

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 23, 2016

Findings Date: December 2, 2016

Project Analyst: Tanya S. Rupp

Assistant Chief: Martha Frisone

### COMPETITIVE REVIEW

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Project ID #: G-11200-16  
Facility: Piedmont Stone Center  
FID #: 060074  
Service Area: Statewide  
Applicant: Piedmont Stone Center, PLLC  
Project: Acquire one mobile lithotripter for a total of five

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Project ID #: J-11201-16  
Facility: Eastern Carolina Lithotripsy  
FID #: 160294  
Service Area: Statewide  
Applicant: Eastern Carolina Lithotripsy, Inc.  
Project: Acquire one mobile lithotripter

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### REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C - PSC

NC - ECL

The 2016 State Medical Facilities Plan (2016 SMFP) includes a methodology for determining the need for additional lithotripters by service area, which is the entire state. Application of

the need methodology in the 2016 SMFP identified a need for one additional lithotripter. Two applications were submitted to the Healthcare Planning and Certificate of Need Section (Agency), each proposing to acquire one mobile lithotripter.

**Piedmont Stone Center, PLLC [PSC]** proposes to acquire one mobile lithotripter to serve 10 existing host sites and add 2 additional host sites in north central and north western North Carolina. PSC does not propose to acquire and operate more lithotripters than are determined to be needed in the 2016 SMFP. Therefore, the application is consistent with the need determination.

**Eastern Carolina Lithotripsy, Inc. [ECL]** proposes to acquire one mobile lithotripter to serve four host sites in eastern and central North Carolina. ECL does not propose to acquire and operate more lithotripters than are determined to be needed in the 2016 SMFP. Therefore, the application is consistent with the need determination.

### **Policies**

There is one policy in the 2016 SMFP which is applicable to this review: Policy GEN-3: Basic Principles, which states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

### **PSC**

*Promote Safety and Quality* - In Section II.5, pages 15 - 19, Section II.7, pages 24 - 28, Section III.1, page 53, Section III.2, pages 72 - 73, and Section V.7, pages 92 - 95, the applicant describes how it believes the proposed project would promote safety and quality. In addition, Exhibit 6 contains a copy of the applicant’s *“Quality Improvement and Patient Safety Plan.”* The information provided by the applicant is reasonable and adequately supports a determination that the applicant’s proposal would promote safety and quality in the delivery of lithotripsy services.

*Promote Equitable Access* - In Section II.5, pages 19 - 20, Section III.2, pages 71 - 72, Section V.7, page 92, and Section VI, pages 97 - 108, the applicant describes how it believes the project would promote equitable access to lithotripsy services. In addition, Exhibit 8 contains a copy of the applicant’s financial policies and procedures which describe access to

the proposed services. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal will promote equitable access to lithotripsy services.

*Maximizing Healthcare Value* - The applicant describes how it believes the proposed project would maximize healthcare value in Section II.5, pages 21-22, Section III.1, pages 35-69, Section III.2, pages 69-71, and Section V.7, pages 90-92. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value. Furthermore, the applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2016 SMFP.

The application is consistent with Policy GEN-3.

In summary, the application is consistent with the need determination in the 2016 SMFP and Policy GEN-3. Consequently, the application is conforming to this criterion.

## **ECL**

*Promote Safety and Quality* - In Section III.2, pages 58 – 59 and Section V.7, page 102, the applicant describes how it believes the proposed project would promote safety and quality. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

*Promote Equitable Access* - In Section III.2, page 59, Section V.7, page 102 and Section VI, pages 105 - 115, the applicant describes how it believes the project would promote equitable access to lithotripsy services. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

*Maximizing Healthcare Value* - The applicant describes how it believes the proposed project would maximize healthcare value in Section III.1, pages 33-57, Section III.2, page 60, and Section V.7, pages 101-102. However, the information provided by the applicant in the application as submitted does not adequately support a determination that the applicant's proposal would maximize healthcare value. Furthermore, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximum value for resources expended in meeting the need identified in the 2016 SMFP. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference. The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.

The application is not consistent with Policy GEN-3.

In summary, the application is consistent with the need determination in the 2016 SMFP. However, the application is not consistent with Policy GEN-3. Consequently, the application is not conforming to this criterion.

### **Conclusion**

In summary, each applicant adequately demonstrates that its proposal is consistent with the need determination in the 2016 SMFP for one lithotripter for use statewide. However, the limit on the number of lithotripters that may be approved in this review is one. Collectively, the two applicants propose a total of two lithotripters. Therefore, even if both applications are conforming to all statutory and regulatory review criteria, both applications cannot be approved. See the Summary following the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C - PSC  
NC - ECL

PSC proposes to acquire one mobile lithotripter to serve patients with renal (kidney) and ureteric (urinary) stones at 10 existing host sites (Randolph Hospital, Novant Health Rowan Medical Center, Alamance Regional Medical Center, Morehead Memorial Hospital, Hugh Chatham Memorial Hospital, Wesley Long Hospital, CMC Blue Ridge, Wilkes Regional Medical Center and Piedmont Stone Center) and 2 new host sites (Caldwell Memorial Hospital and UNC Hospitals) in north central and north western North Carolina. PSC is a professional limited liability company which has operated since 1983. PSC currently owns and operates four mobile lithotripters which serve patients at 25 host sites in north central and northwestern North Carolina and Virginia. In Section II.1, page 12, the applicant states,

*“Piedmont Stone Center proposes to acquire a Siemens Modularis Variostar mobile lithotripter, mounted in a customized transport trailer. The Siemens Modularis Variostar urology system can improve patient outcomes in stone treatment by offering gentle, highly-effective electromagnetic stone disintegration and viewing even tiny stones in crisp, low-dose images.”*

### **Patient Origin**

On page 122, the 2016 SMFP defines the service area for lithotripters as *“the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.”* Thus, the service area consists of the entire state. Providers may serve residents of other states.

PSC currently owns and operates four mobile lithotripters which provide services throughout north central and north western North Carolina and Virginia. In Sections III.4 and III.5, pages 77 - 79, the applicant provides the current (FY 2015) and projected (FY 2018 – FY 2019) patient origin for its mobile lithotripsy services, as shown in the table below:

**PSC Current and Projected Patient Origin**

COUNTY	STATE	CURRENT (FFY 2015)	PROJECTED	
			FFY 2018	FFY 2019
Forsyth	NC	12.3%	11.4%	11.1%
Guilford	NC	11.7%	11.0%	10.7%
Davidson	NC	6.5%	8.4%	9.1%
Randolph	NC	5.5%	6.5%	6.8%
Alamance	NC	4.4%	4.4%	4.3%
Surry	NC	4.2%	4.9%	5.2%
Rowan	NC	3.8%	3.7%	3.2%
Pittsylvania	VA	3.6%	3.1%	3.0%
Wilkes	NC	3.6%	4.8%	5.2%
Henry	VA	3.3%	2.9%	2.7%
Iredell	NC	3.3%	2.9%	2.7%
Rockingham	NC	2.9%	2.9%	2.8%
Campbell	VA	2.9%	2.5%	2.4%
Yadkin	NC	2.7%	2.4%	2.3%
Burke	NC	2.3%	2.6%	2.7%
Albemarle	VA	2.3%	2.0%	1.9%
Stokes	NC	2.2%	1.9%	1.8%
Davie	NC	2.0%	1.8%	1.7%
Carroll	VA	1.5%	1.3%	1.2%
Caldwell	NC	1.3%	1.1%	1.5%
Bedford	VA	1.2%	1.1%	1.0%
Ashe	NC	1.1%	0.9%	0.9%
Watauga	NC	1.1%	0.9%	0.9%
Orange	NC	0.0%	2.2%	3.1%
Other*		14.4%	12.5%	11.9%
<b>Total</b>		<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

\*On pages 77 and 79, the applicant lists the other counties in North Carolina and Virginia which are included in the current and projected patient origin.

In Section III.5(d), page 80, the applicant states:

*“The projected patient origin for Piedmont Stone Center’s mobile lithotripsy services is primarily based on its historical patient origin. The proposed lithotripter will be used to expand access at existing host site facilities in Alamance, Burke, Davidson, Forsyth, Guilford, Randolph, Rockingham, Rowan, Surry and Wilkes counties. Residents of these counties comprised approximately 57.2% of Piedmont Stone Center patient origin during FY 2015. ...*

*Additionally, the proposed lithotripter will serve two new host sites in Caldwell and Orange counties, respectively.”*

All of the proposed host sites for the new mobile lithotripter are located in North Carolina.

The applicant adequately identified the population proposed to be served.

**Analysis of Need**

In Section III.1, pages 35 – 48, the applicant describes the factors which it states support the need for the proposed project, including:

- The need identified in the 2016 SMFP (pages 35 – 36).
- Historical utilization of PSC’s existing lithotripters (pages 37 - 41).
- Projected service area population growth (pages 41 - 42).
- Environmental and health factors which contribute to the incidence of stone disease nationally and in North Carolina (pages 43 - 48).
- Relationships with local physicians who support the project and who will refer patients to the proposed service (page 49).

The information provided by the applicant on the pages referenced above is reasonable and adequately supported.

**Projected Utilization**

In Section IV.1, page 84, the applicant provides the historical and projected utilization for its existing lithotripters and the proposed lithotripter through the first three years of operation following completion of the project (FY 2018 – FY 2020), which is summarized in the table below:

<b>Historical and Projected Utilization</b>							
ANNUAL PROCEDURES	ACTUAL		INTERIM		PROJECT YEARS		
	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Procedures on existing Lithotripters	4,266	4,180	4,205	4,231	4,244	4,257	4,271
Procedures on proposed lithotripter					516	781	1,045
Total number of Procedures	4,266	4,180	4,205	4,231	4,760	5,038	5,316
Average # Procedure / Lithotripter	1,067	1,045	1,051	1,058	952	1,008	1,063

Source: Tables on page 84 of the application.

As shown in the above table, the applicant projects the proposed lithotripter will perform 1,045 procedures and all the units will perform an average of 1,067 procedures per unit in the third operating year. The applicant describes the assumptions and 8-step methodology used to project utilization in Section III.1, pages 49 - 69, which are summarized below.

*Step 1: Identify Existing Host Sites to be Served by Proposed Lithotripter*

On pages 49 – 53, the applicant identifies ten of its current host sites which it projects to serve with the proposed lithotripter. The applicant states it chose these ten sites because it states utilization has been high and additional days served by an additional lithotripter will provide increased access to patients. Additionally, the applicant states that it is currently

unable to provide mobile lithotripsy service on a weekly basis for many of its host sites, which results in patients waiting for long periods of time in significant pain for lithotripsy treatment or electing instead to undergo costly and invasive surgical stone removal. Adding additional service to the ten selected host sites will, according to the applicant, alleviate the current burden placed on patients when they are unable to receive treatment.

*Step 2: Determine Historical Utilization for the Selected Host Sites*

In Section III, page 54, the applicant provides the historical utilization of the ten host sites, as shown in the following table:

SITE	COUNTY	FY 2015 PROCEDURES	FY 2015 AVG. PROCEDURES PER DAY
Novant Health Rowan Medical Center	Rowan	220	4.4
Randolph Hospital	Randolph	138	5.3
Blue Ridge Healthcare Hospital - Valdese	Burke	184	4.6
Wesley Long Hospital	Guilford	315	3.4
Wilkes Regional Medical Center	Wilkes	89	4.0
Alamance Regional Medical Center	Alamance	175	4.1
Lexington Memorial Hospital	Davidson	50	4.2
Morehead Memorial Hospital	Rockingham	217	5.3
Hugh Chatham Memorial Hospital	Surry	149	6.0
Piedmont Stone Center	Forsyth	780	4.8
<b>Total / Average</b>		<b>2,317</b>	<b>4.5</b>

Source: application page 54. The applicant states utilization at Wesley Long Hospital was affected when one urologist left in September 2015.

As shown in the table above, nine of the ten sites averaged at least 4.2 procedures per day per site.

To project utilization at the ten selected host sites, the applicant examined the projected population growth and calculated the compound annual growth rate (CAGR) for each of the ten counties for the years 2016 – 2020. The applicant projected future utilization using the average CAGR for all ten sites, which is 0.53%. On page 55, the applicant states:

*“Utilizing the weighted average population growth rate to project mobile lithotripsy procedures is reasonable and conservative. ... Procedures performed at Randolph Hospital during FY 2016 year-to-date have increased three percent compared to FY 2015 year-to-date. Procedures performed at Hugh Chatham Memorial Hospital during FY 2016 year-to-date have increased 10 percent compared to FY 2015 year-to-date. In an abundance of conservatism, Piedmont Stone Center applied the weighted average population growth rate to project mobile lithotripsy procedures....”*

*Steps 3 and 4: Project Utilization During Interim Years and First Three Project Years*

On page 57, the applicant projects that procedures at the selected host sites will increase by an average of two, three and four procedures per day per site in project years one, two and three respectively, based on what the applicant states is “*over two decades of experience providing lithotripsy services as well as its established knowledge of utilization patterns at each existing host site.*” On pages 58 – 59, the applicant provides a table to illustrate the projected utilization at each host site for the existing lithotripters, and the incremental increase for the proposed lithotripter. The applicant calculates the number of procedures performed at the ten selected sites and the remaining sites, to determine the number of additional procedures to be performed. See the following table, from page 59:

**PSC Projected Utilization Existing and Proposed Lithotripter**

	INTERIM		PROJECT YEARS		
	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Total Procedures Performed at Selected Sites	2,329	2,341	2,714	2,906	3,099
Procedures on Existing Lithotripters	2,329	2,341	2,341	2,341	2,341
<b>Additional Procedures on Proposed Lithotripter</b>			<b>372</b>	<b>565</b>	<b>757</b>

*Step 5: Project New Host Site Utilization During First Three Project Years*

In pages 60 – 64, the applicant projects utilization for the proposed lithotripter at the two proposed new host sites, UNC Health Hospitals Hillsborough Campus in Orange County, and Caldwell UNC Health Care in Caldwell County. Relying on the methodology in the 2016 SMFP Chapter 9, the applicant assumes the incidence of stone disease at a rate of 16 per 10,000 population, and that 90% of stone cases will be treated by lithotripsy rather than surgery. The applicant states it currently serves Caldwell County residents through the host site located in Burke County, which is adjacent to Caldwell County. The applicant projects to serve the same number of Caldwell County patients in the first project year at the new host site that it did in Burke County in FY 2015. With regard to Orange County, the applicant used patient origin for outpatient MRI procedures performed at UNC Hospitals as a proxy for lithotripter patient origin.

The following tables, from pages 61-62, illustrate total projected cases based on an incidence rate of 16 cases per 10,000 population and the number of procedures projected to be performed at each new host site (90%).

**Stone Cases Appropriate for Lithotripsy in Host Counties**

COUNTY	2016	2107	2018	2019	2020
Caldwell	119	119	118	118	118
Orange	206	209	211	213	216



**Piedmont Stone Center Projected Lithotripsy Procedures at New Host Sites**

SITE	DAYS/MONTH ON SITE	PY 1 FY 2018	PY 2 FY 2019	PY 3 FY 2020
Caldwell UNC Healthcare	2	48	72	96
UNCH Hillsborough Campus	4	96	144	192
<b>Total</b>	<b>6</b>	<b>144</b>	<b>216</b>	<b>288</b>

*Step 6: Total Projected Procedures on Proposed Lithotripters*

The following table, from page 65, illustrates the projected total procedures on the proposed lithotripter:

	FY 2018	FY 2019	FY 2020
Existing host site procedures on proposed lithotripter (step 4)	372	565	757
Proposed new host site procedures (step 5)	144	216	288
<b>Total procedures proposed lithotripter</b>	<b>516</b>	<b>781</b>	<b>1,045</b>

*Step 7: Project Utilization for Existing Lithotripters*

The applicant projected utilization of existing lithotripters at the remaining host sites currently served using the same method used in Steps 2 and 3. On page 67, the applicant shows the average population growth of the remaining sites served is 0.71%. See the following table, from page 67, which illustrates the projected utilization using the different growth rates for the selected and remaining host sites:

	ACTUAL	INTERIM		PROJECT YEARS		
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Procedures performed on existing lithotripter at selected sites	2,317	2,329	2,341	2,341	2,341	2,341
Remaining host sites served by existing lithotripters	1,863	1,876	1,889	1,903	1,916	1,930
<b>Total procedures</b>	<b>4,180</b>	<b>4,205</b>	<b>4,231</b>	<b>4,244</b>	<b>4,257</b>	<b>4,271</b>

\*Source: Application page 67

*Step 8: Combine for Total Projected Procedures*

The following table illustrates total projected lithotripsy procedures to be performed on the existing and proposed lithotripters:

	ACTUAL	INTERIM		PROJECT YEARS		
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Procedures performed on four existing lithotripters	4,180	4,205	4,231	4,244	4,257	4,271
Procedures performed on proposed lithotripter				516	781	1,045
<b>Total procedures on five lithotripters</b>	<b>4,180</b>	<b>4,205</b>	<b>4,231</b>	<b>4,760</b>	<b>5,038</b>	<b>5,316</b>

In 2015, PSC's four existing lithotripters performed at total of 4,180 procedures, which is an average of 1,045 procedures per unit. Based on historical utilization growth, projected population growth, and new host sites, the applicant projects the five mobile lithotripters will perform 5,316 procedures by the third project year, which is an average of 1,063 procedures

per unit. The applicant's projections are also supported by the projected incidence of stone disease in the proposed service area. Exhibits 15 and 16 contain letters from physicians in the proposed service area expressing support for the proposed project and their intention to refer patients to the proposed service. Projected utilization is based on reasonable and adequately supported assumptions.

Based on the Agency's review of the information provided by the applicant in Section III, pages 35 – 83, including referenced exhibits; comments received during the first 30 days of the review cycle; and the applicant's response to the comments received at the public hearing, the applicant adequately documents the need for the project for the reasons discussed above.

### **Access**

In Section VI.2, pages 97 - 98, the applicant states it will continue to provide services to all patients who need the services regardless of race, color, religion, gender, age, national origin, handicap or ability to pay. In Section VI.15, page 108, the applicant projects that in second year of operation 32.5% of patients to be served will be Medicare beneficiaries and 7.8% will be Medicaid recipients. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identified the population to be served, demonstrated the need the population has for the project and adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services. Therefore, the application is conforming to this criterion.

ECL proposes to acquire one mobile lithotripter to serve four or five host sites in eastern and central North Carolina (WakeMed Cary, Rex Surgery Center, CarolinaEast Medical Center and Sampson Regional Medical Center and/or Harnett Health). ECL is a new corporation formed in 2016 for the purpose of providing mobile lithotripsy services to patients with renal and ureter stones. In Section II.1, page 19, the applicant states,

*“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 take to sites in three service clusters in eastern North Carolina.”*

### **Patient Origin**

On page 122, the 2016 SMFP defines the service area for lithotripters as *“the lithotripter planning area in which the lithotripter is located. The lithotripter planning area is the entire state.”* Thus, the service area consists of the entire state. Providers may serve residents of other states.

ECL does not currently provide lithotripsy services and thus has no current patient origin to report. In Section III.5(b), page 69, the applicant states it assumes its patient origin will be “*similar to [Triangle Lithotripter Corporation’s] historical patient origin.*” In Section III.4, page 65, the applicant states Triangle Lithotripter Corporation (TLC) is a related company. TLC’s actual patient origin in 2015 is provided in Section III.4, page 65. Patient origin for TLC was not provided by host site. The applicant does not state whether the historical patient origin for TLC includes all TLC host sites combined or is for only selected host sites.

In Section III.5(a), page 68, the applicant projects patient origin for the proposed mobile lithotripter, as shown in the table below:

County	FY 2018		FY 2019	
	# Procedures	Percent of Total	# Procedures	Percent of Total
Wake	471	39.2%	425	39.5%
Cumberland	114	10.7%	114	10.6%
Onslow	97	9.2%	97	9.1%
Durham	78	7.3%	79	7.4%
Harnett	60	5.6%	61	5.6%
Orange	46	4.4%	47	4.4%
Craven	44	4.2%	44	4.1%
Johnston	40	3.8%	41	3.8%
Sampson	36	3.4%	37	3.4%
Carteret	23	2.1%	23	2.1%
Duplin	20	1.9%	20	1.8%
Lenoir	18	1.7%	18	1.7%
Beaufort	11	1.1%	11	1.0%
Pamlico	4	0.4%	4	0.4%
Nash	2	0.2%	2	0.2%
Jones	1	0.1%	1	0.1%
Other (9)	51	4.8%	52	4.8%
<b>Total</b>	<b>1,061</b>	<b>100.0%</b>	<b>1,075</b>	<b>100.0%</b>

\*The applicant states “other” is calculated as a percent of total by host site county. See also Step 4 of the methodology

The applicant adequately identified the population proposed to be served. However, see discussion below regarding the reasonableness of the applicant’s algorithm used to determine projected patient origin.

**Analysis of Need**

In Section III, pages 33 – 42, the applicant describes the factors which it states support the need for the proposed project, including:

- Need determination in the 2016 SMFP for one additional lithotripter (page 33)
- Lack of access in 45 North Carolina counties, 28 of which are located in eastern North Carolina (page 39)
- Access to lithotripsy services offers a noninvasive alternative to surgery (page 41)

- Access to lithotripsy services may enhance physician retention in rural areas of the state (page 41)
- Current health status of the residents of the counties to be served (pages 41 – 42)

The applicant states that there is a greater need for lithotripsy services in eastern North Carolina. On page 57, the applicant provides a table, reproduced below, that illustrates the proposed host sites and the county residents expected to use these host sites.

HOST SITE COUNTY	HOST SITE FACILITY	COUNTIES SERVED
Wake	WakeMed Cary	Wake, Orange, Durham, Johnston, Harnett, Nash
	Rex Surgery Center	
Sampson and/or Harnett	Sampson Regional Medical Center	Sampson, Duplin, Harnett, Cumberland
	Harnett Health	
Craven	CarolinaEast Medical Center	Craven, Onslow, Beaufort, Lenoir, Carteret, Pamlico, Jones

On pages 43 – 56, the applicant describes the 8-step methodology it used to estimate the need for lithotripsy services for all 100 counties in North Carolina. In Step 1, page 46, the applicant states that it obtained utilization data by host site for 2011 – 2015 from the Agency. The applicant correctly notes that the utilization data does not include any information on the county of residence of the patients utilizing the existing mobile lithotripters. On page 46, the applicant states that it:

*“developed an algorithm to estimate patient origin based on distance from host sites. The applicant used TLC historical data to determine the percentage of patient origin associated with distance from the host site. The algorithm assumes that 64 percent of patients originate from the host-site [sic] county, 34 percent from counties that share a border with the host-site [sic] county, and two percent from counties that do not share a border with the host-site [sic], but are within a 45-mile radius. The method does present some vulnerabilities ....” [Emphasis added.]*

The applicant admits in the application as submitted that the method includes “*some vulnerabilities*.” The applicant does not state in the application as submitted that the assumption that 64 percent of patients using a specific host site are residents of that county is based on TLC’s historical data leaving the Agency to assume that is the case. The applicant did not identify in the application as submitted which TLC host sites were used to arrive at that assumption. The applicant did not include in the application as submitted the historical TLC data for those host sites. Based on the application as submitted, the Agency does not know how many years of historical TLC data was used. Was it one, two, three, four, or more than four years of data? Consequently, the Agency was unable to determine if use of TLC’s experience would be a reliable indicator of the experience of all other providers in the state. As the projections in the rest of six steps are based on the results of Step 2, those projections are also questionable. Therefore, the applicant does not adequately demonstrate in the application as submitted that the assumptions used to determine an “unmet need” for additional mobile lithotripsy services at the proposed host sites is based on reasonable and adequately supported assumptions.

Projected Utilization

In Section IV.1, pages 77 - 86, the applicant projects utilization for the proposed mobile lithotripter through the first three years of operation following completion of the project (FY 2018 – FY 2020) in six steps, which are summarized below.

*Step 1: Establish Need Criteria, and Step 2: Identify Counties that Meet the Need Criteria*

The applicant used the projected lithotripsy procedure deficit it calculated in the 8-step methodology described on pages 43 – 56 of the application and Exhibit 10. On page 77, the applicant states:

*“To help prioritize the need, the applicant sorted the data based on counties with an estimated 2015 county use rate of less than ten cases per 10,000 population, and an estimated deficit of more than 50 annual procedures. State estimated average use rate for 2015 was nine cases per 10,000 population. At a capacity of five procedures per day, the applicant selected ten-day estimated annual site-service, or 50 procedures per year as a candidate for consideration.”*

The applicant states that this will identify clusters of counties that are good candidates for host sites for the proposed lithotripter. On page 78, the applicant provides a table that illustrates 26 counties that it determined are in need of a host site for mobile lithotripsy services, due to the number of patients served in 2015 and the projected procedure deficit using the state use rate. The applicant also included the number of urologists in each of those 26 counties.

However, as noted above, the results of the applicant’s 8-step methodology described on pages 43-56 of the application and Exhibit 10 are questionable. Since the 6-step methodology described on pages 77-86 of the application relies on the results of the 8-step methodology, the results of the 6-step methodology are also questionable.

*Step 3: Cluster the Need Counties*

On page 79, the applicant states it identified geographic clusters that would easily be served by the host site county, as shown below:

- Wake County: would serve Durham, Johnston, Nash and Orange counties;
- Craven County: would serve Beaufort, Carteret, Jones, Lenoir, Onslow and Pamlico counties;
- Sampson / Harnett: would serve Sampson, Cumberland, Duplin, Harnett counties.

The applicant bases these clusters and counties to be served within those clusters based on geographic proximity.

*Step 4: Determine Market Share for Each County*

Relying on historical utilization information obtained from TLC, historical ambulatory surgery utilization from the proposed host counties, and the experience of the management company proposed for this project, the applicant projects the following market share:

- Within host site county: market share would be 60% or less
- Adjacent to host site county: market share would be 35% or less

The applicant states letters of support and projected referrals from urologists also support the market share projections.

*Step 5: Calculate Total Procedures by County in the Clusters and Step 6: Verify that Each Proposed Host Site will be Sufficient*

On page 80, the applicant uses the following formula to calculate projected procedures by county:

*Estimated Lithotripsy Surplus or (Deficit) \* Percent Market Share = Total Procedures by County Served*

The results are illustrated in the following table, reproduced from pages 81-82.

HOST COUNTY	COUNTIES SERVED	% MKT SHARE	2018		2019		2020	
			Estimated unmet need	Total Procedures	Estimated unmet need	Total Procedures	Estimated unmet need	Total Procedures
Wake	Wake	45%	926	417	943	425	961	433
	Durham	25%	311	78	316	79	322	80
	Johnston	25%	160	40	164	41	167	42
	Orange	25%	186	46	188	47	190	47
	Harnett	20%	119	24	121	24	123	25
	Nash	25%	7	2	7	2	7	2
	Other*	n/a		39		39		40
<b>Cluster Total</b>				<b>645</b>		<b>657</b>		<b>669</b>
Sampson	Sampson	55%	66	37	66	37	67	37
	Duplin	25%	79	20	79	20	80	20
	Harnett	30%	119	36	121	36	123	37
	Cumberland	30%	379	114	381	114	383	115
	Other*	n/a		6		6		6
<b>Cluster Total</b>				<b>212</b>		<b>213</b>		<b>215</b>
Craven	Craven	60%	80	48	80	48	82	49
	Beaufort	35%	32	11	32	11	32	11
	Carteret	35%	65	23	65	23	65	23
	Jones	35%	3	1	3	1	3	1
	Onslow	35%	278	97	278	97	283	99
	Lenoir	35%	51	18	51	18	51	18
	Pamlico	35%	12	4	12	4	12	4
	Other*	n/a		6		6		6
<b>Cluster Total</b>				<b>208</b>		<b>208</b>		<b>211</b>
<b>Target Service Area Total</b>				<b>1,065</b>		<b>1,079</b>		<b>1,095</b>

Source: pages 81 – 82 of the application

\*The applicant states “other” includes any county served by the host site according to the 2016 ambulatory surgical facility license renewal applications.

Thus the applicant projects the proposed mobile lithotripter will perform at least 1,000 procedures in each of the first three years of operation.

On pages 83 and 84, the applicant calculated the number of procedures to be performed per day per host site. On page 86, the applicant states:

*“ECL believes that by concentrating on the proposed target service area, it will be able to reach the highest unmet need in the state, and meet the necessary criteria. ... ECL will increase access to ESWL [extracorporeal shock wave lithotripsy] services for 2.8 million North Carolinians and over 90 urologists. Additionally, with an estimated unmet need of 2,949 procedures in 2020, ECL can propose a conservative market share, 37 percent, and still reach 1,000 procedures by the third operating year.”*

However, projected utilization is not based on reasonable and adequately supported assumptions. One, as noted above, the results of the applicant’s 8-step methodology

described on pages 43-56 of the application and Exhibit 10 are questionable. Since the 6-step methodology described on pages 77-86 of the application relies on the results of the 8-step methodology, the results of the 6-step methodology are also questionable.

Two, ECL proposes to provide services at four host sites.<sup>1</sup> However, three of those four host sites already receive mobile lithotripsy services from TLC<sup>2</sup> or Carolina Lithotripsy. ECL does not adequately demonstrate in its application as submitted the need for the proposed lithotripter to provide additional days of service for those three host sites. While ECL does not clearly state in its application as submitted that it proposes to offer additional days of service at these host sites, at the public hearing, a speaker for ECL indicated that ECL does propose to offer additional days of service at these three host sites. The spokesperson stated that these “*sites do not have enough service.*” However, historical utilization data provided by ECL in its application as submitted for these three host sites casts doubt on ECL’s assertion that these sites do not “*have enough service.*” See the following table.

	<b>CarolinaEast Medical Center</b>	<b>Rex Surgery Center of Cary</b>	<b>Sampson Regional Medical Center*</b>
FFY 2011	85		37
FFY 2012	110		13
FFY 2013	95	48	13
FFY 2014	103	168	15
FFY 2015	89	371	7
Compound Annual Growth Rate (CAGR)	1.16%	178.0%	-34.05%

Source: Section III, pages 43-45, ECL Application. ECL states that its source was Table 9A in the 2013-2016 SMFP and the Proposed 2017 SMFP.

\*On page 44 of the ECL application, the number is incorrectly reported as 54 procedures in FFY 2011. The correct number is 24, which when added to the 13 performed by TLC, is a total of 37.

As shown in the table above, utilization at CarolinaEast Medical Center has only increased at a CAGR of 1.16% per year between FFY 2011 and FFY 2015 while utilization at Sampson Regional Medical Center has decreased at a CAGR of 34.05% per year during the same time frame. Utilization at Rex Surgery Center of Cary has increased but it has only been providing services for three years and is currently served by two different providers. The growth rate between FFY 2013 and FFY 2014 was 250.0%. However, the growth rate was less than half that (120.8%) between FFY 2014 and FFY 2015. ECL does not adequately document that the two existing providers cannot meet the needs of patients utilizing a mobile lithotripter at Rex Surgery Center of Cary.

Based on the Agency’s review of the information provided by the applicant in Section III, pages 33-75, including referenced exhibits, and Section IV, pages 76-92; comments received during the first 30 days of the review cycle; and the applicant’s response to the comments

<sup>1</sup> See the discussion in the Increasing Geographic Accessibility section of the Comparative Analysis regarding whether or not it is four host sites or five host sites.

<sup>2</sup> In its response to public comments submitted to the Agency at the public hearing, ECL responded to comments that TLC and ECL are related by stating that “*ECL is an independent Limited Liability Corporation. The affiliation relationship is in its management company, American Diagnostics, Inc., its Registered Agent and in some owners.*” (emphasis added) What exactly is meant by “*and in some owners*” is not clear.



received at the public hearing, the applicant does not adequately document the need for the project for the reasons discussed above.

### **Access**

In Section VI.2, page 105, the applicant states all of its procedures will be performed in licensed acute care hospitals or Rex Surgery Center of Cary; therefore, the discrimination policies will be those of the host sites. In Section VI.6, page 107, the applicant states the business model it will use does not discriminate against any patients based on financial status or the lack of third party insurance. In Section VI.15, pages 114 - 115, the applicant provides four tables to illustrate projected percentages of Medicare and Medicaid recipients at various host sites. The applicant adequately demonstrates the extent to which all residents, including underserved groups, will have access to the proposed services.

### **Conclusion**

In summary, the applicant adequately identified the population to be served and adequately demonstrated the extent to which all residents, including underserved groups, will have access to the proposed services. However, the applicant did not adequately demonstrate the need the population to be served has for the proposed mobile lithotripter. Therefore, the application is not conforming to this criterion.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

C - PSC  
NC - ESL

**PSC:** In Section III.3, pages 74 - 76, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because it would not address current demand at existing host sites for additional lithotripsy coverage. Furthermore, it would not allow for expanding coverage into new host sites in Orange and Caldwell counties, both of which currently lack lithotripsy services.

- Establish Different Host Sites for the Proposed Lithotripter – The applicant states that this is not an effective alternative because demand at existing sites is increasing beyond what the existing units can provide. Therefore, a fifth mobile unit will allow expansion of services at some existing sites to meet patient demand.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

Based on the Agency's review of the application, including referenced exhibits, the comments submitted during the first 30 days of the review and the applicant's response to those comments submitted at the public hearing, the applicant adequately demonstrates that the proposal is the most effective alternative to meet the identified need. Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. Therefore, the application is conforming to this criterion.

**ECL:** In Section III.3, pages 62 - 64, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that maintaining the status quo is not an effective alternative because TLC, a related entity, is unable to add additional days to its current lithotripsy service. ECL would add host sites and additional days to accommodate increasing demand for services. In addition, the applicant states the 2016 SMFP indicates a need for additional lithotripsy service, and maintaining the status quo ignores the published need.
- Joint Venture With an Existing Provider – The applicant states that this is not an effective alternative, because after consulting with another provider, ECL determined that it would not be mutually beneficial to pursue a joint venture.
- Add a Lithotripter to the Current TLC Host Site Locations – The applicant states this is not an effective alternative because TLC's current host sites do not include host sites to the area east of the I-95 corridor, where there is a greater unmet need for services.
- Wait for SMFP to Generate Another Need for Lithotripsy Services – The applicant states this is not an effective alternative because North Carolina needs additional lithotripsy service now, and to prolong providing the service does not meet current need.
- Add More Host Sites in Eastern North Carolina – The applicant states this is not an effective alternative because current demand for lithotripsy services exceeds what TLC's unit can provide. The applicant states an additional lithotripter is needed to service this area.

After considering those alternatives, the applicant states the alternative represented in the application is the most effective alternative to meet the identified need.

However, based on the Agency's review of the application, including referenced exhibits, the comments submitted during the first 30 days of the review and the applicant's response to those

comments submitted at the public hearing, the applicant does not adequately demonstrate that the proposal is the most effective alternative to meet the identified need. The applicant does not adequately demonstrate a need for its proposal because the assumptions and methodology used to project the “unmet need” are questionable. Thus, projected utilization based on those assumptions and methodology are also questionable. Furthermore, the application is not conforming to all other statutory and regulatory review criteria, and thus, is not approvable. A project that cannot be approved cannot be an effective alternative. Therefore, the application is not conforming to this criterion.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C - PSC  
NC - ECL

**PSC:** In Section VIII.1, page 117, the applicant states the total capital cost is projected to be as follows:

<b>DESCRIPTION</b>	<b>COST</b>
Site Costs	\$0
Construction/Renovation Costs	\$0
Equipment/Miscellaneous	\$1,368,634
<b>TOTAL CAPITAL COST</b>	<b>\$1,368,634</b>

Source: Table on page 117 of the application.

In Section IX.1, page 123, the applicant states there will be \$30,000 in start-up expenses and \$45,000 in initial operating expenses associated with the project, for a total working capital of \$75,000.

### **Availability of Funds**

In Section VIII.3, page 119, the applicant states that \$55,000 of the project capital and working capital costs will be funded with the accumulated reserves of Piedmont Stone Center, PLLC; and \$1,313,634 of the project costs will be funded with a line of credit through Wells Fargo Bank. In Section IX.2, page 123, the applicant states that the working capital will be funded with a line of credit through Wells Fargo Bank. In Exhibit 14, the applicant provides a June 6, 2016 letter from the CEO of PSC, documenting its intention to fund the capital and working capital costs for the proposed project. Exhibit 14 also contains June 6, 2016 letter from Wells Fargo Bank documenting its intention to extend a line of credit to PSC sufficient to fund the capital and working capital costs for the proposed project. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

**Financial Feasibility**

In the pro forma financial statements for PSC (Form B), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below:

<b>PSC</b>			
<b>PROPOSED LITHOTRIPTER</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Total Cases	516	781	1,045
Total Gross Revenue	\$2,323,508	\$3,513,308	\$4,703,403
Average Gross Revenue / Case	\$4,503	\$4,498	\$4,501
Total Net Revenue	\$1,478,448	\$2,200,385	\$2,898,707
Average Net Revenue / Case	\$2,865	\$2,817	\$2,774
Total Operating Expenses	\$1,475,359	\$1,785,449	\$1,985,267
Average Operating Expense / Case	\$2,859	\$2,286	\$1,900
<b>Net Income (Loss)</b>	<b>\$3,089</b>	<b>\$414,936</b>	<b>\$913,441</b>

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates the availability of sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

**ECL:** In Section VIII.1, page 131, the applicant states the total capital cost is projected to be as follows:

<b>ECL Capital Cost</b>	
<b>DESCRIPTION</b>	<b>COST</b>
Site Costs	\$0
Construction/Renovation Costs	\$0
Equipment/Miscellaneous Project Costs	\$973,049
<b>TOTAL CAPITAL COST</b>	<b>\$973,049</b>

Source: Table on page 131 of the application.

In Section IX.1, page 135, the applicant states there will be \$61,605 in start-up expenses and \$60,450 in initial operating expenses associated with the project, for a total working capital of \$122,055.

**Availability of Funds**

In Section VIII.3, page 132, the applicant states that the entire capital and working capital costs will be funded with a commercial loan. Exhibit 19 contains a June 10, 2016 letter from North State Bank documenting its intention to consider extending financing to ECL sufficient to fund the capital and working capital costs for the proposed project. Exhibit 19 contains a second letter dated June 8, 2016 from Park Sterling Bank documenting its intention to consider extending financing to ECL sufficient to fund the capital and working capital costs for the proposed project. The applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project.

**Financial Feasibility**

In the pro forma financial statements for ECL's lithotripsy services (Form C), the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below.

**ECL**

<b>PROPOSED LITHOTRIPTER</b>	<b>FY 2018</b>	<b>FY 2019</b>	<b>FY 2020</b>
Total Cases	1,061	1,075	1,090
Total Gross Revenue	\$2,532,573	\$2,564,272	\$2,601,960
Average Gross Revenue / Case	\$2,387	\$2,385	\$2,387
Total Net Revenue	\$2,491,341	\$2,522,523	\$2,559,598
Average Net Revenue / Case	\$2,348	\$2,347	\$2,348
Total Operating Expenses	\$1,053,890	\$1,063,505	\$1,072,741
Average Operating Expense / Case	\$993	\$989	\$984
<b>Net Income (Loss)</b>	<b>\$1,437,450</b>	<b>\$1,459,018</b>	<b>\$1,486,857</b>

See the financial section of the application for the assumptions used regarding costs and charges. The applicant does not adequately demonstrate that projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. Therefore, since projected revenues (charges) and costs are based at least in part on projected utilization, projected positive net income is questionable. Thus, the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges and does not adequately demonstrate the availability of sufficient funds for the operating needs of the proposal.

**Conclusion**

In summary, the applicant adequately demonstrates that sufficient funds will be available for the capital and working capital needs of the project. However, the applicant did not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges or that sufficient funds will be available for the operating needs of the proposal. Therefore, the application is conforming to this criterion.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C - PSC  
NC - ECL

The 2016 SMFP includes a methodology for determining the need for additional lithotripters by service area, which is the entire state. Application of the need methodology in the 2016 SMFP identified a need for one additional lithotripter.

On page 122, the 2016 SMFP defines the service area for lithotripters as “*the lithotripter planning area in which the lithotripter is located. The lithotripter planning area in the entire state.*” Thus, the service area consists of the entire state. Providers may serve residents of other states.

There are 14 existing lithotripters operating in North Carolina. Thirteen are mobile. The following table identifies the provider, number of machines, and utilization of the machines, summarized from Table 9A on pages 124 - 128 of the 2016 SMFP.

**Table 6.1**

PROVIDER	AREA SERVED	TYPE OF UNIT	# UNITS	# PROC.	PROC. / UNIT
Carolina Lithotripsy, LTD	Eastern North Carolina	Mobile	2	1,360	680
Catawba Valley Medical Center	Western and Central North Carolina	Mobile	2	563	282
Fayetteville Lithotripters Limited Partnership-South Carolina II	Western North Carolina and South Carolina	Mobile	1	593	593
Fayetteville Lithotripters Limited Partnership-Virginia I	Eastern North Carolina and Virginia	Mobile	1	312	312
Piedmont Stone Center, PLLC	Western and Central NC and Virginia	Mobile	4	4,266	1,067
Stone Institute of the Carolinas, LLC	Western and Central North Carolina	Mobile	2	1,945	973
Triangle Lithotripsy Corporation	East Central North Carolina	Mobile	1	1,125	1,125
Mission Hospital, Inc.	Asheville, North Carolina	Fixed	1	295	295
<b>Total</b>			<b>14</b>	<b>10,459</b>	<b>747</b>

Source: 2016 SMFP, Table 9A, pages 124 – 128.

PSC proposes to acquire one mobile lithotripter. The 2016 SMFP identifies a need for one additional lithotripter for use statewide. The applicant adequately demonstrates that the mobile lithotripter it proposes to acquire to serve north central and central North Carolina and Virginia is needed in addition to the existing lithotripters already serving PSC’s proposed host sites. In Section III, page 54, the applicant provides the historical utilization of the ten host sites, as shown in the following table:

**Table 6.2**

SITE	COUNTY	FY 2015 PROCEDURES	FY 2015 AVG. PROCEDURES PER DAY
Novant Health Rowan Medical Center	Rowan	220	4.4
Randolph Hospital	Randolph	138	5.3
Blue Ridge Healthcare Hospital - Valdese	Burke	184	4.6
Wesley Long Hospital	Guilford	315	3.4
Wilkes Regional Medical Center	Wilkes	89	4.0
Alamance Regional Medical Center	Alamance	175	4.1
Lexington Memorial Hospital	Davidson	50	4.2
Morehead Memorial Hospital	Rockingham	217	5.3
Hugh Chatham Memorial Hospital	Surry	149	6.0
Piedmont Stone Center	Forsyth	780	4.8
<b>Total / Average</b>		<b>2,317</b>	<b>4.5</b>

Source: application page 54. The applicant states utilization at Wesley Long Hospital was affected when one urologist left in September 2015.

As shown in Table 6.1, PSC’s four existing lithotripters performed an average of 1,067 procedures per unit. As shown in Table 6.2, nine of the ten sites averaged at least four procedures per day per site. To project utilization at the ten selected host sites, the applicant examined the projected population growth and calculated the compound annual growth rate (CAGR) for each of the ten counties for the years 2016 – 2020. The applicant projected future utilization using the average CAGR for all ten sites, which is 0.53%. On page 55, the applicant states:

*“Utilizing the weighted average population growth rate to project mobile lithotripsy procedures is reasonable and conservative. ... Procedures performed at Randolph Hospital during FY 2016 year-to-date have increased three percent compared to FY 2015 year-to-date. Procedures performed at Hugh Chatham Memorial Hospital during FY 2016 year-to-date have increased 10 percent compared to FY 2015 year-to-date. In an abundance of conservatism, Piedmont Stone Center applied the weighted average population growth rate to project mobile lithotripsy procedures....”*

The applicant adequately documents that utilization at the existing host sites will increase. PSC also proposes to offer mobile lithotripsy services at two new host sites in counties where there are no host sites presently.

Based on the Agency’s review of the application, including referenced exhibits; comments received during the first 30 days of the review cycle; and the applicant’s response to the comments received at the public hearing, the applicant adequately demonstrates that its proposal would not result in an unnecessary duplication of existing or approved lithotripters in North Carolina. Consequently, the application is conforming to this criterion.

**ECL** proposes to acquire one mobile lithotripter. The 2016 SMFP identifies a need for one additional lithotripter for use statewide. However, the applicant does not adequately demonstrate that the mobile lithotripter it proposes to acquire to serve central and eastern North Carolina is needed in addition to the existing lithotripters already serving ECL’s

proposed host sites. ECL proposes to provide services at four host sites.<sup>3</sup> However, three of those four host sites already receive mobile lithotripsy services from TLC<sup>4</sup> or Carolina Lithotripsy. ECL does not adequately demonstrate in its application as submitted the need for the proposed lithotripter to provide additional days of service for those three host sites. While ECL does not clearly state in its application as submitted that it proposes to offer additional days of service at these host sites, at the public hearing, a speaker for ECL indicated that ECL does propose to offer additional days of service at these three host sites. The spokesperson stated that these “*sites do not have enough service.*” However, historical utilization data provided by ECL in its application as submitted for these three host sites casts doubt on ECL’s assertion that these sites do not “*have enough service.*” See the following table.

	<b>CarolinaEast Medical Center</b>	<b>Rex Surgery Center of Cary</b>	<b>Sampson Regional Medical Center*</b>
FFY 2011	85		37
FFY 2012	110		13
FFY 2013	95	48	13
FFY 2014	103	168	15
FFY 2015	89	371	7
Compound Annual Growth Rate (CAGR)	1.16%	178.0%	-34.05%

Source: Section III, pages 43-45, ECL Application. ECL states that its source was Table 9A in the 2013-2016 SMFP and the Proposed 2017 SMFP.

\*On page 44 of the ECL application, the number is incorrectly reported as 54 procedures in FFY 2011. The correct number is 24, which when added to the 13 performed by TLC, is a total of 37.

As shown in the table above, utilization at CarolinaEast Medical Center has only increased at a CAGR of 1.16% per year between FFY 2011 and FFY 2015 while utilization at Sampson Regional Medical Center has decreased at a CAGR of 34.05% per year during the same time frame. Utilization at Rex Surgery Center of Cary has increased but it has only been providing services for three years and is currently served by two different providers. The growth rate between FFY 2013 and FFY 2014 was 250.0%. However, the growth rate was less than half that (120.8%) between FFY 2014 and FFY 2015. ECL does not adequately document that the two existing providers cannot meet the needs of patients utilizing a mobile lithotripter at Rex Surgery Center of Cary. Therefore, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved lithotripters in North Carolina. Consequently, the application is not conforming to this criterion.

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

<sup>3</sup> See the discussion in the Increasing Geographic Accessibility section of the Comparative Analysis regarding whether or not it is four host sites or five host sites.

<sup>4</sup> In its response to public comments submitted to the Agency at the public hearing, ECL responded to comments that TLC and ECL are related by stating that “*ECL is an independent Limited Liability Corporation. The affiliation relationship is in its management company, American Diagnostics, Inc., its Registered Agent and in some owners.*” (emphasis added) What exactly is meant by “*and in some owners*” is not clear.



C – Both Applications

**PSC:** In Section VII.1, page 109, the applicant states it projects to employ a total of 2.0 FTE registered nurses, 2.0 FTE radiology technicians, 1.0 FTE truck driver to transport the unit to host sites, and 0.5 FTS administrative support to assist with scheduling for the proposed lithotripter unit in the second year of the project. In Section VII.3, page 111, the applicant describes its experience and process for recruiting and retaining staff. Exhibit 2 contains a copy of a letter from Charles Fredric Reid, M.D., current medical director of PSC’s mobile lithotripsy services, expressing his interest in continuing to serve in that capacity. Exhibits 15 and 16 of the application contain copies of letters from area physicians and other healthcare providers expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

**ECL:** In Section VII.2, page 120, the applicant states it projects to employ a total of 2.0 FTE radiology technologists for the proposal. In Section VII.2(c), page 125, the applicant states the management company who will manage its operations, American Diagnostics, will serve as a model for its staffing. The radiology technicians it proposes to hire will have commercial driver’s licenses so that the employees will be able to transport the unit to host sites. In Section VII.3, page 125, the applicant states it has accepted resumes for radiology technologists with commercial driver’s licenses. Exhibit 16 contains a copy of a letter from Gordon L. Mathes, Jr., M.D., expressing his interest in serving as the Medical Director for the proposed service. Exhibit 15 of the application contains copies of letters from area physicians and other healthcare providers expressing support for the proposed project. The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C – Both Applications

**PSC:** In Section II.2, page 14, the applicant describes the manner in which it will provide the necessary ancillary and support services. Exhibit 15 contains letters of support from physicians and other health care providers. The applicant adequately demonstrates that necessary ancillary and support services are available and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

**ECL:** In Section II.2, page 25, the applicant provides a table to illustrate the necessary ancillary and support services that will be available for the project. Exhibit 15 contains letters of support from physicians and other health care providers. The applicant adequately demonstrates that necessary ancillary and support services will be available and that the

proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA – Both Applications

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C - PSC  
NA - ECL

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

\*Excludes "White alone" who are "not Hispanic or Latino"

\*\*"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

**PSC:** Section VI.13 requests that existing facilities provide the payor mix during the last full fiscal year of operation. The applicant states on page 105 that Section VI.13 is "not applicable. *Piedmont Stone Center proposes a new mobile lithotripter.*" However, this question is applicable to the review of PSC's proposal to acquire a fifth lithotripter. In Section VI.2, page 98, the applicant states that "*Medicare patients represented 31% of Piedmont Stone Center procedures in FY2015. ... Medicaid patients represented four percent of Piedmont Stone Center procedures in FY2015.*" The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

**ECL:** The applicant does not currently provide lithotripsy services and thus has no current payor mix to report.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C – Both Applications

**PSC:** In Section VI.11, pages 104 - 105, the applicant states, “*Piedmont Stone Center is not obligated under public regulations to provide uncompensated care or community service. Piedmont Stone Center is a recipient of federal funds, and is compliant with all applicable federal regulations to insure continued access to these funds.*” In Section VI.10 (a), page 104, the applicant states that no civil rights access complaints have been filed against it in the last five years. The application is conforming to this criterion.

**ECL:** In Section VI.11, page 111, the applicant states, “*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.*” In Section VI.10 (a), page 111, the applicant states that no civil rights access complaints have been filed against it or any related entities in the last five years. The application is conforming to this criterion.

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C – Both Applications

**PSC:** In Section VI.15, page 108, the applicant projects the following payor mix for its lithotripsy services during the second operating year (FY 2018):

<b>Payor Category</b>	<b>Percent of Total</b>
Self Pay/Charity	4.4%
Medicare	32.5%
Medicaid	7.8%
Commercial / BCBS / SEHP	54.4%
Other	0.9%
<b>Total</b>	<b>100.0%</b>

On page 106, the applicant states it projects payor mix based upon its 2015 payor mix at its host sites, combined with a projection of payor mix at the two proposed new host sites. The applicant demonstrates that medically underserved groups will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

**ECL:** In Section VI.14, page 113, ECL projects the payor mix during the second operating year, as shown in the table below.

**Entire Facility Second Full Federal Fiscal Year  
(10/1/18 – 9/30/19)**

<b>PAYOR CATEGORY</b>	<b>% OF TOTAL</b>
Self Pay / Indigent / Charity	2.2%
Medicare / Medicare Managed Care	35.8%
Medicaid	6.7%
Commercial Insurance	12.2%
Managed Care	36.4%
Other, including Tricare	6.7%
<b>Total</b>	<b>100.0%</b>

In Section VI.15, pages 114 - 115, the applicant projects the following payor mix for its lithotripsy services at each of its proposed host sites during the second operating year (FY 2019):

<b>Payer Category</b>	<b>Percent of Total</b>			
	<b>WakeMed Cary</b>	<b>CarolinaEast Medical Center</b>	<b>Sampson Regional Medical Center and/or Harnett Health</b>	<b>Rex Surgery Center of Cary</b>
Self Pay/Indigent/Charity	2.3%	1.8%	9.0%	1.0%
Medicare/Medicare Managed Care	31.2%	49.0%	50.0%	15.7%
Medicaid	3.1%	8.7%	25.0%	4.6%
Commercial Insurance	0.6%	25.5%	13.0%	6.4%
Managed Care	61.0%	0.0%	0.0%	72.0%
Other	1.8%	15.0%	3.0%	0.3%
<b>Total</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>

On page 115 the applicant states the projected payor mix is based on the experience of each host site. The applicant demonstrates that medically underserved groups will have adequate access to the proposed services. Therefore, the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

**C – Both Applications**

**PSC:** In Section VI.9, page 103, the applicant describes the range of means by which a person will have access to its lithotripsy services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to the proposed services. Therefore, the application is conforming to this criterion.

**ECL:** In Section VI.9, page 110, the applicant describes the range of means by which a person will have access to its lithotripsy services. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have

access to the proposed services. Therefore, the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C – Both Applications

**PSC:** In Section V.1, page 86, the applicant states that it already has established relationships with area health professional training programs. Exhibit 9 contains a copy of a clinical training agreement between the applicant and Wake Forest School of Medicine. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

**ECL:** In Section V.1, page 93, the applicant states that it has contacted Lenoir Community College and Wake Technical Community College to establish relationships with their health professional training programs. Exhibit 12 contains copies of those inquiries. The information provided is reasonable and credible and supports a finding of conformity to this criterion.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.  
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C - PSC  
NC - ECL

The 2016 SMFP includes a methodology for determining the need for additional lithotripters by service area, which is the entire state. Application of the need methodology in the 2016 SMFP identified a need for one additional lithotripter.

On page 122, the 2016 SMFP defines the service area for lithotripters as *“the lithotripter planning area in which the lithotripter is located. The lithotripter planning area in the entire state.”* Thus, the service area consists of the entire state. Providers may serve residents of other states.

There are 14 existing lithotripters operating in North Carolina. Thirteen are mobile. The following table identifies the provider, number of machines, and utilization of the machines, summarized from Table 9A on pages 124 - 128 of the 2016 SMFP.

PROVIDER	AREA SERVED	TYPE OF UNIT	# UNITS	# PROC.	PROC. / UNIT
Carolina Lithotripsy, LTD	Eastern North Carolina	Mobile	2	1,360	680
Catawba Valley Medical Center	Western and Central North Carolina	Mobile	2	563	282
Fayetteville Lithotripters Limited Partnership-South Carolina II	Western North Carolina and South Carolina	Mobile	1	593	593
Fayetteville Lithotripters Limited Partnership-Virginia I	Eastern North Carolina and Virginia	Mobile	1	312	312
Piedmont Stone Center, PLLC	Western and Central NC and Virginia	Mobile	4	4,266	1,067
Stone Institute of the Carolinas, LLC	Western and Central North Carolina	Mobile	2	1,945	973
Triangle Lithotripsy Corporation	East Central North Carolina	Mobile	1	1,125	1,125
Mission Hospital, Inc.	Asheville, North Carolina	Fixed	1	295	295
<b>Total</b>			<b>14</b>	<b>10,459</b>	<b>747</b>

Source: 2016 SMFP, Table 9A, pages 124 - 128.

PSC proposes to acquire one mobile lithotripter. The 2016 SMFP identifies a need for one additional lithotripter for use statewide. In Section V.7, pages 90 - 95, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

*“Piedmont Stone Center will develop the mobile lithotripter project in the most cost-effective manner. The proposed lithotripsy system is modern technology and offers ease of operation, excellent stone disintegration, greater patient comfort, and energy efficiency capabilities. The ease of use will enable a high volume of treatments per day, thus containing the cost per treatment. ...*

...

*Piedmont Stone Center’s proposed lithotripter will be offered to host facilities via a ‘retail’ contractual arrangement. This means that Piedmont Stone Center entirely manages the lithotripsy service, including providing all the support services associated with the lithotripsy procedure, and billing the technical fee for the lithotripsy services. By contrast, some mobile lithotripsy providers may offer services to host facilities via a ‘wholesale’ contractual arrangement. This means that the lithotripter owner rents the equipment to the host facility, which is responsible for managing the lithotripsy service and providing all necessary support services. The host facility then bills for the services....”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and

access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criteria (1) and (20) is incorporated herein by reference.
- The applicant demonstrates that it will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (1) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

**ECL** proposes to acquire one mobile lithotripter. The 2016 SMFP identifies a need for one additional lithotripter for use statewide. In Section V.7, pages 101 - 102, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services. The applicant states:

*“ECL will foster competition. It will increase capacity in parts of the state where access to lithotripsy is limited. It will offer a pricing structure that shares the cost of serving low-income persons and government beneficiaries with the host site. It will be part of improved kidney stone care programs and it will provide a communication mechanism that informs urologists/host sites of daily availability of the lithotripsy unit.*

...

*All proposed sites are community hospitals or a hospital affiliated ambulatory surgery center subject to rigorous quality improvement programs and standards. ECL and its support physicians and Medical Director will actively support these efforts.*

*ECL will significantly improve access to lithotripsy in North Carolina by providing service in three counties that currently have insufficient access to the service. ...”*

See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

However, the information in the application does not adequately demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. This determination is based on the information in the application and the determination that the applicant did not adequately demonstrate the need for the project, that it is a cost-effective alternative or that it would not result in an unnecessary duplication of existing lithotripters. The discussions regarding the analysis of need, alternatives and unnecessary duplication found in Criteria (3), (4) and (6), respectively, are incorporated herein by reference. Therefore, the application is not conforming to this criterion.



- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C - PSC  
NA - ECL

**PSC:** In Section II.7, pages 24 - 28, the applicant describes the methods used by PSC to ensure and maintain quality care. In Section II.7(c), page 27, the applicant states that none of the licenses or certifications held by PSC has ever been revoked. The information provided by the applicant is reasonable and supports the determination that the applicant is conforming to this criterion.

**ECL:** In Section II.7(b), page 29, the applicant describes the methods it will use to ensure and maintain quality care. The applicant does not currently operate any lithotripters in the state. Therefore, there is no evidence of care to consider.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA – Both Applications

The Criteria and Standards for Lithotripter Equipment (Rules), promulgated in 10A NCAC 14C.3200, were repealed effective October 1, 2016, during the pendency of this review which began on July 1, 2016. The process to repeal Section .3200 began in April 2016 when the Agency determined that the Rules were inconsistent with the SMFP and would result in the denial of all applications submitted for review in the July 1, 2016 Review Cycle even though there was a need determination in the 2016 SMFP for one additional lithotripter.

The 2016 SMFP defines the service area for lithotripters as the entire state. The definition in 10A NCAC 14C.3201(6) defined the service area as a *“geographical area defined by the applicant and which has boundaries that encompass at least 1,000,000 of the state’s residents.”*

Regarding the Performance Standards, 10A NCAC 14C.3203(1) required an applicant to demonstrate that all existing fixed lithotripters performed at least 1,000 procedures in the last

year. There is only one existing fixed lithotripter in North Carolina and it performed only 259 procedures during FFY 2015. Applicants were also required by 10A NCAC 14C.3203(4) to demonstrate that each existing mobile lithotripter performed an average of at least four procedures per day per site. The data required to determine the average was not reported by all existing providers and for those providers that did provide the data, not all of those existing mobile lithotripters met the required standard. Thus, no applicant would be able to demonstrate conformity with the Performance Standards Rule, and thus, no application could be approved.

The Agency has determined that the Rules are not applicable to any applicant in this review given that they have been repealed for the reasons described above.

## **COMPARATIVE ANALYSIS**

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2016 SMFP, no more than one additional lithotripter may be approved in this review. Because the two applicants in this review collectively propose to acquire two additional lithotripters, only one of the applicants can be approved. Therefore, after considering all of the information in each application and reviewing each application individually against all applicable review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by PSC is approved and the application submitted by ECL is denied.

### **Demonstration of Need and Unnecessary Duplication**

PSC adequately demonstrates the need for the proposed mobile lithotripter to increase days of service at 10 of its existing host sites and to add 2 new host sites in Orange and Caldwell counties where there are no host sites. Furthermore, PSC adequately demonstrates that its proposed lithotripter will not result in an unnecessary duplication of existing or proposed lithotripters in North Carolina. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.

ECL proposes to provide services at four host sites.<sup>5</sup> However, three of those four host sites already receive mobile lithotripsy services from TLC<sup>6</sup> or Carolina Lithotripsy. ECL does not adequately demonstrate in its application as submitted the need for the proposed lithotripter to provide additional days of service for those three host sites. While ECL does not clearly state in its application as submitted that it proposes to offer additional days of service at these host sites, at the public hearing, a speaker for ECL indicated that ECL does propose to offer additional days of service at these three host sites. The spokesperson stated that these “*sites do not have enough service.*” However, historical utilization data provided by ECL in its application as submitted for these three host sites casts doubt on ECL’s assertion that these sites do not “*have enough service.*” See the following table.

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<sup>5</sup> See the discussion in the Increasing Geographic Accessibility section regarding whether or not it is four host sites or five host sites.

<sup>6</sup> In its response to public comments submitted to the Agency at the public hearing, ECL responded to comments that TLC and ECL are related by stating that “*ECL is an independent Limited Liability Corporation. The affiliation relationship is in its management company, American Diagnostics, Inc., its Registered Agent **and in some owners.***” (emphasis added) What exactly is meant by “*and in some owners*” is not clear.

	<b>CarolinaEast Medical Center</b>	<b>Rex Surgery Center of Cary</b>	<b>Sampson Regional Medical Center*</b>
FFY 2011	85		37
FFY 2012	110		13
FFY 2013	95	48	13
FFY 2014	103	168	15
FFY 2015	89	371	7
Compound Annual Growth Rate (CAGR)	1.16%	178.0%	-34.05%

Source: Section III, pages 43-45, ECL Application. ECL states that its source was Table 9A in the 2013-2016 SMFP and the Proposed 2017 SMFP.

\*On page 44 of the ECL application, the number is incorrectly reported as 54 procedures in FFY 2011. The correct number is 24, which when added to the 13 performed by TLC, is a total of 37.

As shown in the table above, utilization at CarolinaEast Medical Center has only increased at a CAGR of 1.16% per year between FFY 2011 and FFY 2015 while utilization at Sampson Regional Medical Center has decreased at a CAGR of 34.05% per year during the same time frame. Utilization at Rex Surgery Center of Cary has increased but it has only been providing services for three years and is currently served by two different providers. The growth rate between FFY 2013 and FFY 2014 was 250.0%. However, the growth rate was less than half that (120.8%) between FFY 2014 and FFY 2015. ECL does not adequately document that the two existing providers cannot meet the needs of patients utilizing a mobile lithotripter at Rex Surgery Center of Cary.

Moreover, ECL does not adequately demonstrate that its proposed lithotripter will not result in an unnecessary duplication of existing and approved lithotripters in North Carolina. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference.

Therefore, with regard to demonstrating the need for the proposed lithotripter and that the proposal would not result in an unnecessary duplication of existing or approved lithotripters in North Carolina, the application submitted by PSC is the more effective alternative.

### **Conformity with All Applicable Review Criteria**

PSC's application is conforming to all applicable review criteria, and thus, is approvable standing alone. In contrast, ECL's application is not conforming to all applicable review criteria, and thus, cannot be approved standing alone. See the Review Criteria for New Institutional Health Services Section for discussion. Therefore, with regard to conformity with all applicable review criteria, the application submitted by PSC is the more effective alternative.

**Increasing Geographic Accessibility**

The 2016 SMFP identifies the need for one lithotripter. The service area is the entire state. The following table identifies the location of the existing lithotripters in North Carolina.

PROVIDER	FIXED OR MOBILE	AREAS GENERALLY SERVED*	# OF LITHOTRIPTERS
Carolina Lithotripsy, Ltd	Mobile	Eastern NC	2
Catawba Valley Medical Center	Mobile	Western and Central NC	2
Fayetteville Lithotripters Ltd Partnership – SC II	Mobile	Western NC and South Carolina	1
Fayetteville Lithotripters Ltd Partnership – VA I	Mobile	Eastern NC and Virginia (VA)	1
Piedmont Stone Center, PLLC	Mobile	Western and Central NC and VA	4
Stone Institute of the Carolinas	Mobile	Western and Central NC	2
Triangle Lithotripsy Corp.	Mobile	East Central NC	1
Mission Hospital	Fixed	Asheville	1
<b>Total</b>			<b>14</b>

\*As stated in Table 9A in the 2016 SMFP

As shown in the table above, there are 14 existing lithotripters operating throughout the state. Thirteen of them are mobile. The mobile lithotripters provide services in 53 of the 100 counties in North Carolina.

PSC proposes to acquire a mobile lithotripter to add days of service at ten of its existing host sites and to add two new host sites in counties where there is no host site (Orange and Caldwell counties). Residents of these counties needing lithotripsy services must travel to other counties where services are available.

ECL proposes to provide mobile lithotripsy services at four host sites. Two of these are already receiving mobile lithotripsy services from TLC. These two existing host sites are Rex Surgery Center of Cary (Wake) and Sampson Regional Medical Center (Sampson). The proposed host site in Craven County, CarolinaEast Medical Center, is currently served by Carolina Lithotripsy. The fourth proposed host site is at WakeMed Cary, a hospital in Wake County owned by WakeMed which is currently served by TLC. There are already four existing mobile lithotripsy host sites in Wake County (Rex Surgery Center of Cary, WakeMed, Rex Hospital and Duke Raleigh Hospital).

Furthermore, throughout its application, ECL states that the fourth host site will be either at Sampson Regional Medical Center (Sampson) and/or Harnett Health (Harnett). At the public hearing, one of the speakers for ECL stated that there would be five host sites but the application as submitted is not clear and consistent on this point. The application includes projected utilization and projected payor mix for four host sites, not five host sites. Throughout the application, ECL combined the data for Sampson and Harnett counties together, treating them as one host site. On page 85 of the ECL application, ECL provides a chart which states that the proposed mobile lithotripter will provide one day of service each week at “*Sampson Regional Medical Center/Harnett Health BJH.*” In a footnote, ECL states that “*The schedule may only include one site serving the identified patients or splitting time between sites ....*” (Emphasis added.) There is no documentation in the application as submitted from Harnett Health indicating an interest in contracting with ECL for mobile lithotripsy services. The only documentation for Sampson Regional Medical Center included in the application

as submitted is an email from a physician which indicates that the hospital had been contacted but might not be able to sign a letter of interest until the hospital attorney had reviewed the letter. At the public hearing, ECL submitted a letter from Harnett Health supporting the proposal. However, this additional documentation was not requested by the Agency, and thus, it is an impermissible amendment pursuant to 10A NCAC 14C .0204 and cannot be considered by the Agency.

Because PSC proposes to add two new host sites in counties where there is no host site for mobile lithotripsy services, the application submitted by PSC is the more effective alternative with regard to increasing geographic accessibility to mobile lithotripsy services.

**Access by Underserved Groups**

The following table shows the projected number of procedures to be provided to underserved groups in the third full fiscal year of operation following completion of the project based on the information provided by the applicants in Form D of the respective applications. Generally, the application proposing to serve the higher number of patients in each underserved group is the more effective alternative with regard to access by underserved groups.

Payor Category	PSC		ECL	
	# of Patients	% of Total	# of Patients	% of Total
Self-Pay/Indigent/Charity Care	46	4.4%	23	2.2%
Medicaid	82	7.8%	73	6.7%
Medicare	340	32.5%	390	35.8%
Total	1,045	100.0%	1,090	100.0%

As shown in the table above, ECL projects to serve more Medicare recipients. PSC projects to serve more self-pay/indigent/charity care patients and Medicaid recipients. Therefore, the application submitted by ECL is the more effective alternative with regard to access by Medicare recipients. However, the application submitted by PSC is the more effective alternative with regard to access by both Medicaid recipients and self-pay/indigent/charity care patients.

**Ownership of Lithotripters**

PSC owns and operates four existing mobile lithotripters at 27 different host sites. ECL does not currently own or operate any lithotripters in North Carolina. However, the proposed management company currently operates the mobile lithotripter owned by TLC which provides mobile lithotripsy services at ten host sites in eastern North Carolina. In its response to public comments submitted to the Agency at the public hearing, ECL states that it “*is an independent Limited Liability Corporation. The affiliation relationship is in its management company, American Diagnostics, Inc., its Registered Agent **and in some owners.***” (Emphasis added.) What exactly is meant by “*and in some owners*” is not clear. Thus, although technically ECL, as a separate LLC, would be a new provider of mobile lithotripsy services in North Carolina, it appears that ECL and TLC share at least “*some owners*” in common and the services provided by both ECL and TLC would be managed by the same management company. Moreover, the relationships, if any, between either ECL or TLC and the management company was not provided in the application as submitted. Thus, with regard

to introducing a new provider in North Carolina, the applications are comparable as neither proposal results in a new provider.

**Projected Average Gross Revenue and Average Net Revenue per Procedure**

The following tables show the projected average gross revenue and average net revenue per procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Generally, the application proposing the lowest average gross revenue and net revenue per procedure is considered the more effective alternative with regard to this comparative factor.

<b>GROSS PATIENT REVENUES</b>	<b>PSC</b>	<b>ECL</b>
Total Gross Patient Revenue	\$4,703,403	\$2,601,960
Number of Procedures	1,045	1,090
<b>Average Gross Revenue / Procedure</b>	<b>\$4,501</b>	<b>\$2,387</b>

<b>NET PATIENT REVENUES</b>	<b>PSC</b>	<b>ECL</b>
Total Net Patient Revenue	\$2,898,707	\$2,559,598
Number of Procedures	1,045	1,090
<b>Average Net Revenue / Procedure</b>	<b>\$2,774</b>	<b>\$2,348</b>

As shown in the tables above, ECL projects the lowest average gross revenue and average net revenue per procedure in the third operating year.

However, the applications are not comparable. ECL proposes a “wholesale” model whereas PSC proposes a “retail” model. In the ECL “wholesale” model, ECL charges the host site a flat rate for each procedure performed at the host site and the host site bills the patient or the patient’s third party payor for the services provided. In the PSC “retail” model, with the exception of government programs, PSC bills the patient or the patient’s third party payor for the services provided. ECL’s projected gross and net revenues cannot be compared to PSC’s projected gross and net revenues.

**Projected Average Operating Expense per Procedure**

The following table shows the projected average operating expense per procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Form C). Generally, the application proposing the lowest average operating expense per procedure is the more effective alternative with regard to this comparative factor.

<b>OPERATING EXPENSES</b>	<b>PSC</b>	<b>ECL</b>
Total Operating Expenses	\$1,985,267	\$1,072,741
Number of Procedures	1,045	1,090
<b>Average Operating Expense / Procedure</b>	<b>\$1,900</b>	<b>\$984</b>

As shown in the table above, ECL projects the lowest average operating expense per procedure in the third operating year.

However, the applications are not comparable. ECL proposes a “wholesale” model whereas PSC

proposes a “retail” model. In the ECL “wholesale” model. The host site, not ECL, would incur the costs associated with drugs/medical supplies and housekeeping/laundry. In the PSC “retail” model, PSC projects incurring costs associated with these items. ECL’s projected operating expenses cannot be compared to PSC’s operating expenses.

### **SUMMARY**

The following is a summary of the reasons the proposal submitted by PSC is determined to be the most effective alternative in this review:

- PSC adequately demonstrates the need for its proposal and that it will not result in an unnecessary duplication of existing or approved lithotripters in North Carolina. See the Comparative Analysis for discussion.
- PSC’s application is conforming to all applicable review criteria. See the Review Criteria for New Institutional Health Services Section for discussion.
- PSC proposes to offer mobile lithotripsy services in Orange and Caldwell counties where the services are not currently offered. See the Comparative Analysis for discussion.
- PSC projects to serve more Medicaid recipients and self-pay/indigent/charity care patients than ECL. See the Comparative Analysis for discussion.

The following is a summary of the reasons the proposal submitted by ECL is determined to be a less effective alternative in this review than the approved applicant.

- ECL does not adequately demonstrate the need for its proposal and that it will not result in an unnecessary duplication of existing or approved lithotripters in North Carolina. See the Comparative Analysis for discussion.
- ECL’s application is not conforming to all applicable review criteria. See the Review Criteria for New Institutional Health Services Section for discussion.
- ECL does not propose to offer mobile lithotripsy services in counties where the services are not currently offered. See the Comparative Analysis for discussion.
- ECL projects to serve fewer Medicaid recipients and self-pay/indigent/charity care patients than PSC. See the Comparative Analysis for discussion.

### **CONCLUSION**

The Agency determined that the application submitted by Piedmont Stone Center, PLLC, Project I.D. #G-11200-16, is the most effective alternative proposed in this review for the additional mobile lithotripter for statewide use and is approved. The approval of the application submitted by Eastern Carolina Lithotripsy, Inc. would result in lithotripters in excess of the need determination as reported in the 2016 SMFP. Consequently, the application submitted by Eastern Carolina Lithotripsy, Inc. is denied.

The application submitted by Piedmont Stone Center, PLLC is approved subject to the following conditions.



- 1. Piedmont Stone Center, PLLC shall materially comply with all representations made in the certificate of need application.**
- 2. Piedmont Stone Center, PLLC shall acquire no more than one mobile lithotripter for a total of no more than five mobile lithotripters upon completion of this project.**
- 3. Piedmont Stone Center, PLLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section VII of the application and that would otherwise require a certificate of need.**
- 4. Piedmont Stone Center, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**