and Human Services



OFFICE USE ONLY

Project I.D. Number: G-11200-16
Proposal Type:

Batch Category:
Beginning of Review:

I. IDENTIFICATION

I.1. Legal Name of the Applicant: The applicant is the existing legal entity (i. e., person or organization) that will own the facility. If the facility will be leased, complete two copies of Section VIII for the project; one with the lessor as the applicant and the other with the lessee as the applicant.

Piedmont Stone Center, PLLC

(Name of Applicant)

3825 Forrestgate Drive

(Street & Number)

Winston-Salem
(City)

NC
(State)

27103
(Zip)

Forsyth
(County)

I.2. Name of Parent Company (if applicable):

Not applicable.

proposed project will offer patients increased access to lithotripter services, thereby reducing wait times or the need for more costly, invasive procedures.

Additionally, due to the capacity constraints of the existing mobile lithotripters, there is limited opportunity for Piedmont Stone Center to expand its access to new host sites. The implementation of a fifth mobile lithotripter will enable Piedmont Stone Center to expand access at some of its existing host sites to meet patient demand, and also to establish two new host sites in counties which currently do not have access to mobile lithotripsy services (Caldwell and Orange counties).

B. Service Area Population

According to the 2016 SMFP, a lithotripter's service area is the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state. The following provides population projections from the North Carolina Office of State Budget & Management (NCOSBM).

**Piedmont Stone Center
Proposed Mobile Lithotripter Service Area
Projected Population, 2016-2020**

	2016	2017	2018	2019	2020	4-YR CAGR
North Carolina	10,157,928	10,261,956	10,365,986	10,470,286	10,573,611	1.0%

Source: NC Office of State Budget and Management, <http://demog.state.nc.us/>

The statewide population is expected to increase by over 415,000 between 2016 and 2020. Thus, the need determination in the 2016 SMFP for an additional mobile lithotripter is supported by the steady population growth of the lithotripter service area.

Piedmont Stone Center currently provides lithotripsy services at host sites in 13 counties in North Carolina and 6 counties in Virginia. Piedmont Stone Center proposes to add two new host sites (in two additional counties) via the proposed lithotripter. The following table provides projected population data for the current and proposed host site counties.

**Piedmont Stone Center
 Host Site County Locations
 Projected Population, 2016-2020**

County	2016	2017	2018	2019	2020	4-YR CAGR
Alamance	159,522	161,459	163,415	165,388	167,369	1.2%
Burke	89,198	89,198	89,199	89,197	89,196	0.0%
Caldwell	82,350	82,314	82,281	82,250	82,234	0.0%
Davidson	165,399	165,873	166,345	166,815	167,341	0.3%
Forsyth	371,646	375,559	379,554	383,601	387,714	1.1%
Guilford	520,398	524,226	527,911	531,454	534,907	0.7%
Iredell	171,400	173,523	175,645	177,765	179,909	1.2%
Orange	143,264	144,928	146,593	148,257	149,918	1.1%
Randolph	144,254	144,841	145,429	146,020	146,606	0.4%
Rockingham	92,543	92,543	92,545	92,543	92,556	0.0%
Rowan	138,710	138,710	138,710	138,710	138,708	0.0%
Surry	73,834	73,833	73,833	73,833	73,842	0.0%
Vance	44,978	44,940	44,911	44,887	44,875	-0.1%
Watauga	53,706	54,094	54,483	54,874	55,264	0.7%
Wilkes	70,116	70,235	70,352	70,468	70,615	0.2%
Albemarle (VA)	106,039	107,208	108,378	109,547	110,717	1.1%
Amherst (VA)	32,150	32,215	32,280	32,345	32,410	0.2%
Henry (VA)	51,996	51,871	51,745	51,620	51,494	-0.2%
Pittsylvania (VA)	62,545	62,600	62,655	62,710	62,765	0.1%
Wythe (VA)	29,119	29,188	29,257	29,326	29,395	0.2%
Total	2,603,167	2,619,358	2,635,521	2,651,610	2,667,835	0.6%

Source: NCOSBM, The Nielsen Company

The counties of all Piedmont Stone Center's current host sites total more than 2.6 million residents in 2016. The total population is expected to increase by nearly 65,000 between 2016 and 2020. Thus, Piedmont Stone Center's projected lithotripter utilization is supported by the steady population growth of the counties in which its host sites are located.

E. Relationships with Urologic Physicians

With over two decades of experience providing full-service mobile lithotripsy services, Piedmont Stone Center has developed strong clinical relationships with urologic physicians throughout North Carolina and partners with them to provide clinically integrated lithotripsy procedures. Piedmont Stone Center has approximately 100 urologists on its medical staff. A complete list of Piedmont Stone Center's medical staff is included in Exhibit 10.

Letters from urologists further document the need for the proposed lithotripter. Exhibit 15 contains letters of support from urologists who currently utilize Piedmont Stone Center's mobile lithotripsy services. These letters document their willingness to continue to utilize Piedmont Stone Center's mobile lithotripsy services.

F. Methodology for Projecting Piedmont Stone Center Lithotripsy Utilization

Piedmont Stone Center used the following assumptions and methodology in projecting the number of procedures that it will perform on its existing and proposed mobile lithotripters during the initial three years of the proposed project.

1) Identify Existing Host Sites to Be Served by Proposed Lithotripter

As described previously, the proposed mobile lithotripter will be used to expand access to some of Piedmont Stone Center's existing host sites in North Carolina. These host sites include:

- Randolph Hospital
- Novant Health Rowan Medical Center
- Alamance Regional Medical Center
- Morehead Memorial Hospital
- Hugh Chatham Memorial Hospital
- Wesley Long Hospital
- Carolinas HealthCare System Blue Ridge - Valdese
- Wilkes Regional Medical Center
- Lexington Memorial Hospital
- Piedmont Stone Center

The rationale for expanding access at each host site is described in the following narrative:

Randolph Hospital

FY2015 Treatment Days on Existing Units: 26 days ÷ 12 months = 2.2 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 2

Rationale: Procedure volume at host site increased 20% in FY2015 (138) compared to FY2014 (115); Piedmont Stone Center performed an average of over five procedures per day during FY2015 (138 treatments ÷ 26 treatment days); FY2016 year-to-date volume up 3% compared to FY2015 year-to-date.

Novant Health Rowan Medical Center

FY2015 Treatment Days on Existing Units: 50 days ÷ 12 months = 4.2 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 1

Rationale: Procedure volume at host site increased 3.3% in FY2015 (220) compared to FY2014 (213); performed an average of 4.4 procedures per day during FY2015 (220 treatments ÷ 50 treatment days)

Alamance Regional Medical Center

FY2015 Treatment Days on Existing Units: 43 days ÷ 12 months = 3.6 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 1

Rationale: Performed an average of 4.1 procedures per day during FY2015 (175 treatments ÷ 43 treatment days).

Morehead Memorial Hospital

FY2015 Treatment Days on Existing Units: 41 days ÷ 12 months = 3.4 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 1

Rationale: Procedure volume increased 26% in FY2015 (217) compared to FY2014 (172). Treated on average 5.3 patients per day during FY2015 (217 procedures ÷ 41 days).

Hugh Chatham Memorial Hospital

FY2015 Treatment Days on Existing Units: 25 days ÷ 12 months = 2.1 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 2

Rationale: Treated on average six patients per day during FY2015 (149 procedures ÷ 25 days). FY2016 year-to-date volume is up 10% compared to FY2015 year-to-date.

Wesley Long Hospital

FY2015 Treatment Days on Existing Units: 92 days ÷ 12 months = 7.6 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 1

Rationale: Treated on average 3.4 patients per day during FY2015 (315 procedures ÷ 92 days); however, one urologist left in July 2015 and the new urologist did not start until September 2015, which affected FY2015 case volume. FY2016 year-to-date volume is up 17% compared to FY2015 year-to-date.

Carolinas HealthCare System Blue Ridge - Valdese

FY2015 Treatment Days on Existing Units: 40 days ÷ 12 months = 3.3 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 2

Rationale: Performed an average of 4.6 procedures per day during FY2015 (184 treatments ÷ 40 treatment days); FY2016 year-to-date volume is up 27% compared to FY2015 year-to-date

Wilkes Regional Medical Center

FY2015 Treatment Days on Existing Units: 22 days ÷ 12 months = 1.8 days per month

of Days To Be Added Per Month on Proposed Lithotripter: 2

Rationale: Procedure volume increased 19% in FY2015 (89) compared to FY2014 (75); performed an average of 4.0 procedures per day during FY2015 (89 treatments ÷ 22 treatment days)

Lexington Memorial Hospital

FY2015 Treatment Days on Existing Units: 12 days ÷ 12 months = 1.0 days per month

of Days To Be Added on Proposed Lithotripter: 1

Rationale: Performed an average of 4.2 procedures per day during FY2015 (50 treatments ÷ 12 treatment days); FY2016 year-to-date volume is up 26% compared to FY2015 year-to-date.

Piedmont Stone Center

FY2015 Treatment Days on Existing Units: $161 \text{ days} \div 12 \text{ months} = 13.4$
days per month

of Days To Be Added Per Month on Proposed Lithotripter: 2

Rationale: High-volume treatment site; over 70 urologists on Piedmont Stone Center medical staff who treat patients at the Piedmont Stone Center host site. Performed an average of 4.8 procedures per day during FY2015 ($780 \text{ treatments} \div 161 \text{ treatment days}$).

In addition to these quantitative factors, there are also qualitative factors that support the need to increase access at the selected host sites. As described previously, Piedmont Stone Center is unable to provide mobile lithotripsy access on a weekly basis for many of its host sites. Patients with stone disease can experience significant pain and discomfort. If pain becomes unmanageable, many patients cannot wait a week or more until one of Piedmont Stone Center's lithotripters returns to the host site. Consequently, patients may elect to undergo invasive surgical procedures such as ureteroscopy. Lithotripsy is the only completely non-invasive treatment option for urinary stones and thus is preferred by most patients. The proposed project will offer patients increased access to lithotripter services, thereby reducing wait times or need for more costly, invasive procedures.

Additionally, as described in detail in Section II, Piedmont Stone Center is truly a clinically integrated organization in that the organization has developed specific protocols with regards to quality, access, and cost. Physicians of Piedmont Stone Center's medical staff must adhere to these protocols. To Piedmont Stone Center's knowledge, no other lithotripsy provider in NC is a similar clinically integrated organization. This fundamental difference is a key distinction when evaluating the most effective alternative for the need determined lithotripter. Piedmont Stone Center's medical staff has grown from 18 in 1985 to nearly 100 urologists today. This is due, in part, to the strides Piedmont Stone Center has achieved in the field of lithotripsy due to its clinically integrated design. This unique distinction will contribute to the ongoing growth of Piedmont Stone Center's medical staff, thereby supporting the continued growth of Piedmont Stone Center's lithotripsy utilization.