WRITTEN COMMENTS ON 2024 STATEWIDE MOBILE LITHOTRIPTER COMPETITIVE REVIEW

SUBMITTED BY MOBILE STONE CLINIC

October 31, 2024

Two applicants submitted three CON applications in response to the need identified in the 2024 SMFP for two (2) additional mobile lithotripters in North Carolina. The applicants include:

- CON Project ID# G-012558-24 Mobile Stone Clinic (West)
- CON Project ID# G-012559-24 Mobile Stone Clinic (East)
- CON Project ID# J-012551-24 Atrium Urology, PC

Mobile Stone Clinic, LLC (MSC) submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the Atrium Urology, PC (AU) application, including its respective ability to conform with applicable statutory and regulatory review criteria and a discussion of the prospective comparative analysis of the applicable and most significant issues concerning this competitive batch review. Other non-conformities in the competing application may exist and MSC may develop additional opinions, as appropriate upon further review and analysis.

COMMENTS SPECIFIC TO ATRIUM UROLOGY, PC APPLICATION - PROJECT ID NO. J-012551-24

Ownership

It is clear from the application that Atrium Urology is NOT associated in any way with Atrium Health, the large health system with headquarters in Charlotte, NC. In fact, as stated on page 137 of its application, "Atrium Urology is a new company. It does not have experience operating lithotripter equipment." Kevin Khoudary, MD is AU's incorporator and has no relationship with Atrium Health. Based on the information provided in the application, it appears that Dr. Khoudary is the sole owner of AU.

Retail vs. Wholesale

As the Agency reviews the competing applications, it is crucial to emphasize the fundamental distinction between MSC and AU's approaches to mobile lithotripsy services. MSC proposes a **"retail" model**, where it directly manages all aspects of the service, including equipment provision, patient care coordination, and billing. In contrast, AU proposes a **"wholesale" model**, which essentially delegates key operational responsibilities to host sites, and the lithotripsy provider charges only a flat fee for equipment use. Thus, the two proposals are fundamentally different, and the Agency should consider these differences as it reviews the applications.

The following table summarizes the responsibilities for ancillary and support services of each proposal.

	Mobile Stone Clinic Retail Model	Atrium Urology Proposal Wholesale Contract	
		Atrium Urology, PC	Host Site
Patient Scheduling	X		X
Patient Billing & Collections	X		X
Prep & Recovery	X		X
Quality Assurance	X		X
Risk Management	X		X
Lithotripter Tech	X	X	
Transportation	X	X	

The **"retail" model** presented by MSC allows for comprehensive control over every stage of the service. MSC will handle patient scheduling, billing, support services, quality assurance, and risk management—ultimately ensuring a cohesive, standardized, and patient-centered experience. This model allows MSC to establish a more predictable and transparent fee structure for patients, with all billing managed by a single entity. Importantly, MSC will directly bill patients or third-party payors, ensuring that the cost of the procedure remains clear and directly related to the actual service rendered. This typically results in **lower overall charges to consumers and third-party payors**, which can directly benefit patients by reducing out-of-pocket expenses.

In contrast, AU's **"wholesale" model** introduces significant variability in both patient experience and financial outcomes. Under this model, AU's host sites—not AU itself—are responsible for managing critical aspects of the patient care continuum, such as scheduling, preparation, recovery, and billing. The host site is also responsible for quality assurance. Since each host site operates independently and has its own cost structure, **the overall financial impact on patient and the quality of care is highly unpredictable**. The inability to standardize fees across multiple sites creates a fragmented system, making it impossible to determine average gross charges and net revenues per procedure for AU's proposal project. This is further compounded by the fact that AU's host sites are not part of the application and did not submit financial projections. As a result, the Agency cannot accurately assess the costs patients will incur under the AU model, nor can it compare these costs to MSC's proposal.

The **2016 Statewide Lithotripter Review** acknowledged the distinction between "retail" and "wholesale" in evaluating lithotripsy service proposals. Specifically, the Agency determined that average revenues and operating expenses could not be compared between the different service models of the competing applications. See Attachment 1, pp. 39-40 of Agency Findings. Consistent with that determination, AU's "wholesale" model makes any revenue and expense comparison with MSC's proposal inconclusive. Furthermore, given the inherent variability of costs and revenues in AU's wholesale model, the **retail approach proposed by MSC is more aligned with the Agency's goals of cost transparency, predictability, and patient-centered care**.

Moreover, from a financial standpoint, MSC's model better positions the provider to manage and optimize costs associated with lithotripsy services. MSC's direct control over operations translates into greater

efficiency in managing revenues and expenses, which not only stabilizes costs for patients but also ensures higher accountability in service delivery. By maintaining control of the entire service, MSC can streamline operations and reduce overhead, passing these savings onto patients and payors.

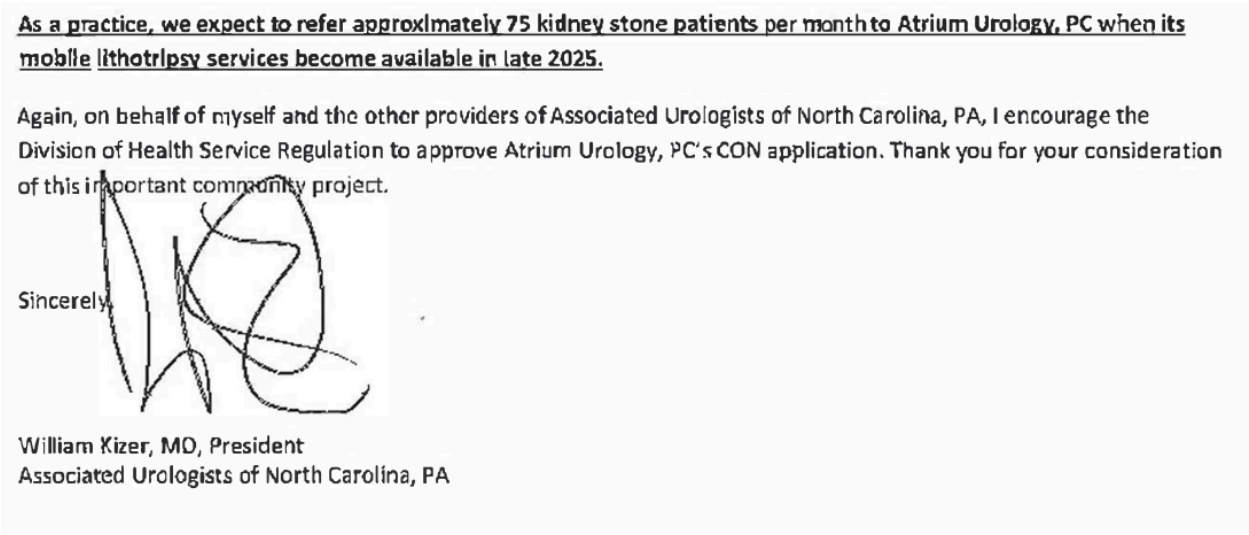
Conformity to Statutory Review Criteria

The AU application fails to conform with the statutory review criteria based on the following:

1. **The Atrium Urology application fails to adequately demonstrate the reasonableness of its projected utilization.**

   AU fails to provide support for the reasonableness of its projected utilization of 1,021 procedures in its third year of operation as it has overstated its support from referring providers, will rely narrowly on a single practice and one provider for referrals, and has unreasonably projected its market capture rates given historical experience in the market.

   On page 52 under the heading "Referring Provider Interest", AU states, "[a]s demonstrated by copies of letters in Exhibit I.2, p118, referring providers have expressed an interest in referring more than 1,000 ESWL cases to AU's mobile lithotripter." However, the single letter included in Exhibit I.2 and excerpted below from William Kizer, President of Associated Urologists of North Carolina, states, "[a]s a practice, we expect to refer approximately 75 kidney stones patients per month to Atrium Urology, PC when its mobile lithotripsy services become available in late 2025."



As a practice, we expect to refer approximately 75 kidney stone patients per month to Atrium Urology, PC when its mobile lithotripsy services become available in late 2025.

Again, on behalf of myself and the other providers of Associated Urologists of North Carolina, PA, I encourage the Division of Health Service Regulation to approve Atrium Urology, PC's CON application. Thank you for your consideration of this important community project.

Sincerely,

William Kizer, MD, President
Associated Urologists of North Carolina, PA

   As such, AU has overstated its support from "referring providers" as its single letter of support from one practice indicates 75 referrals per month or 900 referrals annually, not "more than 1,000 ESWL cases" as Atrium Urology states on page 52 of its application. Further, there is no evidence in the application than any provider other than Dr. Kevin Khoudary will perform the proposed lithotripsy procedures. Dr. Khoudary is a member of Associated Urologists of North Carolina, the sole owner of Atrium Urology, and the only lithotripsy provider referred to in AU's application.

   AU's clear, narrow reliance on a single referring practice and one lithotripsy provider underscores the failure of AU to demonstrate the need for the proposed service. Three of the six proposed host sites for AU's proposed mobile lithotripter are offices of Associated Urologists of North

Carolina. As stated above, it is possible that AU's proposed service will essentially be used as personal equipment by Dr. Khoudary and that its sites of care are essentially restricted by the locations to which Dr. Khoudary is willing to travel. A proposed lithotripsy service that only receives referrals from one urology practice and is only used by one provider cannot meet the statewide need identified for mobile lithotripsy services in the 2024 SMFP.

Given its clear, narrow reliance on a single referring practice and one provider, AU's projected utilization is entirely unreasonable and based on flawed market capture assumptions. On page 13 of its Section Q Utilization Methodology, AU states:

> By 2028, Atrium Urology proposes to provide 919 ESWL procedures to PSA residents, or 41.1 percent of unmet ESWL procedures needed in the PSA (919/2,235 = 41.1%, Table 10 row d / Table 9 row a). The Applicant will slightly more than double access (one full time equivalent compared 0.9 full time equivalent).
>
> The estimated market share of need is reasonable because between FFY2019 and FFY2023, existing ESWL providers focused on a broader geography and provided an estimated average of 743 annual ESWL procedures to PSA residents.

In fact, given the limited support provided in its application, AU's estimated market share and the resulting 919 ESWL procedures projected for its single unit of equipment is unreasonable given that two existing ESWL providers serving more sites of care and multiple large health systems (*i.e.*, Duke Health, WakeMed, and UNC REX) with broader referral networks only achieved 743 total procedures combined in CY 2023. AU's application fails to demonstrate that it is reasonable for its single unit of proposed equipment to serve more patients than these two existing units given the differences in support, sites of care, referring practices/physicians, and affiliated healthcare systems.

Further, one of AU's proposed sites (Rex Surgery Center of Cary) is already served by lithotripsy services according to the 2024 SMFP and AU's own data (see Exhibit C.5, page 66). Furthermore, it is clear from AU's utilization assumptions that existing lithotripsy providers are not expected to be impacted by AU (see page 120 where existing providers utilization is assumed to grow consistently with the population growth rate). AU fails to demonstrate how it will serve unmet need and exceed the utilization of existing providers by duplicating service at a site, Rex Surgery Center of Cary, where lithotripsy services are already provided.

Based on the discussion above, the AU application fails to demonstrate the need for its proposed project and that its utilization is based on reasonable and supported assumptions. As such, the AU application is **non-conforming with Criteria (1), (3), (4), (5), (6), (8), and (18a) and should be disapproved.**

2. The Atrium Urology application fails to demonstrate that its proposed costs and revenues are reasonable.

AU states on page 97 that it "will not be responsible for billing patients or third-party payors for its services." On page 77, AU states that it "will not bill patients directly. It will bill the host site for use of the equipment." Yet, in direct contrast to these statements, AU's Form F.2.b includes revenue by payor, contractuals, bad debt, and charity care amounts. **These numbers are entirely**

fictional – as AU makes clear, it will not bill patients. Thus, it will not collect patient revenue from payors, have contractuals, incur bad debt, or provide charity care. AU's customers are the host sites which will handle billing, collections, bad debt, and charity care pursuant to the host sites' individual contracts, procedures, and policies. AU's only role is to provide the lithotriptor to its host sites, for which it will receive a flat fee from each host site. None of the information in Form F.2 can be used for any purpose as it will not occur and cannot be relied upon as it has no basis. For example, AU states that "[t]he average charge is projected at $2,000 with no increase throughout the project years" (page 134). AU cannot and will not charge patients for lithotripsy services as it "will not bill patients directly" per page 97. Thus, the average charge is unsupported and unreasonable. The average charge will be determined by the host sites. These host sites are not applicants and there is no information from which the Agency is able to discern what the average charge will be. Nor is the Agency able to determine the accuracy of the statement that there will be no increase in the average charge throughout the project years. The host sites have provided no documentation to confirm the accuracy of the statement.

On page 32, AU states it will be responsible for several items which are <u>not</u> accounted for or included in any way in Form F.3:

- Contracted legal and accounting for regulatory compliance;
- Maintenance of accreditation for lithotripsy program;
- Train and oversee tech and driver; and,
- Get tech credentialed at each host site.

As such, it is clear that expenses on AU's Form F.3 are understated and unreasonable.

Additionally, AU states that "Employee taxes and benefits are estimated at 15% of total salaries" (page 137). This rate is unreasonably low according to the experience of MSC's members. MSC projects taxes and benefits will be 22% of its annual salary expense, which is more comparable with industry benchmarks. AU's low taxes and benefit percentage could lead to substantial budgetary shortfalls, especially in a competitive labor market where accurate benefit allocation is critical for employee recruitment and retention. MSC's 22% projection aligns more closely with industry benchmarks, ensuring a realistic and sustainable budget that supports long-term operational success.

Based on the discussion above, the AU application fails to demonstrate that its proposed costs and charges are reasonable. As such, the AU application is **non-conforming with Criterion (5) and should be disapproved.**

3. The Atrium Urology application fails to demonstrate that it will promote quality of lithotripsy services.

AU proposes to offer lithotripsy services via "wholesale" contractual arrangement with host sites. As MSC explained in its applications, "[u]nder a 'wholesale' model, the lithotripter owner provides the equipment to the host facility as part of the service agreement and charges the host site a flat rate for each procedure performed at the host site. The host site is responsible for managing the lithotripsy service, providing all necessary support services, and bills the patient or the patient's third-party payor for the services provided" (*see* page 34 of the MSC-East application).

On page 32, AU states, "Atrium Urology proposes to be a mobile equipment provider only. Because of this, responsibilities of a traditional service provider are shared among AU, proposed host sites, and referring physicians." AU details those responsibilities and states that host sites will:

- Provide preparation and recovery for patients;
- Provide service support and necessary ancillary services (Exhibit B.20, p6);
- Bill and collect payment from patients for procedures.

AU further states that "Atrium Urology lithotripsy host sites will be responsible for the promotion of safety and quality with regard to procedures and patients" (page 25). As reflected on the table on page 2 of these comments, the host sites, not AU, will be responsible for quality assurance. The host sites are not applicants and there is no way for the Agency to determine the host sites' quality assurance procedures.

Thus, it is clear that AU will have no responsibility for the quality of the proposed lithotripsy service. The application only identifies Dr. Kevin Khoudary as a potential practicing physician for its equipment. As such, it is possible that AU's proposed service will essentially be used as personal equipment by Dr. Khoudary with the only oversight provided by host sites who have zero or limited experience providing lithotripsy services. AU will not have mechanisms or processes to improve quality, monitor patient safety, or standardize care.

Given its lack of responsibility, it is clear that AU cannot promote safety and quality for its proposed service and the Agency has no basis to conclude otherwise. AU's host sites offer a broad range of healthcare services (*e.g.*, full-service hospital services or ambulatory surgery services) and do NOT specialize in lithotripsy services. As such, AU's proposed host sites do not possess the same level of expertise in offering lithotripsy services as dedicated lithotripsy providers, like the members of MSC.

By contrast, MSC's two complementary applications propose to offer mobile lithotripsy services via a "retail" model. As noted in its applications, under the "retail" model, MSC will manage the lithotripsy service entirely, including providing all support services and billing the patient or the patient's third-party payor for the technical fee for the procedure. There are significant advantages to MSC's "retail" approach with regard to the promotion of safety and quality, as noted in its applications:

- The lithotripsy service under a "retail" approach is entirely operated by an organization dedicated to the specialty with the corresponding technical expertise and operational efficiencies. Under a "wholesale" model, responsibilities for the service are shared between the lithotripsy provider and the host facility, which does not possess the same level of expertise in offering the service. MSC's "retail" lithotripsy service will provide a comprehensive management and support structure including accreditation, Medical Director, a clinical staff dedicated to and specifically trained for lithotripsy, and a quality improvement and patient safety process specific to lithotripsy. This arrangement delivers the highest-quality clinical outcomes in the most cost-effective way.

- MSC will credential every physician on its medical staff who performs lithotripsy procedures. MSC will have an oversight committee composed of practicing physicians and staff responsible for ensuring the standardization of care across MSC's services as well as a Medical Director for the service. "Wholesale" lithotripsy providers rely on the host site to credential physicians to the host site medical staff, which serves an entire hospital or ambulatory surgery center. As a result, these "wholesale" lithotripsy providers have limited ability to positively influence the behavior and decisions of the physicians delivering patient care. Further, oversight of practicing physicians under "wholesale" arrangements is conducted by a medical staff with far less expertise in lithotripsy services.

  See MSC's applications for further discussion including MSC-East page 34.

AU will pursue lithotripsy certification from Accreditation Commission for Healthcare, Inc. The Accreditation Commission for Health Care, Inc. was previously named The North Carolina Accreditation Commission for In-home Aide Services, Inc. The organization has only two entities posted on its website with Lithotripsy Accreditations issued by ACHC: www.achc.org/search-facilities; whereas Accreditation Association for Ambulatory Health Care (AAAHC) has 102 entities accredited: https://www.aaahc.org/find-accredited-organizations. This is a critical distinction between the two proposals. AAAHC accreditation means that a health care organization meets or exceeds nationally recognized standards for quality of care and patient safety. Note that Piedmont Stone Center, a MSC member, is currently the only lithotripsy provider in the state that goes through the rigorous process of a lithotripsy-specific accreditation. The accreditation process will include an independent review of MSC's policies, procedures, and outcomes against standards which are nationally accepted.

Based on the discussion above, the AU application fails to demonstrate that its project will promote quality. As such, the AU application is **non-conforming with Policy GEN-3 as well as Criteria (1) and (18a).**

4. The Atrium Urology application fails to demonstrate that it will promote value for lithotripsy services.

As noted in the previous comment, AU proposes to offer lithotripsy services via "wholesale" contractual arrangement with host sites. As a result, host sites will "[b]ill and collect payment from patients for procedures" (page 32). Thus, it is clear that AU will have no responsibility for the cost of the proposed lithotripsy service to patients. Further, as noted above, AU will have no responsibility for other aspects of the service that impact efficiency or value such as prep/recovery, ancillary services, patient follow-up, and quality assurance. Given its lack of responsibility, it is clear that AU cannot promote value for its proposed service.

As MSC noted in its applications, "retail" lithotripsy services provide predictable and transparent pricing to consumers and third party-payors in comparison to the surprise bills often associated with "wholesale" hospital-based care. It can be challenging to determine the cost of care at host sites such as hospitals as they are not required to publicly report cost information for every procedure they offer. However, Central Carolina Hospital, a proposed AU host site, provides a list

of all the non-discounted (*e.g.*, Self Pay) charges for all its services on its website.[1] According to Central Carolina Hospital, its charge for lithotripsy (CPT code 50590) is **$24,681.53**. By comparison, MSC's applications propose an average gross charge of **$5,700 or less than ¼ of reported by Central Carolina Hospital**, one of AU's host sites which will be responsible for billing patients.

The AU application states that Dr. Khoudary is a part-owner of Triangle Lithotripsy Corporation, a mobile lithotripsy provider in North Carolina. Triangle Lithotripsy also provides lithotripsy services under a "wholesale" model including to WakeMed Raleigh. WakeMed offers a procedure estimate tool[2] which indicates that the average charge for lithotripsy (CPT code 50590) is **$41,845** and the Self Pay patients are given a discount and pay **$15,901**. **This cost is nearly three times more than the average charge proposed by MSC in its complementary applications.**

MSC's proposed charges are one of the many benefits of its proposed "retail" lithotripsy services with regard to the promotion of value as specified in its applications including:

- The fee structure for "retail" lithotripsy services is set by the lithotripsy provider and is typically a fraction of the fees for the host facility, which results in lower charges to consumers and third-party payors. According to MSC members' experience, hospital facilities, the most typical host site, charge 2.5 to 3.7 times more to commercial payors under a "wholesale" arrangement for lithotripsy services than "retail" providers. These procedures performed in hospital-based settings cost significantly more due to allocations for facility overhead costs and higher administrative costs, which are reduced or eliminated in "retail" fee structures.

- "Retail" lithotripsy services provide predictable and transparent pricing to consumers and third party- payors. Patients benefit from knowing the cost of their treatment in advance under "retail" arrangements, avoiding the surprise bills often associated with "wholesale" hospital-based care.

  See MSC's applications for further discussion including MSC-East page 34.

Based on the discussion above, the AU application fails to demonstrate that its project will promote value. As such, the AU application is **non-conforming with Policy GEN-3 as well as Criteria (1) and (18a).**

5. The Atrium Urology application fails to demonstrate that it will promote access for lithotripsy services.

Under AU's proposed "wholesale" lithotripsy services, host sites will "[s]chedule patients" as well as "[b]ill and collect payment from patients for procedures" (page 32). As such, AU will have no ability to ensure that the proposed service will promote equitable access to the elderly and medically underserved groups. On page 97 AU states that it "is committed to providing at least 1.0 percent of charity care in the form of no-cost procedures to the host sites, which is reported

[1] See https://www.centralcarolinahosp.com/sites/centralcarolina/assets/uploads/1Q24/Central%20Carolina%20Hospital%20%20%2016776.csv

[2] https://mychart.wakemed.org/MyChart-PRD/GuestEstimates/

as a deduction from revenue." However, AU provides no discussion of how it will deliver on such a commitment given it will not schedule patients or bill/collect payment. As such, this commitment is unreliable.

AU's proposed service area of six counties and six sites will not promote geographic access for the statewide lithotripsy service area per SMFP need. Three of the six host sites for AU's proposed mobile lithotripter are offices of Associated Urologists of North Carolina. A fourth site, Rex Surgery Center of Cary, is already served by another mobile lithotripsy provider. As such, AU proposes to duplicate access at Rex Surgery Center of Cary as there is no evidence provided in AU's application that expansion of access is needed at that site. As stated above, it is possible that AU's proposed service will essentially be used as personal equipment by Dr. Khoudary and that its sites of care are essentially restricted by the locations to which Dr. Khoudary is willing to travel. A proposed lithotripsy service that only receives referrals from one urology practice and is only used by one provider cannot meet the statewide need identified for mobile lithotripsy services in the 2024 SMFP. AU's clear, narrow reliance on a single referring practice and one provider underscores the failure of AU to provide access to the proposed service.

By contrast, MSC's two complementary applications propose to expand access across three dimensions: temporal, geographic, and financial access. MSC's proposals will reduce patient wait times, expand the geographic footprint of lithotripsy services, and expand financial access to lithotripsy services through greater access to more affordable "retail" lithotripsy services compared to wholesale services as proposed by AU. Please see further discussion of MSC's positive impact on access to lithotripsy services in its applications (*e.g.*, MSC-East pages 34-35)

Based on the discussion above, the AU application fails to demonstrate that its project will promote access. As such, the AU application is **non-conforming with Policy GEN-3 as well as Criteria (1), (13), and (18a) and should be disapproved.**

COMPARATIVE ANALYSIS OF THE COMPETING MOBILE LITHOTRIPER APPLICATIONS

Conformity to CON Review Criteria

Three CON applications have been submitted to acquire lithotripters and offer mobile lithotripsy services. Based on the 2024 SMFP's need determination, only two lithotripters can be approved. Only applicants demonstrating conformity with all applicable Criteria can be approved, and only the application submitted by Mobile Stone Clinic demonstrates conformity to all Statutory and Regulatory Review Criteria.

Conformity of Applicants

Applicant	Project I.D.	Conforming/ Non-Conforming
Mobile Stone Clinic (West)	G-012558-24	**Yes**
Mobile Stone Clinic (East)	G-012559-24	**Yes**
Atrium Urology, PC	J-012551-24	No

The MSC applications are based on reasonable and supported volume projections and adequate projections of cost and revenues. As discussed separately in this document, the competing application by AU contains errors and flaws which result in one or more non-conformities with statutory and regulatory review Criteria. Therefore, the Mobile Stone Clinic applications are the **most effective** alternatives regarding conformity with applicable review Criteria.

Competition (Patient Access to a New or Alternative Provider)

Both MSC and AU are new entities and do not own lithotripters in North Carolina. For information purposes, the members of MSC (Piedmont Stone Center, Stone Institute of the Carolinas, and HealthTronics Stone Solutions) currently own and operate mobile lithotripters in North Carolina. Similarly, Dr. Khoudary is a part owner of Triangle Lithotripsy Corporation, a mobile lithotripsy provider in North Carolina. Therefore, the MSC and AU applications are **equally effective** regarding competition.

Geographic Accessibility

The following table summarizes the proposed number of host sites and host site counties to be served by each proposal.

Application	# of Total Lithotripsy Sites	# of Counties as Host Site
Mobile Stone Clinic (West)	41	27
Mobile Stone Clinic (East)	29	22
Atrium Urology, PC	6	3

The MSC West proposal identifies 41 host sites in 27 counties. The MSC East proposal identifies 29 host sites in 22 counties. The Atrium Urology application identifies six host sites across only three counties. The MSC West and MSC East applications propose to serve more host sites in more counties compared to the AU application. Therefore, the MSC West and MSC East applications are **more effective alternatives** regarding geographic access.

Additionally, as described in the MSC applications, MSC's members (in aggregate) added 12 sites of care in North Carolina from 2020 to 2023, an increase of 23 percent over three years. By comparison, other providers, including Triangle Lithotripsy (of which Dr. Khoudary is a member) added zero sites of care in aggregate during recent years.

2020 to 2023 North Carolina Lithotripsy Provider Sites of Care

Provider	2020	2021	2022	2023	Change in Number of Sites
Carolina Lithotripsy	17	18	17	18	1
Fayetteville Lithotripters - SC II	9	9	8	8	-1
Fayetteville Lithotripters - VA I	2	2	2	3	1
Piedmont Stone Center	14	21	23	22	8
Stone Institute of the Carolinas	10	12	14	13	3
MSC Members Subtotal	***52***	***62***	***64***	***64***	***12***
Catawba Valley Medical Center	1	1	1	1	0
Mission Hospital	1	1	1	1	0
Triangle Lithotripsy Corporation	7	6	7	7	0
Other Providers Subtotal	***9***	***8***	***9***	***9***	***0***
Lithotripsy Total	***61***	***70***	***73***	***73***	***12***

Source: 2022 to 2024 SMFPs, Proposed 2025 SMFP

The sites of care added by MSC's members vary by type (*e.g.*, surgery center, hospital, Veteran's Administration Health Center) and location (*e.g.*, East Central, Eastern NC, Western and Central NC, and Western NC). This diversity is evidence of MSC members' commitment to expanding access to wherever there is a need for lithotripsy services, as proposed in MSC's applications. Several of the additional sites of care are located in more rural counties such as Ashe Memorial Hospital (Ashe County), Cone Health Annie Penn Hospital (Rockingham County), Hugh Chatham Health (Surry County), Atrium Health Lincoln (Lincoln County), Maria Parham Health (Franklin County), Mission McDowell Hospital (McDowell County), and The Outer Banks Hospital (Dare County).

Additionally, MSC will be available to provide services to any facility in need of lithotripsy access, including host sites served by non-MSC member lithotripters and new host sites with urologist availability and patient demand.

Access By Service Area Residents

According to Chapter 15 of the 2024 SMFP, a lithotripter's service area is statewide. Given a statewide service area, an applicant that proposes a broader geographic reach would not only align with but also better fulfill the SMFP's intent for wide access to services. The following table summarizes the projected patient origin among the competing applications.

Application	# of Counties From Which Patients Are Projected to Originate
Mobile Stone Clinic (West)	46
Mobile Stone Clinic (East)	54
Atrium Urology, PC	6

Source: CON applications, Section C.3

Analyzing the projected patient origin in Section C.3 reveals that MSC's proposed projects are positioned to serve a significantly larger lithotripsy market compared to AU's proposal. Specifically, the MSC West project will serve patients from 46 North Carolina counties, while MSC East projects to serve patients from 54 counties. In contrast, AU's proposal is limited to serving patients from only six counties, leaving a substantial portion of the state underserved by their project.

According to the projected patient origin in Section C.3, MSC's proposed projects will each serve a larger lithotripsy market compared to AU's proposed project. The MSC West proposal will serve lithotripsy patients from 46 North Carolina counties. The MSC East proposal will serve lithotripsy patients from 54 North Carolina counties. The AU proposal will serve lithotripsy patients from only six North Carolina counties.

As a result, the MSC West and MSC East applications offer considerably greater access to residents across the state and are thus **more effective alternatives** regarding access by service area residents than AU.

Access By Underserved Groups

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

"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 access by underserved groups, applications are compared concerning two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for the applicants in the review.

Projected Medicare Revenue Per Procedure – 3rd Full FY

Applicant	Form F.2b	Form F.2b	% of Gross Revenue	Section L.3
	Total Medicare Revenue	Gross Revenue		% of Total Patients
Mobile Stone Clinic (West)	$1,735,650	$4,959,000	35.0%	35.0%
Mobile Stone Clinic (East)	$1,735,650	$4,959,000	35.0%	35.0%
Atrium Urology, PC	$663,828	$2,042,547	32.5%	32.5%

Source: CON applications, Form F.2b, Section L.3

As previously described, AU states that it "will not bill patients directly. It will bill the host site for use of the equipment." *See* application page 77. Thus, it will not collect patient revenue from payors, have contractuals, incur bad debt, or provide charity care. Yet, in Form F.2.b AU includes revenue by payor, contractuals, bad debt, and charity care amounts. **These numbers are entirely fictional – as AU makes clear, it will not bill patients.** Thus, the information in Form F.2 cannot be relied on for a comparison of access by Medicare patients as it will not occur and has no basis. AU's host sites would be in a position to know payor mix, but they are not applicants on the AU application, and AU has provided no information from which the Agency could determine the accuracy of AU's payor mix information.

Section L.3 provides projected payor mix as a percentage of total patients served. Based on a comparison of the applicants' projections in Section L.3, the MSC West and MSC East applications are **more effective alternatives** compared to AU regarding access by Medicare patients.

MSC notes that in response to Section L.3, AU states "[t]he table below is not applicable. As a mobile equipment provider, it will not be responsible for billing patients or third-party payors for its services. Atrium Urology will bill the host for mobile lithotripsy services. For information purposes, the applicant has estimated the payor mix collectively for the proposed sites." *See* application page 97. AU provided no basis to support the reasonableness of its "estimated" payor mix. Therefore, a comparison of access by Medicare patients is inconclusive in this review.

Projected Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants in the review.

Projected Medicaid Revenue Per Procedure – 3rd Full FY

Applicant	Form F.2b	Form F.2b	% of Gross Revenue	Section L.3
	Total Medicaid Revenue	Gross Revenue		% of Total Patients
Mobile Stone Clinic (West)	$347,130	$4,959,000	7.0%	7.0%
Mobile Stone Clinic (East)	$347,130	$4,959,000	7.0%	7.0%
Atrium Urology, PC	$157,276	$2,042,547	7.7%	7.7%

Source: CON applications, Form F.2b, Section L.3

As previously described, AU states that it "will not bill patients directly. It will bill the host site for use of the equipment." *See* application page 77. Thus, it will not collect patient revenue from payors, have contractuals, incur bad debt, or provide charity care. Yet, in Form F.2.b AU includes revenue by payor, contractuals, bad debt, and charity care amounts. **These numbers are entirely fictional – as AU makes clear, it will not bill patients.** Thus, the information in Form F.2 cannot be relied on for a comparison of access by Medicaid patients as it will not occur and has no basis. AU's host sites would be in a position to know payor mix, but they are not applicants on the AU application, and AU has provided no information from which the Agency could determine the accuracy of AU's payor mix information.

Section L.3 provides projected payor mix as a percentage of total patients served. Based on a comparison of the applicants' projections in Section L.3, the competing applications are equally effective alternatives regarding access by Medicare patients.

MSC notes that in response to Section L.3, AU states "[t]he table below is not applicable. As a mobile equipment provider, it will not be responsible for billing patients or third-party payors for its services. Atrium Urology will bill the host for mobile lithotripsy services. For information purposes, the applicant has estimated the payor mix collectively for the proposed sites." *See* application page 97. AU provided no basis to support the reasonableness of its "estimated" payor mix. Therefore, a comparison of access by Medicaid patients is inconclusive in this review.

Projected Average Net Revenue per Patient

The following table shows each applicant's projected average net revenue per patient in the third year of operation, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally, the application proposing the lowest average net revenue is the more effective alternative regarding this comparative factor since a lower average may indicate a lower cost to the patient or third-party payor.

Projected Average Net Revenue per Procedures – 3rd Full FY

Applicant	Form C.1b Total Procedures	Form F.2b Net Revenue	Average Net Revenue per Procedure
Mobile Stone Clinic (West)	870	$1,785,240	$2,052
Mobile Stone Clinic (East)	870	$1,785,240	$2,052
Atrium Urology, PC	1,021	$939,713	$920

Source: CON applications

As previously described, there is a fundamental difference between the MSC and AU applications: MSC proposes to offer retail mobile lithotripsy services and AU proposes to offer a wholesale mobile lithotripsy service. The AU application provides projected net revenue based on lease payments from host sites. In contrast, the MSC applications provided projected net revenue generated from patients receiving lithotripsy procedures. The difference in how revenue is calculated and presented in the proformas does not allow for a comparison between the applications. This determination is consistent with the Agency's conclusion in the 2016 Statewide Lithotripter Review.

Additionally, AU states that it "will not bill patients directly. It will bill the host site for use of the equipment." *See* application page 77. Thus, it will not collect patient revenue from payors, have contractuals, incur bad debt, or provide charity care. Yet, in Form F.2.b AU includes revenue by payor, contractuals, bad debt, and charity care amounts. **These numbers are entirely fictional – as AU makes clear, it will not bill patients.** Thus, the information in Form F.2 cannot be relied on for a comparison of average net revenue per procedure. AU's host sites would be in a position to know average net revenue per procedure, but they are not applicants on the AU application, and AU has provided no information from which the Agency could determine the accuracy of AU's average net revenue per procedure information.

For these reasons, the result of this analysis is inconclusive.

Projected Average Operating Expense per Procedure

The following table shows the projected average operating expense per patient in the third full fiscal year following project completion for each facility. Generally, the application projecting the lowest average operating expense per patient is the more effective alternative concerning this comparative factor to the extent it reflects a more cost-effective service which could also result in lower costs to the patient or third-party payor.

Projected Average Operating Expense per Procedure – 3rd Full FY

Applicant	Form C.1b Procedures	Form F.2b Operating Expense	Average Operating Expense per Procedure
Mobile Stone Clinic (West)	870	$1,364,389	$1,568
Mobile Stone Clinic (East)	870	$1,364,389	$1,568
Atrium Urology, PC	1,021	$538,021	$527

Source: CON applications

As previously described, there is a fundamental difference between the MSC and AU applications: MSC proposes to offer retail mobile lithotripsy services and AU proposes to offer a wholesale mobile lithotripsy service. The host site, not AU, would incur the costs associated with drugs/medical supplies and housekeeping/laundry. In the PSC "retail" model, MSC projects incurring costs associated with these items. AU's projected operating expenses cannot be compared to MSC's operating expenses. This determination is consistent with the Agency's conclusion in the 2016 Statewide Lithotripter Review. AU's host sites would be in a position to know average operating expense per procedure, but they are not applicants on the AU application, and AU has provided no information from which the Agency could determine the accuracy of AU's average operating expense per procedure information.

Summary

Comparative Factor	Mobile Stone Clinic (West)	Mobile Stone Clinic (East)	Atrium Urology
Conformity with Statutory Review Criteria	**More Effective**	**More Effective**	Less Effective
Historical Utilization	Equally Effective	Equally Effective	Equally Effective
Geographic Accessibility	**More Effective**	**More Effective**	Less Effective
Access by Service Area Residents	**More Effective**	**More Effective**	Less Effective
Access by Medicaid	Inconclusive	Inconclusive	Inconclusive
Access by Medicare	Inconclusive	Inconclusive	Inconclusive
Competition (Access to a New or Alternate Provider)	Equally Effective	Equally Effective	Equally Effective
Projected Average Net Revenue per Lithotripsy Procedure	Inconclusive	Inconclusive	Inconclusive
Projected Average Operating Expense per Lithotripsy Procedure	Inconclusive	Inconclusive	Inconclusive

For each of the comparative factors previously discussed, Mobile Stone Clinic's application is determined to be the most or more effective alternative for the following factors:

- Conformity with Review Criteria
- Geographic Accessibility
- Access by Service Area Residents

AU's application fails to conform with all applicable statutory and regulatory review criteria; thus, it cannot be approved. In addition, AU's application fails to measure more favorably for the aforementioned comparative factors.

Based on the previous analysis and discussion, the applications submitted by Mobile Stone Clinic West and Mobile Stone Clinic East are comparatively superior and should be approved for this competitive review.

Attachment 1
Agency Findings 2016 Statewide Mobile Lithotriptor Review

North Carolina Department of Health and Human Services
Division of Health Service Regulation

Pat McCrory
Governor

Richard O. Brajer
Secretary DHHS

Mark Payne, Director
Health Service Regulation

December 2, 2016

Charles Hauser
3825 Forrestgate Drive
Winston-Salem, NC 27103

Findings and Conclusions
Type of Review: 2016 State Lithotripter
County: Forsyth

Dear Mr. Hauser:

As indicated in the letter dated **November 23, 2016**, enclosed is written notice of all findings and conclusions upon which the Healthcare Planning and Certificate of Need Section, Division of Health Services Regulation (Agency) based its decision in the above referenced review. These findings and conclusions are provided to the applicants in accordance with G.S. 131E-186.

Please refer to the Project ID # and Facility ID # (FID) in all correspondence.

Sincerely,

Tanya S. Rupp
Project Analyst

Martha J. Frisone
Assistant Chief, Certificate of Need

Attachment

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

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

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

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%
Total		**100.0%**	**100.0%**	**100.0%**

*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:

Historical and Projected Utilization

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
Total / Average		**2,317**	**4.5**

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
Additional Procedures on Proposed Lithotripter			**372**	**565**	**757**

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
Total	**6**	**144**	**216**	**288**

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
Total procedures proposed lithotripter	**516**	**781**	**1,045**

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
Total procedures	4,180	4,205	4,231	4,244	4,257	4,271

*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
Total procedures on five lithotripters	**4,180**	**4,205**	**4,231**	**4,760**	**5,038**	**5,316**

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%
Total	**1,061**	**100.0%**	**1,075**	**100.0%**

*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
Cluster Total				**645**		**657**		**669**
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
Cluster Total				**212**		**213**		**215**
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
Cluster Total				**208**		**208**		**211**
Target Service Area Total				**1,065**		**1,079**		**1,095**

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.[1] However, three of those four host sites already receive mobile lithotripsy services from TLC[2] 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.

	CarolinaEast Medical Center	Rex Surgery Center of Cary	Sampson Regional Medical Center*
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

[1] 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.
[2] 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:

PSC Capital Cost

DESCRIPTION	COST
Site Costs	$0
Construction/Renovation Costs	$0
Equipment/Miscellaneous	$1,368,634
TOTAL CAPITAL COST	**$1,368,634**

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:

PSC

PROPOSED LITHOTRIPTER	FY 2018	FY 2019	FY 2020
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
Net Income (Loss)	**$3,089**	**$414,936**	**$913,441**

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:

ECL Capital Cost

DESCRIPTION	COST
Site Costs	$0
Construction/Renovation Costs	$0
Equipment/Miscellaneous Project Costs	$973,049
TOTAL CAPITAL COST	**$973,049**

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

PROPOSED LITHOTRIPTER	FY 2018	FY 2019	FY 2020
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
Net Income (Loss)	**$1,437,450**	**$1,459,018**	**$1,486,857**

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
		Total	**14**	**10,459**	**747**

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
Total / Average		**2,317**	**4.5**

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.[3] However, three of those four host sites already receive mobile lithotripsy services from TLC[4] 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.

	CarolinaEast Medical Center	Rex Surgery Center of Cary	Sampson Regional Medical Center*
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.

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[3] 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.

[4] 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):

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

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)

PAYOR CATEGORY	% OF TOTAL
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%
Total	**100.0%**

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):

Payer Category	Percent of Total			
	WakeMed Cary	CarolinaEast Medical Center	Sampson Regional Medical Center and/or Harnett Health	Rex Surgery Center of Cary
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%
Total	**100.0%**	**100.0%**	**100.0%**	**100.0%**

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
		Total	**14**	**10,459**	**747**

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 than 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.[5] However, three of those four host sites already receive mobile lithotripsy services from TLC[6] 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.

[5] See the discussion in the Increasing Geographic Accessibility section regarding whether or not it is four host sites or five host sites.

[6] 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.

	CarolinaEast Medical Center	Rex Surgery Center of Cary	Sampson Regional Medical Center*
FFY 2011	85		37
FFY 2012	110		13
FFY 2013	95	48	13
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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
Total			**14**

*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.

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

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

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.

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

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.**