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Delivered Via Email

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Re: Comments on Competing Applications for a Certificate of Need for a Mobile Lithotriptor based on a statewide need; CON Project ID Numbers:

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

Dear Ms. Bradford,

On behalf of Atrium Urology, PC, Project ID# J-012551-24, thank you for the opportunity to comment on the above referenced applications, which were submitted in response to a statewide need for two additional lithotriptors, identified in the *2024 State Medical Facilities Plan*.

Historically, an SMFP need determination for lithotriptors is rare; the *2024 SMFP* identifies need for two. The need identified for these two units is statewide. The Agency has an opportunity to select a project that would provide mobile lithotripsy services to communities that have geographic access deficiencies. Because the need for lithotripsy equipment occurs so infrequently, the decision in this CON batch will have a lasting impact on the state of North Carolina. Atrium Urology is the only application that **proposes new host sites.**

We believe that the applications submitted confirm and support the proposal from Atrium Urology as the most qualified to address the identified need. We also believe that the applications filed by Mobile Stone Clinic ("MSC") have significant deficits. These are described in Attachment C.

Relative to population, western North Carolina has better access to lithotripsy equipment than eastern North Carolina and HSA IV has the largest access deficit. This is illustrated in the map in Attachment A, which compares existing and proposed service sites. Atrium Urology proposes locations in the most underserved part of the state.

Competition is important. MSC Applicant members own and operate 11 of the 14 existing North Carolina lithotripters and performed over 88 percent of all NC lithotripsy procedures in FY2023, see Attachment D. Atrium Urology **proposes to introduce important balance to statewide competition.** The owner of Atrium Urology, as noted in Form O, has a percent ownership of Triangle Lithotripsy. However, Triangle Lithotripsy is not an owner of Atrium Urology. By contrast, MSC is wholly owned by three existing lithotripsy providers.

We recognize that the decision regarding these Certificate of Need ("CON") applications for the proposed mobile MRIs will be based upon the statutory CON review criteria, as outlined in G.S. 131E-183. We also understand that the Healthcare Planning and Certificate of Need Section of the Division of Health Service Regulation ("Agency") can also review conforming applications against comparative measures of the Agency's choice.

In reviewing the applications, we know that the Agency will consider the extent to which each applicant meets all statutory review criteria. We also understand that the Agency has discretion regarding Comparative Metrics in competitive batches.

COMPARATIVE METRICS

Regarding comparative metrics, we request that the Agency consider metrics that have special bearing on this identified need, specifically Geographic Accessibility and Competition. The Agency used both metrics in a recent agency review of mobile medical equipment (Mobile MRI 2023).

We also request that the Agency consider other factors related to Access by Underserved Groups, Access by Service Area Residents, and Average Operating Expenses per Procedure. We believe that any challenge associated with billing differences among applicants can be resolved from data in the applications as filed. The following describes our rationale.

Geographic Accessibility

Comparing geographic accessibility by the **total number of new host sites proposed** affords a strong measure of a more effective proposal. New host sites, especially in underserved areas, increase healthcare accessibility.

In this review, the Agency's alternative metric, Total Number Of Host Sites, masks the project's contribution to Geographic Access, because in two applications, all proposed locations have coverage. Only new host sites change the number of points of access. All applications filed indicate that it will be difficult to address the entire North Carolina statewide need with the two units of equipment permitted by the *2024 SMFP*. As noted in Table 15D-1 of the *2024 SMFP*, six of the state's 14 lithotripters are mobile and offer services at sites outside of North Carolina. However, the 2024 SMFP treats these six as if they are in service full-time in North Carolina.

Competition

While all applicants are "new legal entities," each has overlapping ownership with related entities that are currently providing mobile lithotripsy services in North Carolina. An applicant, whether direct or via a related entity, which has ownership in **fewer existing lithotripsy services** offers a more effective proposal because it will provide relatively more competitive challenge to existing services.

Access by Underserved Groups

The Agency frequently compares Total Proposed Medicare And Medicaid Beneficiaries Served to determine more effective applications. While percentage of patients, percentage of revenue, and total dollar amounts have been used in comparisons, in this review the application with the **highest total number of Medicare and Medicaid patients served** is the best indicator of a more effective proposal. Percentages can be misleading when applied to the small numbers of patients in this review.

Access by Service Area Residents

Each application utilizes North Carolina population data to support need for additional mobile lithotripsy services. The *2024 SMFP Need* permits host sites anywhere in the state, meaning there is potential for certain host sites to serve patients from outside of North Carolina – the defined service area. While this is an acceptable practice, for comparative purposes, the applicant who **proposes to serve more patients from the service area (North Carolina)** presents the more effective proposal.

Projected Average Operating Expense

The Agency can compare Projected Operating Expense per Procedure (PY3) because data in Form F.3b Expenses provides a basis for comparison, regardless of differences in proposed pricing approaches among the proposals. Applicants with the **lowest average operating expense per procedure** are a strong indicator of which proposal has presented the most effective application.

Attachment B details how the applicants compare on these metrics.

Thank you for the time and attention you and your staff give to reviewing these important and detailed documents. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kevin Khoudary, MD
Incorporator
Atrium Urology, PC

ATTACHMENTS

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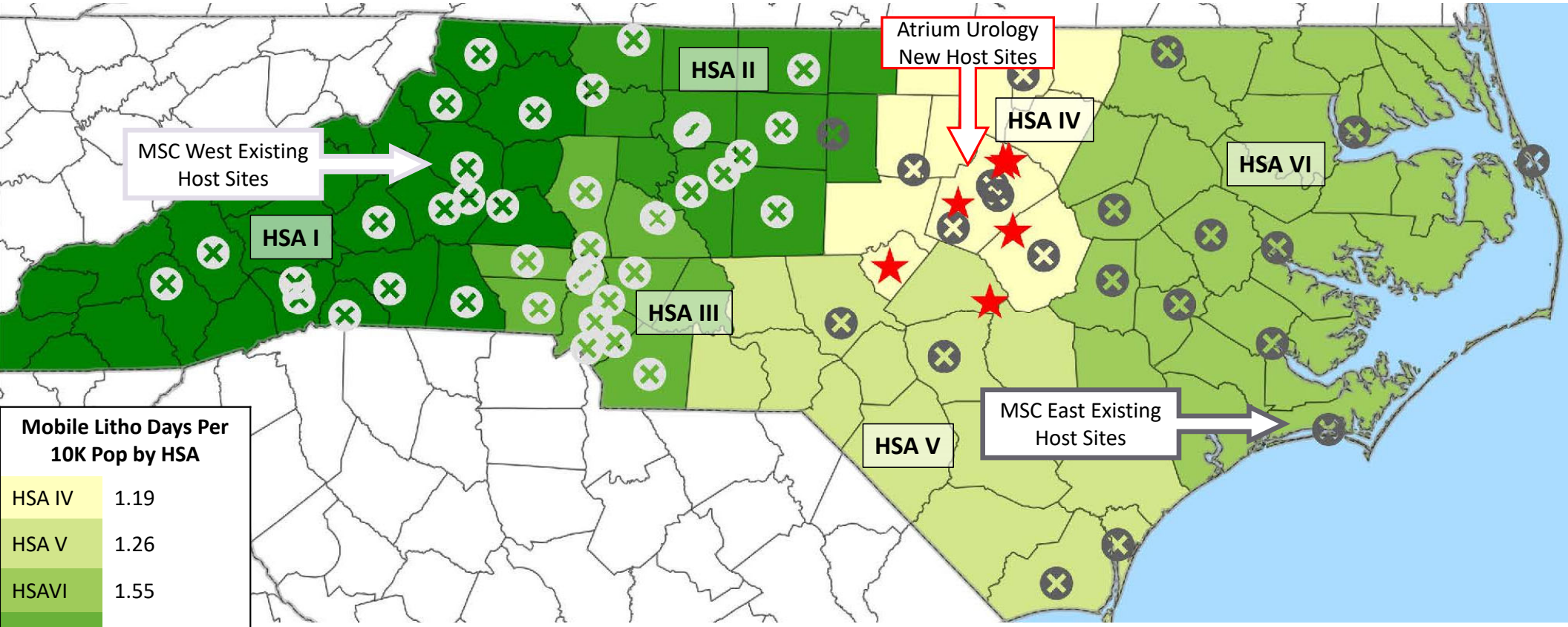
ATTACHMENT A

Existing and Proposed Host Sites Compared to Days of Service per 10,000 Population by HSA, FY2023



Mobile Litho Days Per 10K Pop by HSA	
HSA IV	1.19
HSA V	1.26
HSAVI	1.55
HSA III	3.15
HSA II	4.27
HSA I	4.29

ATTACHMENT B

Comparative Matrix: Statewide Mobile Lithotripsy 2024

Table 1: Raw Data for Proposed Comparative Matrix

Comparative Factor	Description	Reasoning	Atrium Urology	MSC East	MSC West
Geographic Accessibility	Total Number of New Host Sites	Applicant who proposes sites that do not already have providers of the service are more effective	5	0	0
Competition	Applicant with Fewer Existing Health Services	Applicant or related entity that owns / operates fewer mobile lithotriptors is more effective	1	11	11
Access by Underserved Groups	Total Number of Medicare Patients	Applicant proposing to serve more Medicare patients is more effective	332	305	305
Access by Underserved Groups	Total Number of Medicaid Patients	Applicant proposing to serve more Medicaid patients is more effective	79	61	61
	Total Number of North Carolina Patients	The service area is North Carolina; the applicant proposing to serve the most North Carolina patients is more effective	920	870	870
Projected Avg. Operating Expense	Avg. Operating Expense per Procedure	Applicant with a lower net revenue per procedure is more effective	$526	$1,568	$1,568

Table 2: Total Score by Applicant, Proposed Comparative Matrix

Comparative Factor	Description	Reasoning	Atrium Urology	MSC East	MSC West
Geographic Accessibility	Total Number of New Host Sites	Applicant who proposes sites that do not already have providers of the service are more effective	More Effective	Less Effective	Less Effective
Competition	Applicant with Fewer Health Services	Applicant or related entity that owns / operates fewer mobile lithotriptors is more effective	More Effective	Less Effective	Less Effective
Access by Underserved Groups	Total Number of Medicare Patients	Applicant proposing to serve more Medicare patients is more effective	More Effective	Less Effective	Less Effective
	Total Number of Medicaid Patients	Applicant proposing to serve more Medicaid patients is more effective	More Effective	Less Effective	Less Effective
Access by Service Area Residents	Total Number of North Carolina Patients	The service area is North Carolina; the applicant proposing to serve the most North Carolina patients is more effective	More Effective	Less Effective	Less Effective
Projected Avg. Operating Expense	Avg. Operating Expense per Procedure	Applicant with a lower net revenue per procedure is more effective	More Effective	Less Effective	Less Effective

ATTACHMENT C

Competitive Review of – Mobile Stone Clinic, LLC / Project ID #s G-012558-24 & G-012559-24

Overview

Mobile Stone Clinic, LLC ("MSC") proposes to develop two new mobile lithotripters to serve North Carolina in response to the need determination in the *2024 SMFP* for two new statewide mobile lithotripters. MSC proposes two routes, MSC-East and MSC-West, serving 22 and 41 host sites, respectively.

The Applicant submitted two virtually identical applications presented as "concurrent and complementary," (p23). As a result, the Commenter is submitting one set of comments addressing both applications together.

Both MSC applications should be found non-conforming to the following criteria: 1, 3, 4, 5, 6, 7, 8, and 18a.

Please see the discussion on the following pages for more information.

Criterion 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, ambulatory surgery operating rooms, or home health offices that may be approved.

Overview

The proposed projects are in response to a 2024 SMFP need determination for two new lithotriptors in North Carolina. They are therefore subject to Policy GEN-3: Basic Principles, which states:

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

Access

MSC's applications do not demonstrate how either will promote equitable access for the proposed lithotripsy services. Neither application demonstrates the availability of capacity at the proposed host sites to offer the proposed services, nor do they identify capacity constraints experienced by applicant members at the proposed host sites. Thus, it is not clear that proposed volumes indicate need for additional access. See discussions in Criteria 3, 7, and 8.

Value

For the expenditure of $1.8M, one application offers 11 days of service per site per year, and the other only six. See discussions in Criteria 4 and 5.

Because they do not meet GEN-3's basic principles of Access and Value, MSC's applications should be found non-conforming to Criterion 1.

Criterion 3

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

Failure to Meet Statute

The Applications state, on pages 63 and 132, that,

> *"there is no statute or rule requiring an applicant for mobile lithotripsy services to identify proposed host sites or a proposed schedule."*

This is not correct. CON Statute GS 131E-181(a) says,

> *"A certificate of need shall be valid only for the defined scope, physical location, and person named in the application…."*

Defining the host sites and the route is necessary to both define the scope and determine physical location of the proposed CON.

MSC further confuses the site issue by saying

> *"Expanding the geographic footprint of lithotripsy services is also a key goal of MSC. By identifying and establishing **new sites of care**, MSC will bring high-quality lithotripsy services closer to patients, reducing the need for long distance travel." [pp35 & 111, emphasis added]*

and

> *"…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 **lithotripter's plan must frequently change**," [p63, emphasis added].*

Together this information is confusing. It says that MSC plans to serve existing sites, but those may change; it says that MSC will also serve unidentified new sites, which could also change. Based on this contradictory and incomplete information, the Agency has no means of determining the "physical location" of either project, nor can it clearly identify proposed scope of services for either application.

Access to Services

The information on page 63 (quoted above) clearly states that MSC plans to "frequently change" its lithotripsy host sites. This suggests that despite proposing 22 eastern and 41 western host sites, the Applicant will change which and how many of those sites are served at any given time. This calls into question the Applicant's demonstration that **all residents** of the respective 54- and 46-county service areas will actually have access to services.

MSC proposes that the western route requires 41 host sites across 26 host counties to serve lithotripsy patients from 46 Western NC counties. However, the eastern route requires only 22 host sites across 19 counties to serve lithotripsy patients from 56 Eastern NC counties.
According to the methodology in Section Q, p133, both routes propose to serve exactly the same number of patients by the third project year—870.

MSC does not explain how it can serve the same number of patients from a larger service area with substantially fewer host sites. Does one route have too few sites and too broad a service area, or is one route is severely over served? Either way the means of improving access by the service area residents is unclear. See Table 1 below and detail in Attachment D.

Table 1: Comparison of MSC Host Sites, Host Counties, and Service Area Counties by Route

Route	Host Sites	Host Counties	Service Area Counties	PY3 Patients Served	Patients per Site
East	22	19	54	870	Undefined
West	41	26	46	870	Undefined

Source: Applications pp38, 125, & 133; Exhibit Q

Even the argument for increased access at individual host sites is comparatively weak. As demonstrated in the following table, neither project would average more than one extra day per month per host site or 11.4 and 6.1 annual days, respectively.

Table 2: Estimated Annual and Monthly Access Increase per MSC Host Site by Route

Metric	East Route	West Route	Sources / Notes
a. Days of Operation per Week	5	5	p132
b. Weeks of Operation per Year	50	50	p132
c. Total Annual Days of Service	250	250	a * b
d. Total Number of Host Sites	22	41	Exhibit Q
e. Total Days per Year per Host Site	11.4	6.1	c / d
f. Total Days per Month per Host Site	0.95	.51	e / 12

The average addition of one day per month per site is small impact for a service associated with extreme patient pain that calls for immediate attention. The alternative that some sites will get multiple new days per month, while other sites will get barely any over the course of a year, suggests even less increased access. See estimations in Attachment D.

Methodology Flaws

Section C.3a in both applications specifically states, "MSC will provide additional lithotripsy access to these **existing host sites**," [emphasis added, p38]. However, MSC's utilization methodology is not tied to the host sites it proposes to serve on each route. Thus, there is no way for the reviewer to determine the utilization at each respective host site.

The methodology has a serious omission regarding site of service. With **no information about utilization of individual host sites** it is impossible to determine the need that this population has for the services proposed.

Neither application provides rationale or methodology to explain capacity limitations that Applicant members currently experience at existing sites. However, both imply that if MSC adds capacity at existing sites, utilization ***will*** increase.

Patient Origin Flaws

Both applications broadly identify approximately half of the state as the respective service areas, 54 western and 46 eastern counties. Both Methodologies in Section Q estimate population need for lithotriptor services in those respective counties. However, patient origin does not include all respective counties (see p39). At best, the methodology is confusing regarding "all residents of the service area."

For these reasons, MSC's applications should be found non-conforming to Criterion 3.

Criterion 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.

In Section E, the applications address two alternatives, Status Quo and Different Host Sites. The applications fail to address the obvious alternative equipment utilization presented by the vendor quote in Exhibit F.1. The proposed equipment, a Delta III Pro, is not described in Section C.1. However, the vendor website[1] offers substantial detail on alternative deployments of the mobile version of this equipment. The website discussion on "Enhanced Efficiency"[2] indicates that all Delta III lithotriptors, including the Delta III Pro, can be "*easily transported in, out and within the facility.*"

[1] *https://www.dornier.com/products-item/dornier-delta-iii-pro/*
[2] *https://www.dornier.com/products-item/dornier-delta-iii/*

The costliest part of this proposal is the tractor, mobile trailer, and CDL driver. MSC opted to permanently install the Delta III Pro lithotriptor in a mobile trailer that it plans to park at different sites for purposes of providing services inside the trailer. The applications contain no information to demonstrate why the Applicant rejected use of proposed equipment's portability feature. That feature would have substantially reduced the capital cost of both applications and could have made services more patient friendly.

A more effective and less costly alternative was publicly available. Because the applications fail to demonstrate that proposed projects are the least costly alternative, MSC's applications should be found non-conforming to Criterion 4.

Criterion 5

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

MSC has submitted identical pro formas for its two complementary and concurrent applications.

Retail Model Revenue Not Supported

Under the proposed "retail model" MSC "will manage the lithotripsy service entirely, including providing all support services and **billing the patient or the patient's third party payor for the technical fee for the procedure**," (p62, emphasis added).

As shown in Section L of its applications, MSC proposes to provide services to Medicare and Medicaid beneficiaries. According to the CMS website, the technical billing fee falls under "Facility Price,"[3] which applies only to recognized healthcare facilities. **The Applicant is not a healthcare facility**. The applications provide no evidence to demonstrate that the Applicant will be certified as a healthcare facility for either route. CMS prohibits offering covered services to Medicare and Medicaid beneficiaries by other than certified providers.

Because Medicare and Medicaid billing is not supported, and the Applicant proposes that 42 percent of proposed services will be provided to these beneficiaries, the Applicant's Forms F.2b revenue statements are not supported. Without Medicare and Medicaid, income would be less than expenses in all three full fiscal years. See Table 3 below.

[3] https://www.cms.gov/medicare/physician-fee-schedule/search; HCPCS 50590, ESWL

Table 3: MSC's Revenues Excluding Medicare and Medicaid Beneficiaries

Metric	PY1	PY2	PY3	Notes/Sources
a. Net Revenue	$1,017,792	$1,272,240	$1,785,240	Form F.2b, p135
b. Medicare + Medicaid Percentage	42.0%	42.0%	42.0%	Section L.3b, p106
c. Net Revenue Excluding Medicare & Medicaid	$590,319	$737,899	$1,035,439	a * (1 – b)
d. Operating Expenses	$1,016,953	$1,333,754	$1,364,389	Form F.3b, p136
e. Adjusted Net Income	$(426,633)	$(595,854)	$(328,949)	c - d

The Applicant provides no alternative financial support for the project.

Payor Mix Not Supported

MSC does not explain why both routes will have identical payor mixes. The only information provided for payor mix is on page 106 where the Applicant says it is "based on the aggregate operating experience of its members in North Carolina." No further assumptions or historical data are provided to support the reasonableness of the proposed mix. It is impossible to determine from information provided whether the applications are correct.

Expenses Deficient

Neither application details proposed routes and / or days of service per site. Without this detail, it is hard to understand how expenses for a 41-site route that covers a largely mountainous area are ***exactly the same*** as the expenses for a 22-site route that covers a mostly flat coastal / piedmont region (see Form F.3b on page 136). It is likely that one is either grossly understated, or one is substantially overstated. Regardless, this attempt to be uniform casts doubt on the feasibility of MSC's financial projections.

The applications indicate that MSC will be fully responsible for all expenses but neither application provides expenses associated with access to power and / or water, access to a restroom and waiting area, and a way to transport patients from inside the host site to the trailer. See additional discussion in Criterion 8 below.

For these reasons MSC's applications should be found non-conforming to Criterion 5.

Criterion 6

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

The applications propose to duplicate services. Neither application describes capacity limitations of the proposed host sites; and each focus on increasing service days at sites already served by its members. Instead of expanding into underserved counties, MSC proposes to continue servicing host locations that have lithotripsy coverage (pp63-65). The applications lack justification for adding capacity to these existing sites. MSC's plans fail to expand geographic reach and – as presented -- duplicate services in areas that already have access.

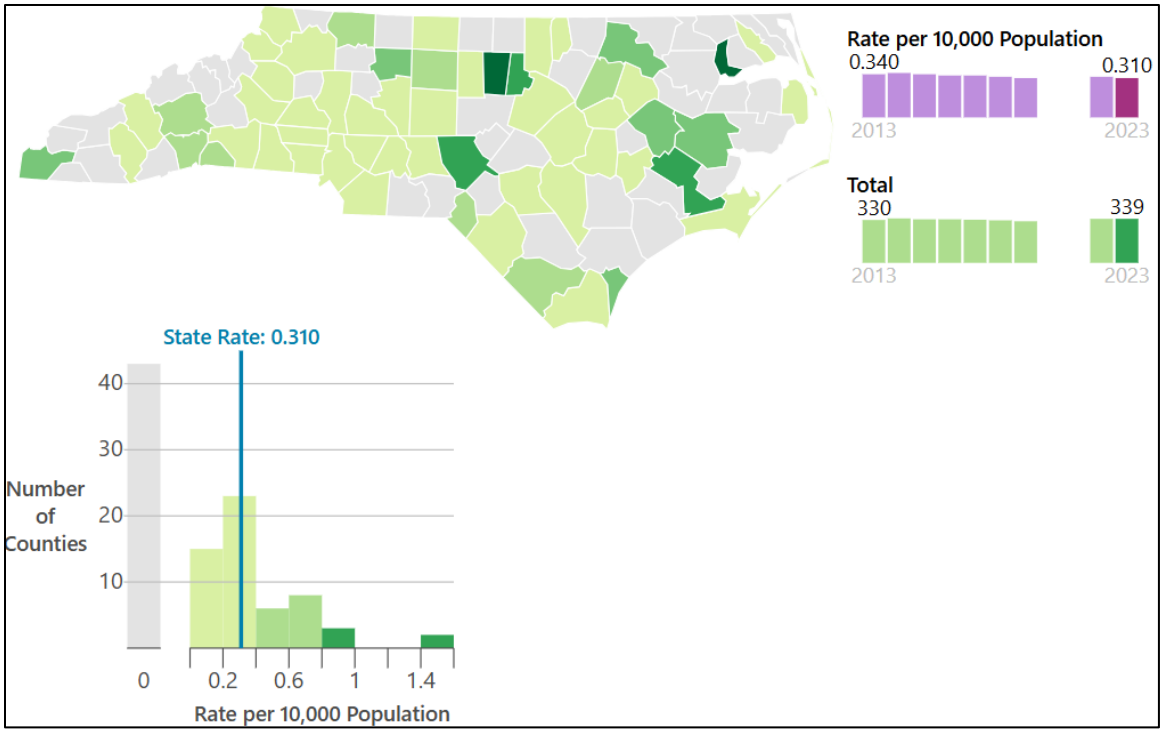
This conflicts with Criterion 6's requirement to avoid unnecessary duplication of health services and therefore MSC's applications should be found non-conforming.

Criterion 7

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

The applications clearly state that urologists are **essential** to offer lithotripsy services, see page 63. The applications provide no evidence of expanded urologist capacity to cover more days or more sites. As noted on the SHEP's Center Health Workforce website, urologists are limited, or non-existent, in many North Carolina counties.[4] See summary in Figure 1 below.

Figure 1: Physicians with a Primary Area of Practice of Urology per 10,000 Population by County, North Carolina, 2023



Source: North Carolina Health Professional Supply Data; SHEPs Health Workforce NC; https://nchealthworkforce.unc.edu/interactive/supply/

MSC fails to show evidence of the availability of essential health manpower resources and should be found non-conforming to Criterion 7.

[4] *https://nchealthworkforce.unc.edu/interactive/supply/*

Criterion 8

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

MSC would like the reader to believe that because the proposed projects will offer a "retail model" the proposed projects are fully self-contained and require no additional support from the host sites. This is not true.

As presented, the MSC mobile lithotripsy services are not self-sufficient in the proposed trailer units. The service requires a mobile service unit pad on which to park, access to power and / or water, access to a restroom and waiting area, and a way to transport patients from inside the host site to the trailer. MSC agrees. Applications say on page 100 that "[h]ost sites are responsible for providing mobile pad and appropriate patient check-in and waiting space."

With no written correspondence from the host sites, there is no confirmation that the host sites can or will accommodate additional days of service, nor the costs associated with that expansion.

Because MSC's applications fail to demonstrate the availability of all necessary ancillary services, they should be found non-conforming to Criterion 8.

Criterion 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 the service for which competition will not have a favorable impact.

In Section N.2, both applications indicate the projects will have a positive effect on competition with regard to cost-effectiveness, quality, and access. However, both applications fail to demonstrate a positive effect on cost-effectiveness or access.

Cost-Effectiveness

The applications depend on the retail model to support this criterion. See discussion in Criterion 5 above for credibility issues related to its model.

The discussion in Criterion 4 details how the Applicant's proposals are not the least costly alternative and therefore less cost-effective.

Access

MSC's presentation of contradicting statements regarding existing versus new host sites, the suggestion that host sites will frequently change, and the unsupported practicality of such broad service routes do not have a positive impact on access. See discussion in Criterion 3.

Failing either of these sub-criteria would make the MSC applications non-conforming to Criterion 18a.

ATTACHMENT D

Mobile Stone Clinic - Proposed Host Sites - Historical Utilization

Sources:
Table 15D-1, 2021 SMFP - P2025 SMFP; Exhibit Q p116
Equipment and Inventory Forms, 2020-2024
MSC Exhibit Q p116

						Applicant Member Procedures						Applicant Member Days of Service					
MSC Applicant Members	Service Site	Site Type	MSC Route	City	County	FY19	FY20	FY21	FY22	FY23	5Yr Avg	FY19	FY20	FY21	FY22	FY23	5Yr Avg
Piedmont Stone Center	Cone Health Alamance Regional	Hospital	East	Burlington	Alamance	142.0	156.0	72.0	122.0	144.0	127.2	13.0	7.0	8.0	9.0	9.0	9.2
Carolina Lithotripsy	ECU Health Beaufort Hospital	Hospital	East	Washington	Beaufort	24.0	9.0	10.0	4.0	20.0	13.4	21.0	20.0	25.0	18.0	18.0	20.4
Carolina Lithotripsy	Novant Health Brunswick Medical Center	Hospital	East	Bolivia	Brunswick	53.0	53.0	60.0	35.0	45.0	49.2	19.0	21.0	14.0	20.0	14.0	17.6
Carolina Lithotripsy	Carteret Health care	Hospital	East	Morehead City	Carteret	28.0	29.0	15.0	31.0	29.0	26.4	36.0	28.0	33.0	35.0	34.0	33.2
Fayetteville Lithotriptors - VA I	ECU Health Chowan Hospital	Hospital	East	Edenton	Chowan	23.0	21.0	11.0	18.0	8.0	16.2	45.0	36.0	24.0	23.0	12.0	28.0
Carolina Lithotripsy	Carolina East Medical Center	Hospital	East	New Bern	Craven	63.0	53.0	53.0	85.0	121.0	75.0	21.0	18.0	21.0	13.0	17.0	18.0
Carolina Lithotripsy	Highsmith Rainey Specialty Hospital	Hospital	East	Fayetteville	Cumberland	75.0	55.0	31.0	32.0	22.0	43.0	23.0	19.0	18.0	21.0	20.0	20.2
Fayetteville Lithotriptors - VA I	The Outer Banks Hospital	Hospital	East	Nags Head	Dare			8.0	1.0	9.0	6.0	14.0	17.0	15.0	12.0	11.0	13.8
Carolina Lithotripsy	ECU Health North Hospital	Hospital	East	Roanoke Rapids	Halifax	31.0	33.0	30.0	22.0	21.0	27.4	70.0	78.0	78.0	70.0	68.0	72.8
Carolina Lithotripsy	UNC Health Johnston	Hospital	East	Smithfield	Johnston	56.0	42.0	51.0	40.0	53.0	48.4	64.0	48.0	52.0	41.0	37.0	48.4
Carolina Lithotripsy	UNC Lenoir Health Care	Hospital	East	Kinston	Lenoir	18.0	30.0	17.0	16.0	13.0	18.8	60.0	61.0	69.0	51.0	44.0	57.0
Carolina Lithotripsy	FirstHealth Moore Regional Hospital	Hospital	East	Pinehurst	Moore	197.0	223.0	196.0	201.0	173.0	198.0	10.0	8.0	14.0	5.0	2.0	7.8
Carolina Lithotripsy	New Hanover Regional Medical Center	Hospital	East	Wilmington	New Hanover	116.0	111.0	105.0	80.0	102.0	102.8					9.0	9.0
Fayetteville Lithotriptors - VA I	UNC Hospitals Ambulatory Surgery Center	ASC	East	Chapel Hill	Orange					2.0	2.0	26.0	22.0	25.0	26.0	24.0	24.6
Carolina Lithotripsy	ECU Health Medical Center	Hospital	East	Greenville	Pitt	164.0	169.0	170.0	177.0	161.0	168.2	38.0	37.0	36.0	30.0	36.0	35.4
Piedmont Stone Center	Maria Parham Health	Hospital	East	Henderson	Vance	38.0		32.0	25.0	30.0	31.3	12.0	13.0	19.0	20.0	12.0	15.2
Carolina Lithotripsy	Duke Raleigh Hospital	Hospital	East	Raleigh	Wake	21.0		25.0	8.0	2.0	14.0	11.0	11.0	4.0	8.0	10.0	8.8
Carolina Lithotripsy	Holly Springs Surgery Center	ASC	East	Holly Springs	Wake					25.0	25.0	8.0	8.0	8.0	11.0	5.0	8.0
Carolina Lithotripsy	Rex Surgery Center of Cary	ASC	East	Cary	Wake	79.0	68.0	71.0	82.0	87.0	77.4			4.0	1.0	5.0	3.3
Carolina Lithotripsy	WakeMed	Hospital	East	Raleigh	Wake	91.0	81.0	89.0	70.0	64.0	79.0					1.0	1.0
Carolina Lithotripsy	Wayne UNC Health Care	Hospital	East	Goldsboro	Wayne	22.0	20.0	35.0	47.0	22.0	29.2	46.0	48.0	48.0	46.0	47.0	47.0
Carolina Lithotripsy	Wilson Medical Center	Hospital	East	Wilson	Wilson	11.0	12.0	6.0	10.0	19.0	11.6	22.0	14.0	22.0	17.0	18.0	18.6
Piedmont Stone Center	Ashe Memorial Hospital	Hospital	West	Jefferson	Ashe				3.0	50.0	26.5	46.0	34.0	41.0	36.0	39.0	39.2
Piedmont Stone Center	UNC Health Blue Ridge Morganton	Hospital	West	Morganton	Burke	78.0	90.0	72.0	49.0	36.0	65.0	1.0	10.0	12.0	13.0	13.0	9.8
Piedmont Stone Center	UNC Health Blue Ridge Valdese	Hospital	West	Valdese	Burke	112.0	76.0	110.0	119.0	158.0	115.0	36.0	38.0	22.0	19.0	16.0	26.2
Stone Institute of the Carolinas	Atrium Health Cabarrus	Hospital	West	Concord	Cabarrus	146.0	126.0	115.0	149.0	194.0	146.0	45.0	43.0	39.0	34.0	45.0	41.2
Piedmont Stone Center	Caldwell UNC Health Care	Hospital	West	Lenoir	Caldwell	64.0	61.0	97.0	72.0	96.0	78.0	38.0	35.0	36.0	41.0	48.0	39.6
Fayetteville Lithotriptors - SC II	Frye Regional Medical Center	Hospital	West	Hickory	Catawba	1.0	13.0	18.0	19.0	27.0	15.6				1.0	2.0	1.5
Stone Institute of the Carolinas	Atrium Health Cleveland	Hospital	West	Shelby	Cleveland	172.0	143.0	124.0	139.0	147.0	145.0	19.0	12.0	14.0	14.0	15.0	14.8
Piedmont Stone Center	Atrium Health WFB Lexington	Hospital	West	Lexington	Davidson	92.0		110.0	133.0	122.0	114.3	9.0	14.0	14.0	8.0	6.0	10.2
Piedmont Stone Center	Novant Health Thomasville Medical Center	Hospital	West	Thomasville	Davidson	37.0	34.0	16.0	21.0	8.0	23.2				1.0	19.0	10.0
Piedmont Stone Center	Atrium Health WFB	Hospital	West	Winston-Salem	Forsyth	20.0	21.0	149.0	20.0	30.0	48.0	188.0	169.0	174.0	199.0	202.0	186.4
Piedmont Stone Center	Novant Health Forsyth Medical Center	Hospital	West	Winston-Salem	Forsyth	76.0		72.0	100.0	111.0	89.8	95.0	96.0	97.0	97.0	94.0	95.8
Piedmont Stone Center	Piedmont Stone Center, PLLC	Physican Office	West	Winston-Salem	Forsyth	626.0	596.0	590.0	726.0	752.0	658.0	14.0	17.0	7.0	10.0	4.0	10.4
Stone Institute of the Carolinas	CaroMont Regional Medical Center	Hospital	West	Gastonia	Gaston	196.0	265.0	164.0	294.0	342.0	252.2	43.0	40.0	28.0	33.0	33.0	35.4
Piedmont Stone Center	Atrium Health WFB High Point Medical Center	Hospital	West	High Point	Guilford	436.0	453.0	136.0	344.0	406.0	355.0	36.0	33.0	39.0	37.0	38.0	36.6
Piedmont Stone Center	Cone Health	Hospital	West	Greensboro	Guilford	331.0	367.0	299.0	308.0	309.0	322.8	129.0	138.0	133.0	124.0	134.0	131.6
Fayetteville Lithotriptors - SC II	Haywood Regional Medical Center	Hospital	West	Clyde	Haywood	96.0	96.0	91.0	61.0	82.0	85.2			4.0	29.0	41.0	24.7
Fayetteville Lithotriptors - SC II	Advent Health Hendersonville	Hospital	West	Hendersonville	Henderson	79.0	53.0	50.0	78.0	97.0	71.4	30.0	26.0	12.0	11.0	16.0	19.0
Fayetteville Lithotriptors - SC II	Margaret Pardee Hospital	Hospital	West	Hendersonville	Henderson	101.0	56.0	78.0	69.0	73.0	75.4	30.0	33.0	28.0	15.0	15.0	24.2
Piedmont Stone Center	Iredell Memorial Hospital	Hospital	West	Statesville	Iredell	110.0		48.0	125.0	95.0	94.5	48.0	48.0	41.0	40.0	45.0	44.4
Stone Institute of the Carolinas	Lake Norman Regional Medical Center	Hospital	West	Mooresville	Iredell	154.0	138.0	136.0	195.0	137.0	152.0	63.0	69.0	55.0	76.0	80.0	68.6
Fayetteville Lithotriptors - SC II	Harris Regional Medical Center	Hospital	West	Sylva	Jackson	75.0	57.0	35.0	23.0	21.0	42.2	50.0	47.0	46.0	46.0	43.0	46.4
Stone Institute of the Carolinas	Atrium Health Lincoln	Hospital	West	Lincolnton	Lincoln	1.0			2.0	2.0	1.7	46.0	57.0	67.0	55.0	53.0	55.6

Mobile Stone Clinic - Proposed Host Sites - Historical Utilization

Sources:
Table 15D-1, 2021 SMFP - P2025 SMFP; Exhibit Q p116
Equipment and Inventory Forms, 2020-2024
MSC Exhibit Q p116

						Applicant Member Procedures						Applicant Member Days of Service					
MSC Applicant Members	**Service Site**	**Site Type**	**MSC Route**	**City**	**County**	**FY19**	**FY20**	**FY21**	**FY22**	**FY23**	**5Yr Avg**	**FY19**	**FY20**	**FY21**	**FY22**	**FY23**	**5Yr Avg**
Fayetteville Lithotriptors - SC II	Mission Hospital McDowell	Hospital	West	Marion	McDowell				1.0	3.0	2.0	11.0	9.0	6.0	11.0	12.0	9.8
Stone Institute of the Carolinas	Atrium Health Huntersville	Hospital	West	Huntersville	Mecklenburg	86.0		83.0	108.0	56.0	83.3	25.0	25.0	21.0	20.0	24.0	23.0
Stone Institute of the Carolinas	Atrium Health Pineville	Hospital	West	Charlotte	Mecklenburg	425.0	345.0	182.0	142.0	136.0	246.0				11.0	-	5.5
Stone Institute of the Carolinas	Atrium Health Universiy City	Hospital	West	Charlotte	Mecklenburg	225.0	207.0	144.0	119.0	145.0	168.0	38.0	39.0	32.0	18.0	43.0	34.0
Stone Institute of the Carolinas	Carolinas HealthCare System Mercy	Hospital	West	Charlotte	Mecklenburg	134.0	82.0		41.0	87.0	86.0	31.0	22.0	28.0	33.0	7.0	24.2
Stone Institute of the Carolinas	Novant Health Huntersville Medical Center	Hospital	West	Huntersville	Mecklenburg					81.0	81.0	45.0	50.0	49.0	46.0	41.0	46.2
Stone Institute of the Carolinas	Novant Health Matthews Medical Center	Hospital	West	Matthews	Mecklenburg		102.0	66.0	131.0	99.0	99.5	44.0	53.0	53.0	48.0	51.0	49.8
Stone Institute of the Carolinas	Novant Health Presbyterian Medical Center	Hospital	West	Charlotte	Mecklenburg	124.0	193.0	101.0	96.0	56.0	114.0	47.0	49.0	49.0	50.0	50.0	49.0
Fayetteville Lithotriptors - SC II	St. Luke's Hospital	Hospital	West	Columbus	Polk	14.0	24.0	19.0	11.0	6.0	14.8			-	17.0	17.0	11.3
Piedmont Stone Center	Randolph Hospital	Hospital	West	Asheboro	Randolph	155.0	126.0	77.0	81.0	80.0	103.8	1.0	-	-	2.0	2.0	1.0
Piedmont Stone Center	Cone Health Annie Penn Hospital	Hospital	West	Reidsville	Rockingham			11.0	65.0	100.0	58.7		91.0	91.0	51.0	50.0	70.8
Piedmont Stone Center	Novant Health Rowan Medical Center	Hospital	West	Salisbury	Rowan	221.0	110.0	127.0	107.0	84.0	129.8	74.0	77.0	77.0	53.0	51.0	66.4
Piedmont Stone Center	Salisbury VA Health Care System	Hospital	West	Salisbury	Rowan				34.0		34.0	41.0	39.0	39.0	52.0	50.0	44.2
Fayetteville Lithotriptors - SC II	Rutherford Regional Medical Center	Hospital	West	Rutherfordton	Rutherford	40.0	28.0	29.0	28.0	32.0	31.4	39.0	24.0	24.0	37.0	93.0	43.4
Piedmont Stone Center	Hugh Chatham Memorial Hospital	Hospital	West	Elkin	Surry	180.0		133.0	122.0	140.0	143.8	59.0	76.0	76.0	99.0	100.0	82.0
Piedmont Stone Center	Northern Regional Hospital	Hospital	West	Mount Airy	Surry	54.0	45.0	12.0	24.0	36.0	34.2	48.0	55.0	55.0	52.0	40.0	50.0
Stone Institute of the Carolinas	Atrium Health Union	Hospital	West	Monroe	Union	208.0	161.0	63.0	162.0	192.0	157.2	107.0	122.0	122.0	84.0	98.0	106.6
Piedmont Stone Center	Watauga Medical Center	Hospital	West	Boone	Watauga	161.0	134.0	135.0	133.0	112.0	135.0	47.0	46.0	46.0	56.0	52.0	49.4
Piedmont Stone Center	Atrium WFP Wilkes Medical Center	Hospital	West	North Wilkesboro	Wilkes	86.0	75.0	7.0	59.0	67.0	58.8	55.0		-		50.0	35.0
	Total Procedures & Days from MSC Member Entities at Proposed MSC East Route Host Sites Only					*1,252.0*	*1,165.0*	*1,087.0*	*1,106.0*	*1,172.0*		***2,237.0***	***2,250.0***	***2,214.0***	***2,156.0***	***2,285.0***	
	Total Procedures & Days from MSC Member Entities at Proposed MSC Host Sites Only					***7,478.0***	***6,451.0***	***5,801.0***	***6,603.0***	***7,007.0***		*559.0*	*514.0*	*537.0*	*477.0*	*453.0*	
	Total Procedures & Days from MSC Member Entities at Proposed MSC West Route Host Sites Only					*5,116.0*	*4,277.0*	*3,699.0*	*4,513.0*	*4,807.0*		*1,678.0*	*1,736.0*	*1,677.0*	*1,679.0*	*1,832.0*	
	Total Procedures & Days from MSC Member Entities, All Reported Host Sites					*7,481.0*	*6,087.0*	*5,853.0*	*6,944.0*	*7,377.0*		*2,726.0*	*2,762.0*	*2,775.0*	*2,695.0*	*2,688.0*	
	Total Procedures & Days from All North Carolina Providers					*8,952.0*	*7,268.0*	*7,030.0*	*7,926.0*	*8,314.0*		*3,245.0*	*3,255.0*	*3,248.0*	*3,188.0*	*3,174.0*	
	MSC Members as Percent of Total Reported Procedures & NC Days					*83.6%*	*83.8%*	*83.3%*	*87.6%*	*88.7%*		*84.0%*	*84.9%*	*85.4%*	*84.5%*	*84.7%*	

ATTACHMENT E

Date: _____

Delivered via email

Ms. Micheala Mitchell, Chief
Ms. Cynthia Bradford, Analyst
Cynthia.Bradford@dhsr.nc.gov
Dhsr.CON.comments@dhsr.nc.gov

RE: Letter of Support for Atrium Urology, PC's Certificate of Need Application for Mobile Lithotripsy

Dear Ms. Mitchell and Ms. Bradford,

I am writing this letter expressing support for the Certificate of Need ("CON") application from Atrium Urology, PC, to acquire one new mobile lithotriptor to service the state of North Carolina in response to the need determination in the *2024 State Medical Facilities Plan*.

As primary care provider, I see patients presenting with urinary stone symptoms. When this occurs, my next step is to refer patients to a urologist for specialty care, either through an office appointment or through the local emergency department. When this happens, patients often see providers from Associated Urologists of North Carolina, PA, one of the only urology practices serving patients in our area.

As a primary care provider, I understand that lithotripsy is an important therapeutic service for clinically appropriate patients with urinary stones. I serve patients in and around Wake County and am keenly aware of the limited access to lithotripsy in this service area. Urinary stones are very painful. Because of the limited access to lithotripsy, scheduling an appointment can take weeks. This is less than ideal and often forces patients to opt for more expensive and invasive surgery.

I understand that Associated Urologist of North Carolina, PA, and other urologists, will be able to refer urinary stone patients to the proposed Atrium Urology, PC mobile lithotriptor. Its availability will alleviate the scheduling stress, allowing patients better access to a less expensive and non-invasive therapeutic alternative. I am particularly thankful to know that Atrium Urology will be adding service sites in Lee and Harnett Counties, which previously had no in-county service, as well as adding sites in Wake County closer to patients in Franklin and Chatham Counties.

I treat patients from the following counties:
Wake (Lee) Chatham Harnett Johnston

My specialty is PRIMARY CARE

Name: Email:

Practice: Phone:

Address: Central Carolina Hospital

Signature: Gerald O'Donnell, MD

Gerald O'Donnell, MD