

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 13, 2025

Findings Date: February 13, 2025

Project Analyst: Cynthia Bradford

Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: J-12551-24
Facility: Atrium Urology, PC
FID #: 240778
County: Wake
Applicant(s): Atrium Urology, PC
Project: Acquire no more than one mobile lithotripter pursuant to the statewide 2024 SMFP need determination

Project ID #: G-12558-24
Facility: Mobile Stone Clinic (West)
FID #: 240785
County: Forsyth
Applicant(s): Mobile Stone Clinic, LLC
Project: Acquire no more than one mobile lithotripter pursuant to the 2024 SMFP need determination

Project ID #: G-12559-24
Facility: Mobile Stone Clinic (East)
FID #: 240787
County: Forsyth
Applicant(s): Mobile Stone Clinic, LLC
Project: Acquire no more than one mobile lithotripter pursuant to the 2024 SMFP need determination

Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

REVIEW CRITERIA

G.S. 131E-183(a): The Department 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

**Atrium Urology
Mobile Stone Clinic (West)**

NC

Mobile Stone Clinic (East)

Need Determination

The 2024 State Medical Facilities Plan (SMFP) includes a need methodology for determining the need for two lithotripters in North Carolina statewide. Application of the need methodology in the 2024 SMFP identified a need for two lithotripters statewide. Three applications were received by the Healthcare Planning and Certificate of Need Section (CON Section), each proposing to acquire one lithotripter, for a total of three lithotripters statewide. However, pursuant to the need determination, only two lithotripters may be approved in this review.

Policies

There is one policy in Chapter 4 of the 2024 SMFP applicable to all three applications: *Policy GEN-3: Basic Principles*.

Policy GEN-3

Policy GEN-3 on page 29 of the 2024 SMFP 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.”

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

Atrium Urology, PC, hereinafter referred to as “the applicant”, or Atrium Urology, proposes to acquire one mobile lithotripter pursuant to the need determination in the 2024 SMFP. The proposed mobile lithotripter will serve six host sites in four counties and will be identified as Atrium Urology.

Need Determination. The applicant does not propose to develop more lithotripters than are determined to be needed in the statewide service area.

Policy GEN-3. In Section B, pages 25-28, the applicant provides information to show its application is conforming to Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more lithotripters than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of lithotripsy services in the service area.
 - The applicant adequately documents how the project will promote equitable access to lithotripsy services in the service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

Mobile Stone Clinic, LLC, hereinafter referred to as “the applicant”, or Mobile Stone Clinic (West), proposes to acquire one mobile lithotripter pursuant to the need determination in the

2024 SMFP for two lithotripters statewide. The proposed mobile lithotripter will operate at 41 host sites which will serve patients from 46 counties in the western half of the state. The mobile lithotripsy service will be identified as Mobile Stone Clinic (West).

Need Determination. The applicant does not propose to develop more lithotripters than are determined to be needed in the statewide service area.

Policy GEN-3. In Section B, pages 31-35, and Section L, page 106, the applicant provides information to show its application is conforming to Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to develop more lithotripters than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 for the following reasons:
 - The applicant adequately documents how the project will promote safety and quality in the delivery of lithotripsy services in the service area.
 - The applicant adequately documents how the project will promote equitable access to lithotripsy services in the service area; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.

G-12558-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

Mobile Stone Clinic, LLC, hereinafter referred to as “the applicant”, or Mobile Stone Clinic (East), proposes to acquire one lithotripter pursuant to the need determination in the 2024 SMFP to be utilized as a mobile lithotripter. The proposed mobile lithotripter will serve 23 host sites which will serve 54 counties in the eastern half of the state. The mobile lithotripsy service will be identified as Mobile Stone Clinic (East).

Need Determination. The applicant does not propose to develop more lithotripters than are determined to be needed in the statewide service area.

Policy GEN-3. In Section B, pages 31-35, the applicant provides information to show its application is conforming to Policy GEN-3.

However, the applicant does not adequately demonstrate how its projected volumes incorporate the concept of maximizing healthcare value for resources expended. The applicant does not adequately demonstrate the need to acquire a lithotripter and does not adequately demonstrate that acquiring a lithotripter would not be an unnecessary duplication of existing and approved services. The discussions regarding analysis of need (including projected utilization) and unnecessary duplication found in Criterion (3) and Criterion (6), respectively, are incorporated herein by reference. An applicant that does not demonstrate the need for the proposed project (including projected utilization that is reasonable and adequately supported) and does not demonstrate that the proposed project is not an unnecessary duplication of existing and approved health care services in the service area cannot demonstrate that it will maximize healthcare value for resources expended in meeting the need identified in the 2024 SMFP. Thus, the application is not consistent with Policy GEN-3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion.

- (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, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C
Atrium Urology
Mobile Stone Clinic (West)

NC
Mobile Stone Clinic (East)

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

Patient Origin

On page 328, of the 2024 SMFP defines a lithotripter’s service area as statewide. A statewide service area is defined as a planning area that encompasses the entire state when determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, health service areas (HSA), or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions.

The applicant states its proposed service area will consist of six counties: Wake, Lee, Harnett, Chatham, Johnston, and Franklin counties.

The proposed mobile lithotripter would serve six host sites in four different counties. The four counties are: Wake, Lee, Harnett, and Johnston. The applicant proposes to provide mobile lithotripter services at six locations which include three physician offices, a hospital, and two ambulatory surgery centers. One physician office is located in Clayton in Johnston County, and one is located in Dunn in Harnett County. The hospital, Central Carolina Hospital, is located in Lee County. The two ambulatory surgical centers are located in Wake County, in Wakefield and Cary. The proposed mobile lithotripter will operate five days a week.

Historical Patient Origin

In Section C, page 35, the applicant states it has no historical experience as a lithotripsy provider. Therefore, there is no historical patient origin.

Projected Patient Origin

In Section C, page 36, the applicant provides projected patient origin for the first three full fiscal years of operation, FYs 2026-2028, for the proposed mobile lithotripter services, as summarized below:

Lithotripsy Services	Atrium Urology					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	291	59.2%	445	59.2%	605	59.2%
Chatham	20	3.9%	30	4.0%	40	3.9%
Franklin	20	4.1%	31	4.0% [4.1%]	42	4.1%
Harnett	35	7.1%	53	7.1%	72	7.0%
Johnston	61	12.5%	94	12.4%[12.5%]	128	12.5%
Lee	16	3.2%	24	3.2%	33	3.2%
Other*	49	10.0%	75	10.0%	102	10.0%
Total	492	100.0%	752	100.0%	1,021	100.0%

*Includes all other NC counties and other states
 Note: the Project Analyst’s corrections are in brackets

In Section Q, the applicant provides the assumptions and methodology used to project patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant states that Health Service Area (HSA) IV has the greatest deficit of lithotripsy days of service per population among all the HSAs in the state based on historical lithotripsy provider data and population data.
- The applicant states Wake County is in HSA IV and has a significant concentration of urologists who are needed to perform lithotripsy services as compared to the relative scarcity of these specialists throughout the state.

Analysis of Need

In Section C, pages 36-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Need identified in the 2024 SMFP for two lithotripters statewide (page 42).
- Prevalence of Kidney Stones in the Geographical area – The applicant states the rates are 50% higher in the US southern region than in the US on average. Warm weather makes people susceptible to dehydration; diets with high sodium and high sugar and low intake of calcium rich foods appear to be contributing factors (page 43).
- Disparities in Access and Lithotripsy Use Rates – The applicant states the amount of out-of-state service provided by mobile lithotripters in the state masks the true deficit of lithotripsy capacity in North Carolina. The applicant states the disproportionate supply of lithotripsy equipment is in western HSAs. The applicant shows that on a per capita basis, the most underserved area is HSA IV which includes the six counties in the applicant's proposed service area (pages 43-46).
- Social Determinants of Health in the Proposed Service Area - The need for access to Extracorporeal Shock Wave Lithotripsy (ESWL) in the proposed service area will increase in the next several years due to increases in the number of Millennials and Gen X generations who are in age groups most at risk for developing kidney stones. The applicant states that each of the counties in the service area has at least one risk factor such as smoking, BMI>30, no physical activity, or diabetes associated with increased incidence of kidney stones that ranks equal or higher than the state average (pages 46-52).
- Referring Provider Interest – In Exhibit I.2, page 118, The applicant provides a letter of support from the Associated Urologists of North Carolina attesting to the limited access to lithotripsy services and supporting the approval of the applicant's application for a mobile lithotripter in the proposed service area (page 52).

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available

during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2024 SMFP identifies a statewide need for two additional lithotripters statewide. The proposed project meets part of that identified need.
- Population growth overall in the identified service area.
- Age and health status of the population in the identified service area.
- Disparities in lithotripsy assess in HSA IV.

Projected Utilization

In Section Q, Form C.2a, the applicant provides projected utilization for the first three full fiscal years, CYs 2026-2028 for its proposed mobile lithotripter as illustrated in the table below:

Atrium Urology				
Lithotripter	Partial FY	1 st Full FY	2 nd Full FY	3 rd Full FY
	9/1/2025-12/31/2025	1/1/2026-12/31/2026	1/1/2027-12/31/2027	1/1/2028-12/31/2028
# of Units	1	1	1	1
# of Procedures	83	492	752	1,021

In Section Q, pages 111-130, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Determine the Atrium Urology Mobile Lithotripsy PSA

Wake County has a significant concentration of urologists, but there are limited number of urologists who perform ESWL procedures. By adding lithotripsy host sites in and near Wake County, it minimizes travel time for the equipment and patients and offers a most effective and cost-effective way to increase access to lithotripsy for otherwise underserved residents of HSA IV, and for other people who seek care in this health care referral hub county. The applicant proposes a six-county primary service area (PSA) and six host sites that distribute geographical access to residents of HSA IV and nearby underserved HSA V and HSA VI communities (page 112).

Step 2: Determine the 6-County Primary Service Area Population

The North Carolina Office of State Budget and Management (NCOSBM) forecasts population by age, race, and sex, by county, by year for all years associated with this project. The applicant calculated the Compound Annual Growth Rate (CAGR) for each county and the total PSA for the years 2024 through 2028 and came up with an average CAGR of 2.1% (page 114).

Step 3: Calculate the Estimated Number of PSA Kidney Stone Patients, 2024-2028

The applicant calculated the estimated number of kidney stone patients in the PSA based on the lithotripsy methodology in the SMFP which assumes an incidence of 16 kidney stone cases per 10,000 population (page 115).

Step 4: Estimate Number of PSA Kidney Stone Patients Eligible for Lithotripsy, 2024-2028

The lithotripsy methodology in the 2024 SMFP assumes that 90 percent of all kidney stone patients are eligible for ESWL treatment. However, the applicant assumes that only 70 percent of kidney stone patients are ESWL appropriate based on the applicant's experience and information from an academic medical center. The applicant multiplied the estimated number of projected kidney stone patients in the PSA by 70 percent to determine the estimated number of lithotripsy patients in the PSA (page 116).

Step 5: Estimate Number of Lithotripters Needed in the PSA, 2024-2028

The 2024 SMFP lithotripsy need methodology assumes the treatment capacity of a full-time lithotripter is 1,500 annual procedures and that 1,000 procedures, or 67 percent, is a fully utilized unit. Using 1,000 procedures as its baseline, the applicant estimates that the PSA would need 2.2 full time lithotripters by 2028 (page 117).

Step 6: Estimate Number of Lithotripters in the PSA, 2024-2028

The applicant reviewed all existing lithotripsy provider host sites in North Carolina, evaluated the annual days of service provided at those sites, and calculated the five-year average number of annual days of service per lithotripter. The average annual number of service days per mobile lithotripter from FFY2019-FFY2023 was 248 for the entire state. Given that the PSA has only seven existing mobile lithotripsy host sites, the applicant calculated that those seven host sites provided an average of 213 days of lithotripsy service between CY2019 and CY2023. Therefore, Atrium Urology PSA currently only receives 90 percent of one full time mobile unit (page 118).

Step 7: Estimate PSA Surplus / (Deficit) of Lithotripters in the PSA, 2024-2028

The applicant calculated the estimated number of mobile lithotripters needed in the PSA by subtracting the estimated number of full-time equivalent lithotripters in Step 6 from the estimated number of full-time equivalent lithotripters needed in the PSA from Step 5 needed in the PSA for each year. This has resulted in an estimated deficit of 1.2 lithotripters in 2024 and, without a change in supply, the deficit will increase to 1.4 by 2028 (page 119).

Step 8: Estimate Number of ESWL Procedures Served by Existing Providers, 2024-2028

Two mobile lithotripsy providers that have host sites in the PSA that, combined, performed 741 ESWL procedures in CY 2023. Data from the Equipment and Inventory Forms (EIFs) shows that over the last five years, there has been little or no fluctuation in the number of ESWL procedures provided at these nine mobile host sites (page 120).

Step 9: Estimate Unserved ESWL Procedures in the PSA, 2024-2028

The applicant subtracted the estimated number of procedures provided by existing host sites in Step 8 from the total estimated number of ESWL procedures needed in the PSA from Step 4. The result is over 1,400 unserved ESWL procedures in the PSA by 2028 (page 121).

Step 10: Estimate Atrium Urology Market Share of Unmet ESWL Procedure Need in the PSA, 2024-2028

The applicant assumes it will capture 65 percent of the unmet need from the PSA. The applicant determined its market share based on capacity of a new provider operating 252 annual days, 8-hours per day, support from referring providers, patients from Harnett and Lee counties being able to access services in their home county, patients seeking lower cost treatment options for kidney stones, and the proposed equipment is more readily used by providers and patients than lithotripsy equipment that stays in tractor trailer vans outside provider facilities. The applicant states the estimated market share of unmet need is reasonable because between CY2019 and CY2023, existing ESWL providers focused on a broader geography and provided an estimated average of 743 annual ESWL procedures to PSA residents. The applicant gradually ramps up its market share during its first three full fiscal years of operation. The applicant states that it will be able to provide 919 ESWL procedures to PSA residents, or 41.1 percent of unmet ESWL procedures needed in the PSA ($919/2,235 = 41.1\%$) by the end of the third fiscal year of operation, CY2028 (pages 122-123).

Step 11: Estimate Immigration of ESWL Procedures from Outside the PSA, 2024-2028

The applicant assumed that 10 percent of patients will originate outside the PSA. This assumption was based on a review of patient origin data from 2024 NC Hospital and ASC License Renewal Applications for ambulatory surgical cases in the PSA which found that 7.4 to 17.3 percent of their patients originated from outside of the Atrium Urology PSA counties (pages 124-125).

Step 12: Determine Percent Distribution of Service Area Population, 2025-2028

The applicant first distributed estimated ESWL procedures among the PSA counties according to population with the assumption that one patient equals one ESWL procedure. The applicant then distributed county patients to host sites based on available patient data and/or proximity to host site. The applicant then calculated the percentage distribution of population of the PSA counties by utilizing data from NCOSBM (page 125).

Step 13: Distribution of Atrium Urology ESWL Patients, 2025-2028

The applicant multiplied total PSA ESWL patients by the percent distribution of the service area population by county and added in the total number of in-migration patients (page 126).

Step 14: Distribute Atrium Urology ESWL Patients Among Proposed Host Sites, 2025-2028

The applicant estimated patients by host site of service and then multiplied the total number of Atrium Urology ESWL patients by county by year by the percent distribution of host site patients by county by year to determine patient origin by host site (pages 127-130).

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There is a statewide need determination in the 2024 SMFP for two lithotripters and this proposed project will meet part of that identified need.

- The applicant uses reasonable and publicly available data, including population estimates from NCOSBM, and utilization data from EIFs, and LRAs in its methodology to project utilization.
- Projected utilization is supported by determining the number of patients based, in part, on area population for the identified six county service area, and applying a rate lower than the 2024 SMFP assumption for eligibility for ESWL treatment.
- The applicant’s market share is reasonable given the days of service provided by existing providers in the PSA and the calculation of unmet need.

Access to Medically Underserved Groups

In Section C.6, page 57, the applicant states,

“All proposed host sites are North Carolina licensed physician offices, acute care hospitals or ambulatory surgery centers. Host sites are responsible for providing access to medically underserved groups. Atrium Urology has confirmed that each host site provides access to medically underserved groups.”

The applicant provides supporting evidence of this statement in Exhibit B.20.

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	7.9%
Racial and ethnic minorities	31.5%
Women	51.9%
Persons with Disabilities	11.0%
Persons 65 and older	16.8%
Medicare beneficiaries	32.5%
Medicaid recipients	7.7%

Source: Section C, page 59.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina. These members include Piedmont Stone Center, Stone Institute of the Carolinas, and HealthTronics Stone Solutions. These members have come together in a joint venture to submit two concurrent and complementary applications to develop mobile lithotripters. The Mobile Stone Clinic (West) lithotripter would serve patients at its 41-member host sites who serve patients in 46 counties across the western half of the state.

Patient Origin

In Section C, page 38, the applicant provides a list of the 46 counties its member host sites historically served in FY2023.

In Section C, page 39, the applicant provides projected patient origin for the first three full fiscal years, CYs 2026-2028, for the proposed mobile lithotripter services, as summarized below:

Lithotripsy Services	Mobile Stone Clinic					
	1st Full FY		2nd Full FY		3ed Full FY	
	01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	88	17.8%	110	17.8%	155	17.8%
Forsyth	50	10.1%	62	10.1%	88	10.1%
Guilford	49	9.9%	61	9.9%	86	9.9%
Iredell	36	7.2%	45	7.2%	63	7.2%
Davidson	28	5.7%	35	5.7%	50	5.7%
Randolph	26	5.3%	33	5.3%	46	5.3%
Cabarrus	22	4.5%	28	4.5%	39	4.5%
Gaston	20	4.1%	25	4.1%	36	4.1%
Cleveland	20	4.0%	25	4.0%	35	4.0%
Henderson	20	4.0%	25	4.0%	35	4.0%
Wilkes	15	3.0%	18	3.0%	26	3.0%
Burke	14	2.9%	18	2.9%	25	2.9%
Rockingham	12	2.5%	15	2.5%	22	2.5%
Caldwell	11	2.3%	14	2.3%	20	2.3%
Haywood	9	1.9%	12	1.9%	16	1.9%
Yadkin	9	1.8%	11	1.8%	15	1.8%
Stokes	8	1.6%	10	1.6%	14	1.6%
Rowan	8	1.5%	10	1.5%	13	1.5%
Surry	7	1.5%	9	1.5%	13	1.5%
Ashe	7	1.3%	8	1.3%	11	1.3%
Davie	6	1.3%	8	1.3%	11	1.3%
Watauga	5	1.0%	6	1.0%	8	1.0%
Catawba	5	0.9%	6	0.9%	8	0.9%
Rutherford	4	0.8%	5	0.8%	7	0.8%
McDowell	3	0.6%	4	0.6%	6	0.6%
Avery	3	0.5%	3	0.5%	5	0.5%
Jackson	2	0.5%	3	0.5%	4	0.5%
Alleghany	2	0.4%	2	0.4%	3	0.4%
Other*	6	1.2%	8	1.2%	11	1.2%
Total	496	100.0%	620	100.0%	870	100.0%

*Other includes less than one percent of patients from Alexander, Lincoln, Stanly, Union, Polk, Buncombe, Madison, Montgomery, Macon, and Mitchell counties

In Section Q, the applicant provides the assumptions and methodology used to project patient origin.

The Agency notes that the applicant’s projected patient origin by county differs slightly from its members’ historical patient origin by county. However, the Agency concludes this was an inadvertent oversight since the applicant states in Section C, page 38, and Section Q, page 125, that it proposes to serve all 46 counties in its defined west service area at its 41 host sites. In addition, its methodology for projecting utilization includes projections of unserved lithotripsy demand in each of its members’ historical patient origin counties. Therefore, the applicant’s assumptions are reasonable and adequately supported because the applicant based its

assumptions on the historical patient origin of the existing lithotripsy providers who have provided lithotripsy services in the projected service areas.

Analysis of Need

In Section C, pages 41-66, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **Need identified in the 2024 SMFP for two lithotripters statewide** (page 43).
- **Population Growth**– North Carolina’s statewide population is expected to increase by more 750,000 between 2024 and 2030 with a compound annual growth rate (CAGR) of 1.1 percent. Thus, the 2024 SMFP need determination is supported by the projected significant population growth of the lithotripter service area. (page 44).
- **Stone Disease**– The applicant states that studies have documented an increasing incidence and prevalence of stone disease nationally, with higher increases predicted for areas with warmer climates, such as North Carolina. The specific risk factors prevalent in the southern United States significantly impact the rate at which the population develops stone disease, with obesity, diabetes, heart disease, and chronic kidney disease being notably associated with increased risk. (pages 43-46).
- **Obesity, Diabetes, Heart Disease, and Chronic Kidney Disease**- The applicant states that the prevalence in North Carolina of diseases such as obesity, diabetes, heart disease, and chronic kidney diseases which are risk factors for stone disease will contribute to the need for lithotripsy services statewide. The high rates of obesity and diabetes in many of the counties served by the MSC’s members are likely to contribute to a disproportionate need for lithotripsy. (pages 46-52).
- **Benefits of the Proposed Joint Venture**– The applicant states MSC will create a new lithotripsy provider in North Carolina with associated benefits of enhanced competition while leveraging the deep experience of its members to collaborate on developing a new higher standard of care and optimize resources. Letters from urologists supporting MSC’s proposed project is included in Exhibit I.2 (pages 52-63).
- **Proposed Host Sites** - The ability to adapt the schedule based on real-time needs ensures that patients receive the necessary care without undue delay, even if that means the schedule for the use of the lithotripter must frequently change. The applicant states they will leverage the relationships of its members to provide supplemental access to their existing host site locations. Specifically, MSC will provide additional days of service to the existing host sites of MSC’s members, as needed to enhance access. (pages 63-64)

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2024 SMFP identifies a statewide need for two additional lithotripters statewide. The proposed project meets part of that identified need.
- Population growth overall in the identified service area.
- Prevalence of stone disease and medical conditions contributing to stone disease necessitating the need for additional lithotripsy services.
- The applicant proposes to increase their collaboration with more urologists across the state and increase the availability of lithotripsy services by increasing service hours at the proposed host sites.

The applicant provides reasonable and adequately supported information to support its projected utilization including physician support.

Projected Utilization

In Section Q, Forms C.2b, page 122, the applicant provides projected utilization for the first three full fiscal years, CYs 2026-2028 for its projected mobile lithotripter as illustrated in the table below:

Mobile Stone Clinic - West			
Lithotripter	1st Full FY	2nd Full FY	3rd Full FY
	1/1/2026-12/31/2026	1/1/2027-12/31/2027	1/1/2028-12/31/2028
# of Units	1	1	1
# of Procedures	496	620	870

In Section Q, pages 124-133, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify MSC-West Service Area

The following North Carolina counties are included in the MSC-West 46-county service area: Alexander, Alleghany, Anson, Ashe, Avery, Buncombe, Burke, Cabarrus, Caldwell, Catawba, Cherokee, Clay, Cleveland, Davidson, Davie, Forsyth, Gaston, Graham, Guilford, Haywood, Henderson, Iredell, Jackson, Lincoln, Macon, Madison, McDowell, Mecklenburg, Mitchell, Montgomery, Polk, Randolph, Richmond, Rockingham, Rowan, Rutherford, Stanly, Stokes, Surry, Swain, Transylvania, Union, Watauga, Wilkes, Yadkin, and Yancey counties. (page 125).

Step 2: Determine the Service Area Population

The applicant utilized NCOSBM forecasted population by age, race, and sex by county, and by year for all years associated with this project. The applicant provides projected adult population (20+) for the counties included in the MSC-West service area for the years 2024 through 2028. (page 126).

Step 3: Urinary Stone Disease Incidence

Based on a published study from 2019, the applicant utilized an incidence rate of 80 cases per 10,000 adults or approximately eight cases per 1,000 adults (page 127).

Step 4: Projected Lithotripsy Procedure Demand

The applicant projected lithotripsy demand in the west service area by applying the urinary stone incidence rate in Step 3 to the projected population in Step 2 with the assumption that 85 percent of urinary stones are appropriate for lithotripsy. The applicant chose to use the lower estimated rate of 85 percent as published in the lithotripter methodology in the 2024 SMFP (pages 127-128).

Step 5: Projected Lithotripsy Procedures Served by Existing Lithotripters

The applicant obtained FY2023 lithotripsy procedure data by facility location from the proposed 2025 SMFP. The applicant then matched this data to the county where each facility is located as shown in Exhibit Q. The applicant recognized that some patients may have come from outside the facility's county but assumed that patient origin from each facility's county location resulted in lithotripsy procedure demand likely to be met by existing providers in those counties. According to the 2022 to 2024 SMFPs, lithotripsy procedures increased by a CAGR of 4.6 percent from 2020 to 2023, and from 2022 to 2023 increased to 4.9 percent. For MSC members, the CAGR was 6.8 percent statewide from 2020-2023, (Section C, page 58). The applicant projects lithotripsy procedures served by existing providers in the west service area will increase 5 percent annually. (pages 128-129).

Step 6: Unserved Lithotripsy Procedures

The applicant subtracted the lithotripsy procedures likely to be served by existing providers in Step 5 from the projected lithotripsy procedure demand in Step 4. The applicant, after accounting for the lithotripsy procedure demand to be served by the existing lithotripter providers, determined that there would be over 24,000 unserved lithotripsy procedures in the identified service area each year from 2024-2028. The applicant states this is a conservative number given that the data does not include patients under 20 years of age who may require lithotripsy services. (pages 130-131).

Step 7: MSC-West Projected Lithotripsy Procedures

The applicant does not intend to replace or otherwise unnecessarily duplicate the existing access provided by its members' existing lithotripters. Rather, MSC will leverage the relationships of its members to provide supplemental access to their existing host site locations. Specifically, MSC will provide additional days of service to the existing host sites of MSC's members, as needed, to enhance access and reduce patient wait times. The applicant projects a gradual ramp up in average lithotripsy procedures from 2.0 per day during Project Year One to 3.5 lithotripsy procedures per day during Project Year Three.

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- There was a statewide need determination in the 2024 SMFP for two lithotripters and this proposed project will meet part of that identified need.
- The applicant uses information from publicly available sources to determine unmet need for lithotripsy services in its proposed service area.
- The applicant uses the lower, more conservative rate published in the 2024 SMFP for estimating the percentage of stones eligible for lithotripsy in the service area.
- The applicant conservatively projects that utilization at MSC member host sites will increase annually at a lower rate than it did historically from FY2023-FY2024.

Access to Medically Underserved Groups

In Section C.6, page 71, the applicant states,

“MSC will not discriminate against any individual based on race, color, ethnicity, national origin, ancestry, religion, creed, sex, gender identity or expression, sexual orientation, marital status, pregnancy, age, disability (physical or mental), genetic information, military or veteran status, socioeconomic status, citizenship status, language, or any other characteristic protected by applicable federal, state, or local law. The proposed lithotripter will be available to and accessible to any patient having a clinical need for lithotripsy services.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	8.5%
Racial and ethnic minorities	25.0%
Women	44.0%
Persons with Disabilities*	See Below
Persons 65 and older	35.0%
Medicare beneficiaries	35.0%
Medicaid recipients	7.0%

Source: Section C, page 73.

*MSC does not have a means of estimating the number or percentage of disabled persons it will serve. However, as previously described, disabled persons will not be denied access to MSC’s services. MSC will be accessible to persons with disabilities, as required by the Americans with Disabilities Act.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina. These members include Piedmont Stone Center, Stone Institute of the Carolinas, and HealthTronics Stone Solutions. These members have come together in a joint venture to submit two concurrent and complementary applications to develop mobile lithotripters. The Mobile Stone Clinic (East) lithotripter would serve patients at its 23-member host sites who serve patients in 54 counties across the eastern half of the state.

Patient Origin

The mobile lithotripter would serve patients at its 23-member host sites who serve patients in 54 counties. In Section C, page 38, the applicant provides a list of the 54 counties its member host sites historically served in FY2023.

In Section C, page 39, the applicant provides projected patient origin for the first three full fiscal years, FYs 2026-2028, for the proposed mobile lithotripter services, as summarized below:

Lithotripsy Services	Mobile Stone Clinic (East)					
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027		01/01/2028 to 12/31/2028	
County	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Wake	66	13.4%	83	13.4%	117	13.4%
Moore	57	11.5%	71	11.5%	100	11.5%
Pitt	55	11.1%	69	11.1%	96	11.1%
Craven	47	9.4%	58	9.4%	82	9.4%
Scotland	44	8.8%	55	8.8%	77	8.8%
New Hanover	39	7.9%	49	7.9%	69	7.9%
Alamance	37	7.6%	47	7.6%	66	7.6%
Johnston	20	4.1%	26	4.1%	36	4.1%
Brunswick	17	3.5%	22	3.5%	30	3.5%
Beaufort	14	2.7%	17	2.7%	24	2.7%
Carteret	12	2.3%	14	2.3%	20	2.3%
Lee	10	2.1%	13	2.1%	18	2.1%
Halifax	8	1.7%	11	1.7%	15	1.7%
Wayne	8	1.7%	11	1.7%	15	1.7%
Robeson	8	1.6%	10	1.6%	14	1.6%
Wilson	7	1.5%	9	1.5%	13	1.5%
Vance	7	1.4%	9	1.4%	12	1.4%
Cumberland	7	1.3%	8	1.3%	12	1.3%
Caswell	5	1.1%	7	1.1%	9	1.1%
Lenoir	5	1.0%	6	1.0%	9	1.0%
Chatham	3	0.7%	4	0.7%	6	0.7%
Dare	3	0.7%	4	0.7%	6	0.7%
Chowan	3	0.6%	4	0.6%	5	0.6%
Other*	11	2.2%	14	2.2%	19	2.2%
Total	496	100.0%	620	100.0%	870	100.0%

*Other includes less than one percent of patients from Edgecombe, Granville, Harnett, Hoke, Martin, Nash, Orange, Pender, and Warren counties

In Section Q, the applicant provides the assumptions and methodology used to project patient origin. The Agency notes that the applicant’s projected patient origin by county differs slightly from its members historical patient origin by county. However, the Agency concludes this was an inadvertent oversight since the applicant states in Section Q, pages 125-126, that it proposes to serve all 54 counties in its defined west service area at its 23 host sites. In addition, its methodology for projecting utilization includes projections of unserved lithotripsy demand in each of its members’ historical patient origin counties.

The applicant’s assumptions are reasonable and adequately supported because the applicant based its assumptions on the historical patient origin of its existing lithotripsy providers who have provided lithotripsy services in the projected service area.

Analysis of Need

In Section C, pages 41-66, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- **Need identified in the 2024 SMFP for two lithotripters statewide** (page 43-44).
- **Population Growth**– North Carolina’s statewide population is expected to increase by more 750,000 between 2024 and 2030 with a CAGR of 1.1 percent and a CAGR of 1.2 percent for the service area counties. Thus, the 2024 SMFP need determination is supported by the projected significant population growth of the lithotripter service area. (pages 44-46).
- **Stone Disease**– The applicant states that studies have documented an increasing incidence and prevalence of stone disease nationally, with higher increases predicted for areas with warmer climates, such as North Carolina. The specific risk factors prevalent in the southern United States significantly impact the rate at which the population develops stone disease, with obesity, diabetes, heart disease, and chronic kidney disease being notably associated with increased risk. (pages 46-50).
- **Obesity, Diabetes, Heart Disease, and Chronic Kidney Disease**- The applicant states that the prevalence in North Carolina of diseases such as obesity, diabetes, heart disease, and chronic kidney diseases which are risk factors for stone disease will contribute to the need for lithotripsy services statewide. The high rates of obesity and diabetes in many of the counties served by the MSC’s members are likely to contribute to a disproportionate need for lithotripsy. (pages 50-54).
- **Benefits of the Proposed Joint Venture**– The applicant states MSC will create a new lithotripsy provider in North Carolina with associated benefits of enhanced competition while leveraging the deep experience of its members to collaborate on developing a new higher standard of care and optimize resources. Letters from urologists supporting MSC’s proposed project is included in Exhibit I.2 (pages 54-63).
- **Proposed Host Sites** - The ability to adapt the schedule based on real-time needs ensures that patients receive the necessary care without undue delay, even if that means the schedule for the use of the lithotripter must frequently change. The applicant states they will leverage the relationships of its members to provide supplemental access to their existing host site locations. Specifically, MSC will provide additional days of service to the existing host sites of MSC’s members, as needed to enhance access. (pages 63-65)

The information is reasonable and adequately supported based on the application, exhibits to the application, written comments, responses to comments, and information publicly available during the review and used by the Agency, including, but not limited to, the highlighted points listed below:

- The 2024 SMFP identifies a statewide need for two additional lithotripters statewide. The proposed project meets part of that identified need.
- Population growth overall in the identified service area.
- Prevalence of stone disease and medical conditions contributing to stone disease necessitating the need for additional lithotripsy services.

- The applicant proposes to increase their collaboration with more urologists across the state and increase the availability of lithotripsy services by increasing service hours at the proposed host sites.

Projected Utilization

In Section Q, Forms C.2b, page 122, the applicant provides projected utilization for the first three full fiscal years, CYs 2026-2028 for its projected mobile lithotripter as illustrated in the table below:

Mobile Stone Clinic - East			
Lithotripter	1st Full FY	2nd Full FY	3rd Full FY
	1/1/2026-12/31/2026	1/1/2027-12/31/2027	1/1/2028-12/31/2028
# of Units	1	1	1
# of Procedures	496	620	870

In Section Q, pages 123-133, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify MSC-East Service Area

The following North Carolina counties are included in the MSC-East 54-county service area: Alamance, Beaufort, Bertie, Bladen, Brunswick, Camden, Carteret, Caswell, Chatham, Chowan, Columbus, Craven, Cumberland, Currituck, Dare, Duplin, Durham, Edgecombe, Franklin, Gates, Granville, Greene, Halifax, Harnett, Hertford, Hoke, Hyde, Johnston, Jones, Lee, Lenoir, Martin, Moore, Nash, New Hanover, Northampton, Onslow, Orange, Pamlico, Pasquotank, Pender, Perquimans, Person, Pitt, Robeson, Sampson, Scotland, Tyrrell, Vance, Wake, Warren, Washington, Wayne, and Wilson County. (page 124).

Step 2: Determine the Service Area Population

The applicant utilized NCOSBM forecasted population by age, race, and sex by county and by year for all years associated with this project. The applicant provides projected adult population (20+) for the counties included in the MSC-East service area for the years 2024 through 2028. (pages 125-126).

Step 3: Urinary Stone Disease Incidence

Based on a published study from 2019, the applicant utilized an incidence rate of 80 cases per 10,000 adults or approximately eight cases per 1,000 adults (page 126).

Step 4: Projected Lithotripsy Procedure Demand

The applicant projected lithotripsy demand in the east service area by applying the urinary stone incidence rate in Step 3 to the projected population in Step 2 with the assumption that 85 percent of urinary stones are appropriate for lithotripsy, choosing to use the lower estimated rate as published in the 2024 SMFP (pages 126-128).

Step 5: Projected Lithotripsy Procedures Served by Existing Lithotripters

The applicant obtained FY2023 lithotripsy procedure data by facility location from the proposed 2025 SMFP. The applicant then matched this data to the county where each facility is located as shown in Exhibit Q. The applicant recognized that some patients may have come from outside the facility's county but assumed that patient origin from each facility's county location resulted in lithotripsy procedure demand likely to be met by existing providers in those counties. According to the 2022 to 2024 SMFPs, lithotripsy procedures increased by a CAGR of 4.6 percent from 2020 to 2023, and from 2022 to 2023, increased 4.9 percent. For MSC members only, the CAGR was 6.8% statewide from 2020-2022 and was 6.2% from 2022-2023 (Section C, page 58). The applicant projects lithotripsy procedures served by existing providers in the east service area will increase five percent annually. (pages 128-129).

Step 6: Unserved Lithotripsy Procedures

The applicant subtracted the lithotripsy procedures likely to be served by existing providers in Step 5 from the projected lithotripsy procedure demand in Step 4. The applicant, after accounting for the lithotripsy procedure demand to be served by the existing lithotripter providers, determined that there are over 26,000 unserved lithotripsy procedures in the identified service area each year from 2026-2028. The applicant states this is a conservative number given that the data does not include patients under 20 years of age who may require lithotripsy services. (pages 129-131).

Step 7: MSC-East Projected Lithotripsy Procedures

The applicant does not intend to replace or otherwise unnecessarily duplicate the existing access provided by its members' existing lithotripters. Rather, MSC will leverage the relationships of its members to provide supplemental access to their existing host site locations. Specifically, MSC will provide additional days of service to the existing host sites of MSC's members, as needed to enhance access and reduce patient wait times. The applicant projects a gradual ramp up in average lithotripsy procedures from 2.0 per day during Project Year One to 3.5 lithotripsy procedures per day during Project Year Three.

However, projected utilization is not reasonable and adequately supported based on the following analysis:

- The applicant uses a growth rate that is not reasonable and adequately supported based on historical utilization of lithotripsy services in the eastern counties it proposes to serve. The applicant bases its five percent CAGR on its members' historical utilization of lithotripsy services statewide. Based on utilization data from the 2021-2024 SMFPs, MSC members' utilization at its eastern counties' host sites decreased by a CAGR of -3.66 percent. Furthermore, based on data from the 2022-2024 SMFPs, MSC members' utilization decreased by a CAGR of -4.29 percent. Therefore, the applicant's methodology and assumptions do not support its utilization projections.

Access to Medically Underserved Groups

In Section C.6, page 70, the applicant states,

“MSC will not discriminate against any individual based on race, color, ethnicity, national origin, ancestry, religion, creed, sex, gender identity or expression, sexual orientation, marital status, pregnancy, age, disability (physical or mental), genetic information, military or veteran status, socioeconomic status, citizenship status, language, or any other characteristic protected by applicable federal, state, or local law. The proposed lithotripter will be available to and accessible to any patient having a clinical need for lithotripsy services.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons [^]	8.5%
Racial and ethnic minorities	25.0%
Women	44.0%
Persons with Disabilities*	See Below
Persons 65 and older	35.0%
Medicare beneficiaries	35.0%
Medicaid recipients	7.0%

Source: Section C, page 72

*MSC does not have a means of estimating the number or percentage of disabled persons it will serve. However, as previously described, disabled persons will not be denied access to MSC’s services. MSC will be accessible to persons with disabilities, as required by the Americans with Disabilities Act.

[^]The applicant estimates this percentage to represent Medicaid beneficiaries and self-pay/charity care.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to written comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (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, ... persons [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA – All 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

Atrium Urology Mobile Stone Clinic (West)

NC

Mobile Stone Clinic (East)

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

In Section E, pages 67-69, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain Status Quo – The applicant states the population residing within the 6-county service area is growing and its community health risk factors indicate sustained need for the proposed lithotripter through the third year of operation. Maintaining the status quo would not address the growing need for services or for improved access to lithotripsy services. Therefore, this is a less effective alternative.

Propose a Different Service Geography – The applicant states that HSA 4 has the largest deficit of days of service among the three underserved HSAs. Adding service at the proposed sites in HSA IV is the most effective way to improve access for lithotripsy services. HSA IV includes Wake County which is a healthcare referral hub. Patients in surrounding smaller counties travel to Wake County for specialty services. Urologists are in short supply statewide. By adding host sites in Wake, Harnett, Lee, and Johnston Counties where urologists are already practicing, the applicant states this offers the most effective alternative.

Acquire Different Equipment – The applicant considered less expensive new and refurbished equipment. The applicant states that the equipment they are proposing will cost less than some units and is more adaptable to various venues because it is not permanently affixed inside a trailer. The proposed equipment is designed for set up inside an operating or procedure room in an office or health care facility and can be disinfected and returned to the truck for transport to the next site. The applicant rejected the purchase of different equipment because it would be a less effective alternative.

Develop the Project as Proposed – On pages 68-69, the applicant states that its proposal is the most effective alternative because the Delta III Pro lithotripter offers the latest technology, is portable, and by serving the six-county service area, Atrium Urology will be able to best meet the needs of the population in an area of the state with unmet need. The applicant provides letters of support in Exhibit I.2.

The applicant adequately demonstrates that the alternative proposed in this application is its most effective alternative to meet the need based on the following:

- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section E, pages 80-82, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo – The applicant states that recent studies regarding stone disease have found much higher incidence rates which suggest that the kidney stone incidence in North Carolina may be much higher than that stated in the assumptions for lithotripter need in the 2024 SMFP. Additionally, the data strongly supports the ongoing demand for ESWL procedures and the need for additional lithotripsy units in the state. Therefore, maintaining the status quo would not be an effective alternative to meet the need.

Identify Different Host Sites for the Proposed Lithotripter - The applicant is submitting two complementary applications, each proposing to develop one mobile lithotripter. To maximize efficiency, the MSC East proposal will serve host sites across the eastern half of the

state and the MSC West proposal will serve host sites across the western half of the state. The applicant states that it will leverage the relationships of its members to provide supplemental access to their existing host site locations. The applicant states that by adopting this model, they 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 sufficient urologist availability and patient demand. Therefore, identifying different host sites would not enable the applicant to leverage the relationships of their members, nor provide supplemental access and thus would not be the most effective alternative.

Develop the Project as Proposed – The applicant states that MSC’s members are well-known and are trusted community healthcare providers that provide specialized medical services to residents throughout North Carolina. The applicant states that by implementing their outpatient retail model and collaborating with three existing lithotripsy providers, MSC will greatly improve access to lithotripsy services for the residents of North Carolina in a manner that stimulates competition, enhances quality, and maximizes cost effectiveness.

The applicant adequately demonstrates that the alternative proposed in this application is its most effective alternative to meet the need based on the following:

- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section E, pages 79-81, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo – The applicant states that recent studies regarding stone disease have found much higher incidence rates which suggest that the kidney stone incidence in North Carolina may be much higher than assumed by the 2024 SMFP methodology. Additionally, the data strongly supports the ongoing demand for ESWL procedures and the need for additional lithotripsy units in the State. Maintaining the status quo would not be responsive to the great unmet lithotripter need. Therefore, this is a less effective alternative.

Identify Different Host Sites for the Proposed Lithotripter - The applicant is submitting two complementary applications, each proposing to develop one mobile lithotripter. To maximize efficiency, the MSC East proposal will serve host sites across the eastern half of the state. The applicant states that it will leverage the relationships of its members to provide supplemental access to their existing host site locations which will reduce patient wait times, decrease capacity constraints for the existing lithotripters, and respond to emergency requests for lithotripsy services. Therefore, identifying different host sites would be a less effective alternative.

Develop the Project as Proposed – On page 81, the applicant states that MSC’s members are well-known and trusted community healthcare providers who provide specialized medical services to residents throughout North Carolina. The applicant states that, by implementing their outpatient retail model, MSC will greatly improve access to lithotripsy services for the residents of North Carolina in a manner that stimulates competition, enhances quality, and maximizes cost effectiveness.

However, the applicant does not adequately demonstrate that the alternative proposed in its application is its most effective alternative to meet the need based on the following:

- Because the applicant did not demonstrate the need to develop the proposed project, the applicant cannot demonstrate that a lithotripter is needed in addition to the existing and approved lithotripters in the state. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference. A project that is unnecessarily duplicative cannot be the most effective alternative.
- Because the applicant did not demonstrate the need to acquire a lithotripter, it cannot demonstrate that any enhanced competition in the service area includes a positive impact on the cost-effectiveness of the proposed services. An applicant that did not demonstrate the need for a proposed project cannot demonstrate the cost-effectiveness of the proposed project. The discussion regarding demonstrating 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, found in Criterion (18a) is incorporated herein by reference. A proposed project that cannot show a positive impact on cost-effectiveness as the result of any enhanced competition cannot be the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above.

- (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
Atrium Urology
Mobile Stone Clinic (West)

NC
Mobile Stone Clinic (East)

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant projects the total capital cost of the project as shown in the table below:

Atrium Urology Capital Cost	
Medical Equipment	\$534,105
Non-Medical Equipment	\$77,320
Consultant Fees (CON prep)	\$50,000
Other (Contingency)	\$99,214
Total	\$760,638

In Exhibit F.1, the applicant provides the vendor quotes for the medical and non-medical equipment. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because the medical and non-medical equipment costs are supported by vendor quotations provided in Exhibit F.1.

In Section F.3, page 72, the applicant projects start-up costs for the proposed project will be \$20,576, and initial operating costs will be \$147,032 for a total working capital of \$167,607.

In Section Q, following form F.3b, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant provides additional information regarding cost estimates for equipment and professional services in Exhibit F.1. The applicant adequately demonstrates that the projected working capital needs of the project are reasonable and adequately supported based on the following:

- The applicant identifies the types of costs included in the start-up costs.
- The applicant provides a detailed line-item breakdown of the start-up costs and working capital.

Availability of Funds

In Section F.2, page 70, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing	
TYPE	ATRIUM UROLOGY, PC
Loans	\$760,638
Total Financing	\$760,638

In Section F.3, page 73, the applicant states that the working capital will be funded as shown in the table below:

Sources of Working Capital	
TYPE	ATRIUM UROLOGY, PC
Loans	\$167,607
Total Financing	\$167,607

In Exhibit F.2, the applicant provides a letter dated August 30, 2024, signed by the Senior Vice President of North State Bank agreeing to provide sufficient funding for the proposed project, and a letter dated August 23, 2024 signed by Kevin Khoudary, MD, Incorporator of Atrium Urology, PC committing to use those funds for the proposed project. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project because the applicant provides a letter from an appropriate bank official, and the incorporator of Atrium Urology confirming the availability of the funding proposed for the capital needs of the project and the commitment to use those funds to develop the proposed project.

Financial Feasibility

The applicant provides pro-forma financial statements for the first three full fiscal years (FY), of operation (2026-2028), following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses for the last two fiscal years following project completion, as shown in the table below:

Atrium Urology Lithotripsy Services			
	1ST PY FY 2026	2ND PY FY 2027	3RD PY FY 2028
Lithotripsy Procedures ^	492	752	1,021
Total Gross Revenues (Charges)	\$983,518	\$1,503,663	\$2,042,547
Total Net Revenue	\$453,143	\$692,188	\$939,713
Average Net Revenue per Procedure	\$921	\$920	\$920
Total Operating Expenses (Costs)	\$476,157	\$513,530	\$538,021
Average Operating Expense per Procedure	\$968	\$683	\$527
Net Income	(\$23,014)	\$178,658	\$401,692

^Source: Section Q, Form C.2b

The assumptions used by the applicant in preparation of the proforma financial statements are provided in Section Q, pages 134-135. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The incorporator has extensive historical experience with health service operations, including lithotripsy.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant projects the total capital cost of the project as shown in the table below:

Mobile Stone Clinic West Capital Cost	
Medical Equipment	\$544,419
Non-Medical Equipment	\$1,237,955
Financing Costs	\$15,000
Other (Contingency)	\$20,000
Total	\$1,817,374

In Section Q, Form F.1a capital cost assumptions and Exhibit F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Medical and non-medical equipment costs are based on vendor quotations in Exhibit F.1.
- The applicant describes its financing and contingency costs.

In Section F.3, page 85, the applicant projects start-up costs for the proposed project will be \$46,258 and initial operating costs will be \$175,000 for a total working capital of \$221,258. On pages 85-86, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the types of costs included in the start-up costs.
- The applicant provides a detailed line-item breakdown of the start-up costs.
- The applicant provides information on the length of the initial operating period and describes how initial operating costs are estimated.

Availability of Funds

In Section F.2, page 83, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing	
TYPE	MOBILE STONE CLINIC WEST
Loans	\$1,817,374
Total Financing	\$1,817,374

In Section F.3, page 86, the applicant states that the working capital will be funded as shown in the table below:

Sources of Working Capital	
TYPE	MOBILE STONE CLINIC WEST
Loans	\$221,258
Total Financing	\$221,258

In Exhibit F.2, the applicant provides a letter dated August 8, 2024, signed by the Senior Vice President of First Citizens Bank committing to provide funding for the project up to \$2.1 million. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposed project because it provides a letter from a bank official stating it will provide funding to be used specifically for the proposed project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years (FY), of operation (2026-2028), following project completion for lithotripsy services form Mobile Stone Clinic (West). In Form F.2b, the applicant projects that revenues will exceed operating expenses for lithotripsy services in the first and third fiscal years following project completion, as shown in the table below:

Mobile Stone Clinic (West)			
Lithotripsy Services			
	1ST PY FY 2026	2ND PY FY 2027	3RD PY FY 2028
Lithotripsy Procedures ^	496	620	870
Total Gross Revenues (Charges)	\$2,827,200	\$3,534,000	\$4,959,000
Total Net Revenue	\$1,017,792	\$1,272,240	\$1,785,240
Average Net Revenue per Procedure	\$2,052	\$2,052	\$2,052
Total Operating Expenses (Costs)	\$1,016,953	\$1,333,754	\$1,364,389
Average Operating Expense per Procedure	\$2,050	\$2,151	\$1,568
Net Income	\$839	(\$61,514)	\$420,851

^Source: Section Q, Form C.2b

The assumptions used by the applicant in preparation of the proforma financial statements are provided in Section Q, pages 134-136. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant clearly describes its revenue and expense assumptions which are based, in part, on the applicant members' experience.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

Capital and Working Capital Costs

In Section Q, Form F.1a Capital Cost, the applicant projects the total capital cost of the project as shown in the table below:

Mobile Stone Clinic (East) Capital Cost	
Medical Equipment	\$544,419
Non-Medical Equipment	\$1,237,955
Financing Costs	\$15,000
Other (Contingency)	\$20,000
Total	\$1,817,374

In Section Q, Form F.1a capital cost assumptions and Exhibit F.1, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Medical and non-medical equipment costs are based on vendor quotations in Exhibit F.1.
- The applicant describes its financing and contingency costs.

In Section F.3, page 85, the applicant projects start-up costs for the proposed project will be \$46,258 and initial operating costs will be \$175,000 for a total working capital of \$221,258. On pages 85-86, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant identifies the types of costs included in the start-up costs.
- The applicant provides a detailed line-item breakdown of the start-up costs.
- The applicant provides information on the length of the initial operating period and describes how initial operating costs are estimated.

Availability of Funds

In Section F.2, page 83, the applicant states that the capital cost will be funded as shown in the table below:

Sources of Capital Cost Financing	
TYPE	MOBILE STONE CLINIC EAST
Loans	\$1,817,374
Total Financing	\$1,817,374

In Section F.3, page 86, the applicant states that the working capital will be funded as shown in the table below:

Sources of Working Capital	
TYPE	MOBILE STONE CLINIC EAST
Loans	\$221,258
Total Financing	\$221,258

In Exhibit F.2, the applicant provides a letter dated August 8, 2024, signed by the Senior Vice President of First Citizens Bank committing to provide funding for the project up to \$2.1 million. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital costs of the proposed project because it provides a letter from a bank official that commits to provide funding to be used specifically for the proposed project.

Financial Feasibility

The applicant provides pro-forma financial statements for the first three full fiscal years (FY), of operation (2026-2028) following project completion. In Form F.2b, the applicant projects that revenues will exceed operating expenses for lithotripsy services for the first and third fiscal years following project completion, as shown in the table below:

Mobile Stone Clinic (West)			
Lithotripsy Services			
	1ST PY	2ND PY	3RD PY
	FY 2026	FY 2027	FY 2028
Lithotripsy Procedures ^	496	620	870
Total Gross Revenues (Charges)	\$2,827,200	\$3,534,000	\$4,959,000
Total Net Revenue	\$1,017,792	\$1,272,240	\$1,785,240
Average Net Revenue per Procedure	\$2,052	\$2,052	\$2,052
Total Operating Expenses (Costs)	\$1,016,953	\$1,333,754	\$1,364,389
Average Operating Expense per Procedure	\$2,050	\$2,151	\$1,568
Net Income	\$839	(\$61,514)	\$420,851

^Source: Section Q, Form C.2b

The assumptions used by the applicant in preparation of the proforma financial statements are provided in Section Q, pages 134-136. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, since projected revenues and expenses are based, in part, on projected utilization, projected revenues and expenses are questionable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to written comments

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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
Atrium Urology
Mobile Stone Clinic (West)

NC
Mobile Stone Clinic (East)

The 2024 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 2024 SMFP identified a need for two additional lithotripters.

On page 328 of the 2024 SMFP, the service area for lithotripters is defined as “*A lithotripter’s service area is statewide. A statewide service area is defined as a planning area that encompasses the entire state when determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, health service areas (HSA), or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions*”. Thus, the service area consists of the entire state.

There are 14 existing lithotripters operating in North Carolina. Thirteen are mobile. The following table identifies the provider, number of lithotripters, and their utilization, summarized from Table 15D-1 on pages 330-333 of the 2024 SMFP.

PROVIDER	AREA GENERALLY SERVED	TYPE OF UNIT	# OF UNITS	# OF PROCEDURES	# OF PROCEDURES/ UNIT
Carolina Lithotripsy	Eastern North Carolina	Mobile	2	1,016	508
Catawba Valley Medical Center	Western and Central North Carolina	Mobile	1	194	194
Fayetteville Lithotripters SC II	Western North Carolina	Mobile	1	290	290
Fayetteville Lithotripters VA I	Eastern North Carolina and Virginia	Mobile	1	332	332
Piedmont Stone Center	Western and Central NC and Virginia	Mobile	5	3,687	737
Stone Institute of the Carolinas	Western and Central North Carolina	Mobile	2	1,619	810
Triangle Lithotripsy Corporation	East Central North Carolina	Mobile	1	669	669
Mission Hospital	Asheville, North Carolina	Fixed	1	119	119
Total			14	7,926	566

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

In Section G, page 79, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing lithotripsy services in the statewide service area. The applicant states:

“The proposed project will offset some of the lithotripsy access disparity in HSA 4 and surrounding counties. Even though, compared to the surgical alternative, lithotripsy is a less expensive, non-invasive treatment option for kidney stones, equipment access is not uniform among North Carolina counties.”

On page 79, the applicant states the service area has limited lithotripter capacity, increasing need and the proposed service area is currently underserved. The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2024 SMFP for the proposed lithotripter in the statewide lithotripter service area.
- The applicant adequately demonstrates that the proposed lithotripter is needed in addition to the existing or approved lithotripters in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section G, page 92, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved lithotripsy services in the across the statewide service area. The applicant states:

“MSC will deliver a superior alternative to meet that need by offering benefits that cannot be matched by any other lithotripsy provider including establishing a new provider to spur competition with the experience and resources of an existing provider, collaboration that will deliver a new higher standard of care, resource optimization, the best-qualified provider to develop additional lithotripter capacity based on demonstrated effectiveness and efficiency, and cost-effective care via its “retail” approach.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- There is a need determination in the 2024 SMFP for the proposed lithotripter in the statewide lithotripter service area.
- The applicant adequately demonstrates that the proposed lithotripter is needed in addition to the existing or approved lithotripters in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section G, page 91, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved lithotripsy services in the across the statewide service area. The applicant states:

“MSC will deliver a superior alternative to meet that need by offering benefits that cannot be matched by any other lithotripsy provider including establishing a new provider to spur competition with the experience and resources of an existing provider, collaboration that will deliver a new higher standard of care, resource optimization, the best-qualified provider to develop additional lithotripter capacity based on demonstrated effectiveness and efficiency, and cost-effective care via its “retail” approach.”

However, the applicant does not adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area based on the following:

- The applicant did not adequately demonstrate the need it has for the proposed project or that its projected utilization is based on reasonable and adequately supported

assumptions. The discussion regarding analysis of need including projected utilization found in Criterion (3) is incorporated herein by reference.

- Because the applicant did not demonstrate the need to acquire a lithotripter, it cannot demonstrate that the lithotripter is needed in addition to the existing and approved lithotripters in the state.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Response to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not conforming to this criterion for all the reasons described above.

- (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.

**C
All Applications**

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed lithotripsy service for the first three full fiscal years (FY), calendar years (CY) 2026-2028, as summarized below:

Atrium Urology Proposed Staffing			
POSITION	1ST FULL FY CY 2026	2ND FULL FY CY 2027	3RD FULL FY CY 2028
Clerical	1.10	1.10	1.10
Driver/Tech	1.10	1.10	1.23
Total	2.20	2.20	2.33

The assumptions and methodology used to project staffing are provided in Section Q, page 137. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 80, the applicant states that staffing includes only applicant staff, and that host sites will have separate operations and

related staff. In Section H, page 81, the applicant describes the methods used to recruit or fill new positions. The applicant provides examples of its proposed training and continuing education programs on pages 81-82 and referenced exhibits.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates its methods for staff recruitment.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed mobile lithotripsy services for the first three full fiscal years (FY), calendar years (CY) 2026-2028, as summarized below:

Mobile Stone Clinic West Proposed Staffing			
POSITION	1ST FULL FY CY 2026	2ND FULL FY CY 2027	3RD FULL FY CY 2028
RN	1.0	2.0	2.0
Technologist	1.0	2.0	2.0
Admin/Scheduler	1.0	1.0	1.0
Admin/Billing/Credentialing	1.0	1.0	1.0
Driver	1.0	1.0	1.0
Total	5.0	7.0	7.0

The assumptions and methodology used to project staffing are provided in Section Q, page 140. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3. In Section H, page 93, the applicant describes the methods used to recruit or fill new positions. The applicant discusses its proposed training

and continuing education programs on page 94 and provides additional documentation in Exhibit H.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates its methods for staff recruitment.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification based on its historical experience.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section Q Form H Staffing, the applicant provides the projected full-time equivalent (FTE) positions for the proposed mobile lithotripsy services for the first three full fiscal years (FY), calendar years (CY) 2026-2028, as summarized below:

Mobile Stone Clinic East Proposed Staffing			
POSITION	1ST FULL FY CY 2026	2ND FULL FY CY 2027	3RD FULL FY CY 2028
RN	1.0	2.0	2.0
Technologist	1.0	2.0	2.0
Admin/Scheduler	1.0	1.0	1.0
Admin/Billing/Credentialing	1.0	1.0	1.0
Driver	1.0	1.0	1.0
Total	5.0	7.0	7.0

The assumptions and methodology used to project staffing are provided in Section Q, page 140. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3. In Section H, page 92, the applicant describes the methods used to recruit or fill new positions. The applicant discusses its proposed training

and continuing education programs on page 93 and provides additional documentation in Exhibit H.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant adequately demonstrates its methods for staff recruitment.
- The applicant adequately demonstrates its methods to train and retain staff, as well as its methods to ensure staff certification.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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 All Applications

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

Ancillary and Support Services

In Section I, page 83, the applicant identifies the necessary ancillary and support services for the proposed services. On page 84, the applicant explains how each ancillary and support service is and will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant states it will provide the necessary ancillary and support services in coordination with the proposed host sites following the addition of the proposed lithotripter.
- The applicant provides letters of support in Exhibit B.20 from the proposed host sites attesting to the ongoing availability of these services.

Coordination

In Section I, page 85, the applicant proposes to provide mobile lithotripsy services at six host sites within the proposed service area, two licensed ambulatory surgical facilities, one licensed hospital, and three physician offices. Atrium Urology has established a relationship with each of these host sites and provides evidence of this with letters of support from the host sites in Exhibit B.20. Each host site has an established relationship with existing healthcare and social service providers within the proposed service area. Referring physicians are identified in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant currently has established relationships with the proposed host sites in the service area.
- The applicant provides documentation of relationships with the host sites and with referring physicians.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

Ancillary and Support Services

In Section I, page 95, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 95-96, the applicant explains how each ancillary and support service is and will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because they are based on the MSC members' experience.

Coordination

In Section I, pages 96-97, the applicant states it maintains a vast network of relationships with health care providers across the service area. The applicant provides letters of support in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant, through its members, currently has established relationships with other local healthcare providers.
- The applicant confirms it will continue those relationships upon project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

Ancillary and Support Services

In Section I, page 94, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 94-95, the applicant explains how each ancillary and support service is and will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because they are based on the MSC members' experience.

Coordination

In Section I, pages 95-96, the applicant states it maintains a vast network of relationships with health care providers across the service area. The applicant provides letters of support in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant, through its members, currently has established relationships with other local healthcare providers.
- The applicant confirms it will continue those relationships upon project completion.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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- All Applications

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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-All Applications

- (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 – All Applications

None of the applicants propose any construction or renovations to facilities in their applications. Therefore, Criterion (12) is not applicable to any of these reviews.

- (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 persons with disabilities, 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;

NA - All Applications

None of the applicants are existing providers of lithotripsy services. Therefore, Criterion (13a) is not applicable to this review.

- (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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA-All Applications

None of the applicants are existing providers of lithotripsy services. Therefore, Criterion (13b) is not applicable to this review.

- (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 All Applications

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

In Section L, page 97, the applicant projects the following payor mix for the proposed lithotripsy services during the third full fiscal year of operation following project completion, as shown in the table below:

Atrium Urology Lithotripsy Services Projected Payor Mix CY 2028	
PAYOR CATEGORY	LITHOTRIPSY SERVICES AS PERCENT OF TOTAL
Self-Pay	5.0%
Charity Care	1.5%
Medicare*	32.5%
Medicaid*	7.7%
Insurance	51.9%
Other (Gov't, VA, TRICARE, etc.)	1.4%
Total	100.0%

*Includes any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 5.0% of total lithotripsy services will be provided to self-pay patients, 32.5% to Medicare patients and 7.7% to Medicaid patients.

In Section Q, pages 134-135, and in Exhibit C.6, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the proposed host sites' license renewal applications (LRAs) for ambulatory surgical cases for FY 2023 and a calculated weighted average.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

J-12558-24 / Mobile Stone Clinic (West) / Acquire one mobile lithotripter

In Section L, page 106, the applicant projects the following payor mix for the proposed lithotripsy services during the third full fiscal year of operation following project completion, as shown in the table below:

Mobile Stone Clinic (West)	
Lithotripsy Services Projected Payor Mix FY 2028	
PAYOR CATEGORY	LITHOTRIPTY SERVICES AS PERCENT OF TOTAL
Self-Pay	1.5%
Charity Care*	--
Medicare**	35.0%
Medicaid**	7.0%
Insurance**	53.0%
Other (Gov't)	3.5%
Total	100%

*On application page 105, the applicant states Charity care is estimated at 0.5 percent of its projected lithotripsy procedures.

**Includes managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.5% of total lithotripsy services will be provided to self-pay patients, 35.0% to Medicare patients and 7.0% to Medicaid patients.

In Section L, page 105, the applicant states that they projected payor mix based on the aggregate operating experience of its members in North Carolina. The projected payor mix is reasonable and adequately supported because it is based on its members historical experience providing lithotripsy services in the state.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reason stated above.

G-12559-24 / Mobile Stone Clinic (East) / Acquire one mobile lithotripter

In Section L, page 105, the applicant projects the following payor mix for the proposed lithotripsy services during the third full fiscal year of operation following project completion, as shown in the table below:

Mobile Stone Clinic (East)	
Lithotripsy Services Projected Payor Mix FY 2028	
PAYOR CATEGORY	LITHOTRIPTY SERVICES AS PERCENT OF TOTAL
Self-Pay	1.5%
Charity Care*	--
Medicare**	35.0%
Medicaid**	7.0%
Insurance**	53.0%
Other (Gov't)	3.5%
Total	100%

*On application page 105, the applicant states Charity care is estimated at 0.5 percent of its projected lithotripsy procedures.

**Includes managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.5% of total lithotripsy services will be provided to self-pay patients, 35.0% to Medicare patients and 7.0% to Medicaid patients.

In Section L, page 106, the applicant states that it projected payor mix based on the aggregate operating experience of its members in North Carolina. The projected payor mix is reasonable and adequately supported because it is based on its members' historical experience providing lithotripsy services in the state.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reason stated above.

- (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 All Applications

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

In Section L, page 99, the applicant adequately describes the range of means by which patients will have access to the proposed lithotripsy services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

J-12558-24 / Mobile Stone Clinic (West) / Acquire one mobile lithotripter

In Section L, page 107, the applicant adequately describes the range of means by which patients will have access to the proposed lithotripsy services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion.

J-12559-24 / Mobile Stone Clinic (East) / Acquire one mobile lithotripter

In Section L, pages 105- 106, the applicant adequately describes the range of means by which patients will have access to the proposed lithotripsy services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that 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 All Applications

Atrium Urology. In Section M, page 100, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the mobile lithotripter for training purposes because the proposed host sites are established providers and have existing relationships with area training programs.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Mobile Stone Clinic (West). In Section M, page 108, the applicant describes the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provides supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

Mobile Stone Clinic (East). In Section M, page 107, the applicant describes the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provides supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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
Atrium Urology
Mobile Stone Clinic (West)

NC
Mobile Stone Clinic (East)

The 2024 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 2024 SMFP identified a need for two additional lithotripters.

On page 328 of the 2024 SMFP, the service area for lithotripters is defined as “*A lithotripter’s service area is statewide. A statewide service area is defined as a planning area that encompasses the entire state when determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, health service areas (HSA), or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions*”. Thus, the service area consists of the entire state.

There are 14 existing lithotripters operating in North Carolina. Thirteen are mobile. The following table identifies the provider, number of lithotripters, and their utilization, summarized from Table 15D-1 on pages 330-333 of the 2024 SMFP.

PROVIDER	AREA GENERALLY SERVED	TYPE OF UNIT	# OF UNITS	# OF PROCEDURES	# OF PROCEDURES/UNIT
Carolina Lithotripsy	Eastern North Carolina	Mobile	2	1,016	508
Catawba Valley Medical Center	Western and Central North Carolina	Mobile	1	194	194
Fayetteville Lithotripters SC II	Western North Carolina	Mobile	1	290	290
Fayetteville Lithotripters VA I	Eastern North Carolina and Virginia	Mobile	1	332	332
Piedmont Stone Center	Western and Central NC and Virginia	Mobile	5	3,687	737
Stone Institute of the Carolinas	Western and Central North Carolina	Mobile	2	1,619	810
Triangle Lithotripsy Corporation	East Central North Carolina	Mobile	1	669	669
Mission Hospital	Asheville, North Carolina	Fixed	1	119	119
Total			14	7,926	566

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 101, the applicant states:

“Competition will work both ways. As a new permanent market entrant, the proposed mobile lithotripter must outperform others to continue to grow and attract and retain patients. The project will foster additional competition by providing expanded access to ESWL in a large geographic area that has few existing options.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 101, the applicant states:

“The project capital cost is reasonable. Atrium Urology will obtain competitive market quotes from equipment vendors for the equipment and transport truck, and as previously described the project involves no construction or renovation.”

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 102, the applicant states:

“Each proposed host site meets all applicable licensure requirements, participates, and complies with conditions of participation for certification with Medicare and Medicaid, and complies with requirements of recognized accreditation bodies like The Joint Commission, or Accreditation Association of Ambulatory Health Care; or CMS and North Carolina Medical Board physician office credentialing all of which provide yet more third-party oversight.”

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 103, the applicant states:

“Host sites will accept referred patients without regard to source of payment and have policies in place to provide charity for medical necessity.”

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 109, the applicant states:

“MSC’s proposal will have a positive effect on competition in North Carolina...”

...the proposed project offers an unparalleled ability to increase quality, cost effectiveness, and access for lithotripsy services given the unique benefits of MSC that cannot be offered by any other lithotripsy provider.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 111, the applicant states:

“MSC will aggressively pursue strategies to eliminate or reduce unnecessary expenses and maximize the use of resources where possible and using appropriate legal arrangements. This resource optimization will include the sharing of staff, equipment management, and administrative functions in order to significantly enhance operational efficiency. These strategies will allow MSC to increase cost-effectiveness, improve service delivery, and make it easier for physicians to work across multiple sites. This integrated and collaborative approach will ultimately lead to better patient outcomes, higher physician satisfaction, and a more sustainable healthcare delivery model.”

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 110, the applicant states:

“As part of its pursuit of the highest quality, MSC will also seek the most stringent and thorough accreditations. MSC will seek to obtain accreditation of its two concurrently proposed lithotripters AAAHC upon completion of the proposed projects. 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, an 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.”

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 113, the applicant states:

“MSC’s project will substantially expand access to lithotripsy services across temporal, geographic, and financial dimensions. By reducing wait times, establishing new sites of care, and adopting a cost-effective retail model, MSC will ensure that more patients can receive the timely, convenient, and affordable care they need. This comprehensive approach to expanding access underscores MSC’s commitment to improving patient outcomes and enhancing the overall quality of care.”

See also Sections B, C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 106, the applicant states:

*“MSC’s proposal will have a positive effect on competition in North Carolina...
...the proposed project offers an unparalleled ability to increase quality, cost effectiveness, and access for lithotripsy services given the unique benefits of MSC that cannot be offered by any other lithotripsy provider.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 110, the applicant states:

“MSC will aggressively pursue strategies to eliminate or reduce unnecessary expenses and maximize the use of resources where possible and using appropriate

legal arrangements. This resource optimization will include the sharing of staff, equipment management, and administrative functions in order to significantly enhance operational efficiency. These strategies will allow MSC to increase cost-effectiveness, improve service delivery, and make it easier for physicians to work across multiple sites. This integrated and collaborative approach will ultimately lead to better patient outcomes, higher physician satisfaction, and a more sustainable healthcare delivery model.”

See also Sections B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 109, the applicant states:

“As part of its pursuit of the highest quality, MSC will also seek the most stringent and thorough accreditations. MSC will seek to obtain accreditation of its two concurrently proposed lithotripters AAAHC upon completion of the proposed projects. 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, an 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.”

See also Sections B and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 111, the applicant states:

“MSC’s project will substantially expand access to lithotripsy services across temporal, geographic, and financial dimensions. By reducing wait times, establishing new sites of care, and adopting a cost-effective retail model, MSC will ensure that more patients can receive the timely, convenient, and affordable care they need. This comprehensive approach to expanding access underscores MSC’s commitment to improving patient outcomes and enhancing the overall quality of care.”

See also Sections B, C and L of the application and any exhibits.

However, the applicant does not adequately demonstrate how any enhanced competition in the service area will have a positive impact on cost-effectiveness of the proposed services. The applicant did not adequately demonstrate the need to acquire a lithotripter or that the project is the least costly or most effective alternative. The discussions regarding analysis of need, including projected utilization, and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference. A project that cannot demonstrate the need for the services proposed and a project that cannot demonstrate it is the least costly or most effective alternative cannot

demonstrate how any enhanced competition will have a positive impact on the cost-effectiveness of the proposal.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion based on all the reasons described above.

- (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.

NA
Atrium Urology

C
Mobile Stone Clinic (West)
Mobile Stone Clinic (East)

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

In Section Q, page 104, the applicant states that they are a new provider. The applicant does not own, operate or manage a lithotripsy service located in North Carolina. Therefore, Criterion (20) is not applicable to this review.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section Q, Form O, the applicant identifies the lithotripsy services located in North Carolina utilized by the applicant or a related entity. The applicant identifies a total of 11 of this type of health service located in North Carolina.

In Section O, page 118, the applicant states that during the 18 months immediately preceding the submittal of the application, it is not aware of any reported incidents related to quality of care occurring at any of the members' host sites. After reviewing and considering the information provided by the applicant, the applicant provided sufficient evidence that quality of care has been provided in the past. Therefore, the application is conforming to this criterion.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter

The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination. Mobile Stone Clinic, LLC (MSC) is a newly established organization formed by the collaboration of three longstanding lithotripsy providers in North Carolina.

In Section Q, Form O, the applicant identifies the lithotripsy services located in North Carolina utilized by the applicant or a related entity. The applicant identifies a total of 11 of this type of health service located in North Carolina.

In Section O, page 118, the applicant states that during the 18 months immediately preceding the submittal of the application, it is not aware of any reported incidents related to quality of care occurring at any of the members host sites. After reviewing and considering the information provided by the applicant, the applicant provided sufficient evidence that quality of care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183(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 - All Applications

There are no CON rules applicable to the proposed projects. The Criteria and Standards for Lithotripter Equipment, promulgated in 10A NCAC 14C .3200, were repealed effective October 1, 2016.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2024 State Medical Facilities Plan, no more than two mobile lithotripters may be approved in the statewide service area in this review. Because three applications in this review collectively propose to develop three additional mobile lithotripters to be located in the statewide service area, all three applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable

statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of all of the proposals to decide which proposal or proposals should be approved.

Below is a brief description of each project included in this review.

J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

G-12559-24 / Mobile Stone Clinic (East)/ Acquire one mobile lithotripter The applicant proposes to acquire no more than one mobile lithotripter pursuant to the 2024 need determination.

Conformity with Statutory and Regulatory Review Criteria

An application that is not conforming or conforming as conditioned with all applicable statutory and regulatory review criteria cannot be approved. The **Atrium Urology** and **Mobile Stone Clinic (West)** applications are conforming to all applicable statutory review criteria. The **Mobile Stone Clinic (East)** application is not conforming to all applicable statutory review criteria and thus cannot be approved. Thus, the **Atrium Urology** and **Mobile Stone Clinic (West)** applications are more effective alternatives than the application submitted by **Mobile Stone Clinic (East)**.

Scope of Services

Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor. All applications are proposing to acquire one mobile lithotripter each to provide lithotripsy services. Therefore, regarding this comparative factor, all three applications are equally effective alternatives.

Historical Utilization

There are eight existing providers of lithotripsy services and a total of 14 existing lithotripters operating in North Carolina. Thirteen lithotripters are mobile. The following table identifies the provider, the general area served, the number of lithotripters, and utilization of the lithotripters, summarized from Table 15D-1 on pages 330-333 of the 2024 SMFP.

PROVIDER	AREA GENERALLY SERVED	TYPE OF UNIT	# OF UNITS	# OF PROCEDURES	# OF PROCEDURES/UNIT
Carolina Lithotripsy	Eastern North Carolina	Mobile	2	1,016	508
Catawba Valley Medical Center	Western and Central North Carolina	Mobile	1	194	194
Fayetteville Lithotripters SC II	Western North Carolina	Mobile	1	290	290
Fayetteville Lithotripters VA I	Eastern North Carolina and Virginia	Mobile	1	332	332
Piedmont Stone Center	Western and Central NC and Virginia	Mobile	5	3,687	737
Stone Institute of the Carolinas	Western and Central North Carolina	Mobile	2	1,619	810
Triangle Lithotripsy Corporation	East Central North Carolina	Mobile	1	669	669
Mission Hospital	Asheville, North Carolina	Fixed	1	119	119
Total			14	7,926	566

Generally, the applicant with the higher historical utilization is the more effective alternative with regard to this comparative analysis factor. While Mobile Stone Clinic (West) and Mobile Stone Clinic (East) would technically be new providers, each is part of a joint venture made up of related entities that are in themselves existing providers of lithotripsy services. Therefore, Mobile Stone Clinic (West) and Mobile Stone Clinic (East) have historical utilization. However, Atrium Urology would be a new provider and thus, has no historical utilization. Therefore, a comparison of historical utilization cannot be effectively evaluated.

Geographic Accessibility (Location within the Service Area)

As of the start date of this review and according to the 2024 SMFP, there are 13 existing mobile lithotripters being utilized across the state. Nine of the existing mobile lithotripters are being utilized in Western and Central North Carolina, and four mobile lithotripters are being utilized in Eastern North Carolina. The Mobile Stone Clinic, through its joint venture members, provides lithotripsy services in the western, central, and eastern areas of the state. The application submitted by **Atrium Urology**, proposes to utilize its mobile lithotripter at six host sites in four counties in East/Central North Carolina. Those counties are Harnett, Johnston, Lee, and Wake. Based on a review of data contained in Table 15D-1, page 330 of the 2024 SMFP, there are currently no host sites for mobile lithotripsy services in Harnett, Johnston, and Lee counties. The application submitted by **Mobile Stone Clinic (West)**, proposes to utilize its mobile lithotripter at existing host sites of its members in Western/Central North Carolina. The application submitted by **Mobile Stone Clinic (East)**, proposes to utilize its mobile lithotripter at existing host sites of its members in East/Central North Carolina.

Therefore, for purposes of this comparative factor, **Mobile Stone (West) and Mobile Stone (East)** are proposing to locate their lithotripters in facilities or locations that already provide lithotripsy services. **Atrium Urology** proposes to operate its lithotripter in three counties that currently don't have any host sites for lithotripsy services. Therefore, the application submitted by **Atrium Urology** is the more effective alternative.

Access by Service Area Residents

The 2024 SMFP defines the service area for lithotripters as “*A lithotripter’s service area is statewide. A statewide service area is defined as a planning area that encompasses the entire state when*

determining need. For mobile equipment, the definition does not imply that a CON applicant is required to project that it will provide mobile services in a certain number of counties, health service areas (HSA), or regions. Similarly, once developed, the equipment does not have to serve a certain number of counties, HSAs, or regions". Thus, the service area for this review is statewide.

Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that service area residents should be able to derive a benefit from a need determination for an additional lithotripter in the lithotripter service area in which they live.

The following table illustrates the projected number of statewide residents to be served by each applicant during the third full fiscal year following project completion:

Mobile Lithotripsy Projected Utilization - Project Year 3

APPLICANT	# OF MOBILE LITHOTRIPTERS	# OF PROCEDURES	# OF PROCEDURES/UNIT
Atrium Urology	1	1,021	1,021
Mobile Stone Clinic (West)	1	870	870
Mobile Stone Clinic (East)	1	870	870

Source: Form C.2a for Atrium Urology and Form C.2b for both Mobile Stone Clinic (West) and Mobile Stone Clinic (East)

As shown in the table above, **Atrium Urology** projects to serve the highest number of lithotripter service area residents during the third full fiscal year following project completion. **Mobile Stone Clinic (East)** and **Mobile Stone Clinic (West)** project to serve a lower number of lithotripter service area residents during the third full fiscal year following project completion. Therefore, regarding this comparative factor, the application submitted by **Atrium Urology** is the more effective alternative.

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 ... persons [with disabilities], 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 with respect to two underserved groups: Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

Projected Medicare

The Project Analyst compared each applicant’s projected Medicare revenue as a percentage of gross revenue. The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicare patients in each applicant’s third full fiscal year of operation following project completion, based on information provided in each applicant’s pro forma financial statements in Section

Q. Generally, the application proposing to provide a higher percentage of services to Medicare patients is the more effective alternative with regard to this comparative factor.

Mobile Lithotripsy Services to Medicare Patients - Project Year 3

Applicant	Total Medicare Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
Atrium Urology	\$663,828	\$2,042,547	32.5%
Mobile Stone Clinic (West)	\$1,735,650	\$4,959,000	35.0%
Mobile Stone Clinic (East)	\$1,735,650	\$4,959,000	35.0%

Source: Form F.2b for Atrium Urology and Form F.2 for both Mobile Stone Clinic (West) and Mobile Stone Clinic (East)

As shown in the table above, the application submitted by **Atrium Urology** projects that 32.5% of its mobile lithotripsy services will be provided to Medicare patients. The application submitted by **Mobile Stone Clinic (West)** projects that 35% of its mobile lithotripsy services will be provided to Medicare patients. The application submitted by **Mobile Stone Clinic (East)** projects that 35% of its mobile lithotripsy services will be provided to Medicare patients. Therefore, with regard to service to Medicare patients, the applications submitted by **Mobile Stone Clinic (West)** and **Mobile Stone Clinic (East)** are the more effective alternatives.

Projected Medicaid

The Project Analyst compared each applicant’s projected Medicaid revenue as a percentage of gross revenue. The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicaid patients in each applicant’s third full fiscal year of operation following project completion, based on information provided in each applicant’s pro forma financial statements in Section Q. Generally, the application proposing to provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

Mobile Lithotripsy Services to Medicaid Patients - Project Year 3

Applicant	Medicaid Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
Atrium Urology	\$157,276	\$2,042,547	7.7%
Mobile Stone Clinic (West)	\$347,130	\$4,959,000	7.0%
Mobile Stone Clinic (East)	\$347,130	\$4,959,000	7.0%

Source: Forms F.2b for Atrium Urology and Forms F.2 for both Mobile Stone Clinic (West) and Mobile Stone Clinic (East)

As shown in the table above, the application submitted by **Atrium Urology** projects that 7.7% of its mobile lithotripsy services will be provided to Medicaid patients. The application submitted by **Mobile Stone Clinic (West)** projects that 7.0% of its mobile lithotripsy services will be provided to Medicaid patients. The application submitted by **Mobile Stone Clinic (East)** projects that 7.0% of its mobile lithotripsy services will be provided to Medicaid patients. Therefore, with regard to service to Medicaid patients, the application submitted by **Atrium Urology** is the more effective alternative.

Competition (Access to a New or Alternate Provider)

The following table illustrates the existing and approved providers located in the service area. Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer mobile lithotripters than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

PROVIDER	AREA GENERALLY SERVED	TYPE OF UNIT	# OF UNITS	# OF PROCEDURES	# OF PROCEDURES /UNIT
Carolina Lithotripsy	Eastern North Carolina	Mobile	2	1,016	508
Catawba Valley Medical Center	Western and Central North Carolina	Mobile	1	194	194
Fayetteville Lithotripters SC II	Western North Carolina	Mobile	1	290	290
Fayetteville Lithotripters VA I	Eastern North Carolina and Virginia	Mobile	1	332	332
Piedmont Stone Center	Western and Central NC and Virginia	Mobile	5	3,687	737
Stone Institute of the Carolinas	Western and Central North Carolina	Mobile	2	1,619	810
Triangle Lithotripsy Corporation	East Central North Carolina	Mobile	1	669	669
Mission Hospital	Asheville, North Carolina	Fixed	1	119	119
Total			14	7,926	566

Both **Mobile Stone Clinic (East)** and **Mobile Stone Clinic (West)** are joint ventures with existing lithotripsy providers. Mobile Stone Clinic members consist of Carolina Lithotripsy, LTD., Fayetteville Lithotripters VA I, Piedmont Stone Center, Fayetteville Lithotripters Limited Partnership SC II, and Stone Institute of the Carolinas. Therefore, in total, Mobile Stone Clinic members operate 11 of the 14, or 78.6%, of the lithotripters in the state. **Atrium Urology** currently owns and operates no lithotripters in the state. If both lithotripters are awarded and one lithotripter is awarded to **Atrium Urology**, it would control 6.25%, or one of 16 lithotripters in the state. Therefore, for purposes of patient access to a new or alternate provider, the application submitted by **Atrium Urology** is the more effective alternative.

Projected Average Net Revenue per Lithotripsy Procedure

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

Projected Average Net Revenue per Lithotripsy Procedure - Project Year 3

Applicant	Net Revenue	# of Lithotripsy Procedures	Average Net Revenue / Lithotripsy Procedure
Atrium Urology	\$939,713	1,021	\$920
Mobile Stone Clinic (West)	\$1,785,240	870	\$2,052
Mobile Stone Clinic (East)	\$1,785,240	870	\$2,052

Source: Forms C.2a and F.2b for Atrium Urology and Forms C.2b and F.2 for both Mobile Stone Clinic (West) and Mobile Stone Clinic (East)

However, the applications are not comparable. **Atrium Urology** proposes a “wholesale” model whereas both **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)** propose a “retail” model. In the **Atrium Urology** “wholesale” model, **Atrium Urology** 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 **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)** “retail” model, with the exception of government programs, **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)** bills the patient or the patient’s third-party payor for the services provided. Therefore, **Atrium Urology’s** projected gross and net revenues cannot be compared to **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)’s** projected gross and net revenues. Therefore, a comparison of projected average net revenue per lithotripsy procedure cannot be effectively evaluated.

Projected Average Operating Expense per Lithotripsy Procedure

The following table compares the projected average operating expense per lithotripsy procedure in the third year of operation for each of the applicants, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally regarding this comparative factor, the application proposing the lowest average operating expense per lithotripsy procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

Projected Operating Expense per Lithotripsy Procedure - Project Year 3

Applicant	Operating Expense	# of Lithotripsy Procedures	Average Operating Expense / Lithotripsy Procedure
Atrium Urology	\$538,021	1,021	\$527
Mobile Stone Clinic (West)	\$1,364,389	870	\$1,568
Mobile Stone Clinic (East)	\$1,364,389	870	\$1,568

Source: Forms C.2a and F.2b for Atrium Urology and Forms C.2b and F.2 for both Mobile Stone Clinic (West) and Mobile Stone Clinic (East)

As shown in the table above, the application submitted by **Atrium Urology** projects the lowest average operating expense per lithotripsy procedure in the third operating year. However, the applications are not comparable. **Atrium Urology** proposes a “wholesale” model whereas both **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)** propose a “retail” model. In the **Atrium Urology** “wholesale” model, the host site, not **Atrium Urology**, would incur the majority of the costs associated with

drugs/medical supplies and housekeeping/laundry. In the **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)** “retail” model, **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)** project incurring costs associated with these items. **Atrium Urology’s** projected operating expenses cannot be compared to **Mobile Stone Clinic (West) or Mobile Stone Clinic (East)’s** operating expenses. Therefore, a comparison of projected operating expense per lithotripsy procedure cannot be effectively evaluated.

Summary

The following table lists the comparative factors and indicates which each application is the more effective alternative for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis, which should not be construed to indicate an order of importance.

Comparative Factor	Atrium Urology	Mobile Stone Clinic (West)	Mobile Stone Clinic (East)
Conformity with Statutory Review Criteria	Equally Effective	Equally Effective	Not Approvable
Scope of Services	Equally Effective	Equally Effective	Not Approvable
Geographic Accessibility (location within the SA)	More Effective	Less Effective	Not Approvable
Historical Utilization	Inconclusive	Inconclusive	Inconclusive
Access by Service Area Residents	More Effective	Less Effective	Not Approvable
Access by Medicare Patients	Less Effective	More Effective	Not Approvable
Access by Medicaid Patients	More Effective	Less Effective	Not Approvable
Competition/Access to New/Alternative Provider	More Effective	Less Effective	Less Effective
Average Net Revenue per Lithotripsy Procedure	Inconclusive	Inconclusive	Inconclusive
Average Operating Expense per Lithotripsy Procedure	Inconclusive	Inconclusive	Inconclusive

The **Atrium Urology** and **Mobile Stone Clinic (West)** applications as submitted are conforming to all applicable statutory review criteria, and thus those applications are approvable standing alone. The application submitted by **Mobile Stone Clinic (East)** is not conforming to all applicable statutory review criteria, and thus, is not approvable. The **Atrium Urology** and **Mobile Stone Clinic (West)** applications propose a total of two mobile lithotripters in the statewide lithotripsy service area, and the need determination in the 2024 SMFP is for only two mobile lithotripters. Therefore, only two mobile lithotripters in the service area can be approved.

As shown in the table above, the application submitted by **Atrium Urology** was determined to be a more effective alternative for the following four factors:

- Geographic Accessibility
- Access by Service Area Residents
- Access by Medicaid Patients
- Competition/Access to New/Alternative Provider

As shown in the table above, the application submitted by **Mobile Stone Clinic (West)** was determined to be a more effective alternative for one factor:

- Access by Medicare Patients

CONCLUSION

G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of lithotripters that can be approved by the Healthcare Planning and Certificate of Need Section. Approval of all applications submitted during this review would result in lithotripters in excess of the need determination for the statewide service area.

The application submitted by **Mobile Stone Clinic (East)** is not approvable and therefore cannot be considered an effective alternative. Consequently, the application submitted by **Mobile Stone Clinic (East)**, Project ID# G-12559-24, is denied.

The applications, **Atrium Urology** and **Mobile Stone Clinic (West)**, are individually conforming to the need determination in the 2024 SMFP for lithotripters in the statewide service area as well as individually conforming to all review criteria.

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the following applications are conditionally approved as submitted:

- **Project ID# J-12551-24 / Atrium Urology/ Acquire one mobile lithotripter**
- **Project ID# G-12558-24 / Mobile Stone Clinic (West)/ Acquire one mobile lithotripter**

Project ID# J-12551-24, **Atrium Urology, PC**, is approved subject to the following conditions:

1. **Atrium Urology, PC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire no more than one mobile lithotripter pursuant to the need determination in the 2024 SMFP.**
3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on September 1, 2025.**
4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**

5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

Project ID# G-12558-24, **Mobile Stone Clinic, LLC, [Mobile Stone Clinic (West)]** is approved subject to the following conditions:

1. **Mobile Stone Clinic, LLC (hereinafter certificate holder), shall materially comply with all representations made in the certificate of need application.**
2. **The certificate holder shall acquire no more than one mobile lithotripter pursuant to the need determination in the 2024 SMFP.**
3. **Progress Reports:**
 - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. **The certificate holder shall complete all sections of the Progress Report form.**
 - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. **The first progress report shall be due on September 1, 2025.**
4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
5. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**