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May 31, 2023

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

Project ID	Name
G-12365-23	Alliance Healthcare Services, Inc.
F-12368-23	Carolina Neurosurgery & Spine Associates, P.A.
F-12381-23	Carolina Neurosurgery & Spine Associates, P.A.
J-12378-23	Duke University Health System, Inc
J-012359-23	EmergeOrtho, PA
J-012358-23	EmergeOrtho, PA
J-012357-23	EmergeOrtho, PA
G-12372-23	Novant Health, Inc
G-12373-23	Novant Health, Inc
J-12375-23	Pinnacle Health Services of NC, LLC

Dear Ms. Mitchell, Mr. McKillip, and Mr. Yakaboski,

On behalf of EmmergeOrtho, PA (“EmmergeOrtho”) which submitted Project IDs, J-012359-23, J-102358-23, and J-012357-23, thank you for the opportunity to comment on the above-referenced applications for a mobile Magnetic Resonance Imaging scanner (“MRI”) which were submitted in response to a 2023 Statewide need determination for three additional mobile magnetic resonance imaging units.



Historically, inclusion of need for any mobile MRI units in a State Medical Facilities Plan is a rare occurrence; the 2023 SMFP included a need for three. In addition, the SMFP typically calculates the need for fixed MRI scanners based on smaller geographic service areas across the State; the 2023 SMFP said the need for these 3 mobile units was statewide in nature. With that in mind, EmERGEOrtho viewed this process as a remarkable opportunity to propose projects that would have mobile MRI services going into communities that have a documented need for the service, but that also may not have easy access to it. The decision on this group of competitive applications will have a lasting impact on residents across the state of North Carolina. Of the six applicants, only EmERGEOrtho has put forth proposals that truly meet the “statewide service area.” Our applications not only propose service to the greatest number of North Carolina counties, but also the largest number of new host sites.

EmERGEOrtho is uniquely positioned to serve a statewide service area. First, EmERGEOrtho is an orthopedic, musculoskeletal, and spine practice. MRI scans used in the support and diagnosis of orthopedic, musculoskeletal, and spine diseases and injuries make up 52 percent of all MRI scans.¹

EmERGEOrtho is the largest orthopedic physician group in North Carolina and the 5th largest in the United States. It has 48 locations stretching from the coast to the mountains. EmERGEOrtho maintains a single medical records database ensuring patients and physicians can access their information regardless of where they are. EmERGEOrtho provides both same-day and walk-in appointments, as well as online scheduling. Because EmERGEOrtho physicians will refer patients to the proposed MRIs, it can ensure no disruption or delay in care.

EmERGEOrtho values high-quality care at an appropriate price point. All locations participate in Medicare and Medicaid, including all five NC Medicaid Managed Care Plans. EmERGEOrtho accepts the majority of commercial insurance payors and offers affordable options for patients without insurance benefits.

Together, its scope of scan types, ease of existing statewide access for patients, and affordable care make EmERGEOrtho an ideal candidate for statewide mobile MRI services.

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”) also can review conforming applications against comparative measures of the Agency’s choice.

In this batch of ten applications, only a few metrics are comparable across all. This reduces truly comparative measures to **Access, Competition, and Quality**.

¹ Luxenburg, Osnat, et al. “National and Regional Trends in MRI Utilization in the Face of the Ongoing COVID-19 Pandemic.” Israel Journal of Health Policy Research, vol. 10, no. 1, 2021, <https://doi.org/10.1186/s13584-021-00472-y>.



Comparison Metrics

Access

The Agency has used several metrics to compare Access:

- Total number of host sites;
- Total number of new host sites;
- Total number of counties served; and
- Percentage of patients served from NC.

EmERGEOrtho excels at all four of these comparatives:

- All three routes each offer four host sites; only PHSNC and Novant East offer more;
- Blue Ridge / Foothills and Triad each offer three new MRI host sites; Triangle offers one; no applicant offers more new sites than EmERGEOrtho;
- Blue Ridge / Foothills offers the most counties to be served, followed closely by Triad and Triangle;
- EmERGEOrtho is a North Carolina-based practice and proposes to serve all North Carolina residents.

The map in Attachment B shows EmERGEOrtho's proposed coverage compared to all other applicants.

Competition

In this batch, every applicant owns MRI units. So, none could be selected on the basis of offering a new competitive alternative. However, the Agency could compare percentage increase in total MRI scanners. This would measure new competition. While EmERGEOrtho does own some fixed and mobile MRI scanners, compared to Alliance, Novant or Duke, its added presence in the market will enhance competition, not enlarge a monopoly.

Quality

Continuity of care is important. With regard to a key diagnostic imaging tool, like MRI, timing is key. The sooner a patient can receive a scan and get its results, the sooner a diagnosis and subsequent care plan can begin. Unlike applicants who are proposing to park and provide a service to another provider, EmERGEOrtho is proposing to park at its own locations. That means there is no delay or disruption in care. With a single medical record, EmERGEOrtho eliminates opportunities for data loss or data error in an exchange between providers.

Comparison of each of these metrics are summarized in Attachment A.



Individual Applicants

Some applications have shortcomings that make them non-conforming to one or more statutory criteria. These are discussed in detail in the Competitive Review included with this letter (Attachments C through H).

Sincerely,

Allison Farmer
Chief Executive Officer

Attachment(s)

Attachments

Comparative Matrix: Raw Data and Scoring A

Comparison Map: Proposed Counties Served and New and Existing Host Sites B

G-12365-23, Alliance Healthcare Services, Inc. C

F-12368-23 & F-12381-23, Carolina Neurosurgery & Spine Associates, P.A. D

J-12378-23, Duke University Health System, Inc E

G-12372-23, Novant Health, Inc F

G-12373-23, Novant Health, Inc G

J-12375-23, Pinnacle Health Services of NC, LLC H

Comparative Matrix: Statewide Mobile MRI 2023

Table 1: Raw Data for Proposed Comparative Matrix

Comparative Factor	EmergeOrtho Triangle	EmergeOrtho Triad	EmergeOrtho Blue Ridge	CNSA #1	CNSA #2	Alliance	Novant 1 East	Novant 2 West	PHSNC	Duke Imaging
Conformity to Statutory Review Criteria	Yes	Yes	Yes	No	No	No	No	No	No	No
Geographic Accessibility – <i>Total Number of Host Sites (Highest)</i>	4	4	4	3	2	3	5	3	5	4
Geographic Accessibility – <i>Total Number of New Host Sites (Highest)</i>	1	3	3	2	-	-	-	2	-	2
Geographic Accessibility – <i>Total Number of Counties Served (Highest)</i>	8	7	12	5	8	3	4	3	6	10
Access by Service Area Residents – <i>Percent of Patients from NC (Highest)</i>	100.0%	100.0%	100.0%	70.1%	75.3%	100.0%	100.0%	100.0%	81.1%	91.0%
Competition – <i>Percent Increase of Owned MRI Scanners (Highest)</i>	37.5%	37.5%	37.5%	66.7%	66.7%	3.7%	4.0%	4.0%	50.0%	5.9%
Continuity of Care (Quality) – <i>Zero Transition between Ordering Provider and Imaging Service</i>	Yes	Yes	Yes	Yes	Yes	No	No	No	No	Yes

Table 2: Total Score by Applicant, Proposed Comparative Matrix – Highest Score is Most Effective

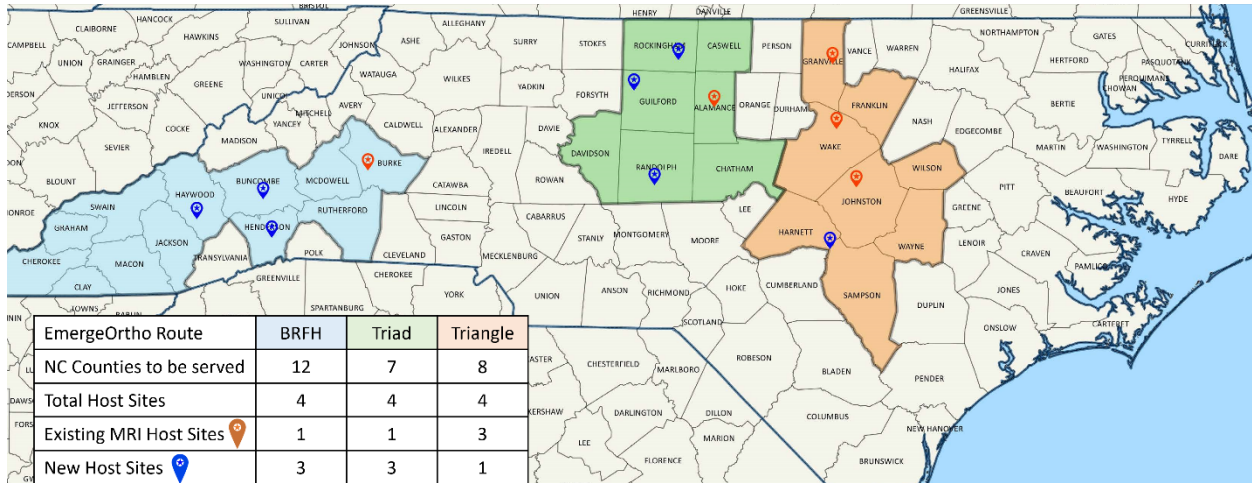
Comparative Factor	EmergeOrtho Triangle	EmergeOrtho Triad	EmergeOrtho Blue Ridge	CNSA #1	CNSA #2	Alliance	Novant 1 East	Novant 2 West	PHSNC	Duke Imaging
Conformity to Statutory Review Criteria rev criteria	3	3	3	1	1	1	1	1	1	1
Geographic Accessibility – Total Number of Host Sites	2	2	2	1	1	1	3	1	3	2
Geographic Accessibility – Total Number of New Host Sites	1	3	3	2	1	1	1	2	1	2
Geographic Accessibility – Total Number of Counties Served	2	1	3	1	2	1	1	1	1	2
Access by Service Area Residents – Percent of Patients from NC	3	3	3	1	1	3	3	3	1	2
Competition – Percent Increase of Owned MRI Scanners	2	2	2	3	3	1	1	1	3	1
Continuity of Care (Quality) – Zero Transition between Ordering Provider and Imaging Service	3	3	3	3	3	1	1	1	1	3
Total Score	16.0	17.0	19.0	12.0	12.0	9.0	11.0	10.0	11.0	13.0
Rank	3	2	1	5	5	10	7	9	7	4

Scoring Notes:
 Most Effective = 3
 More Effective = 2
 Least Effective = 1

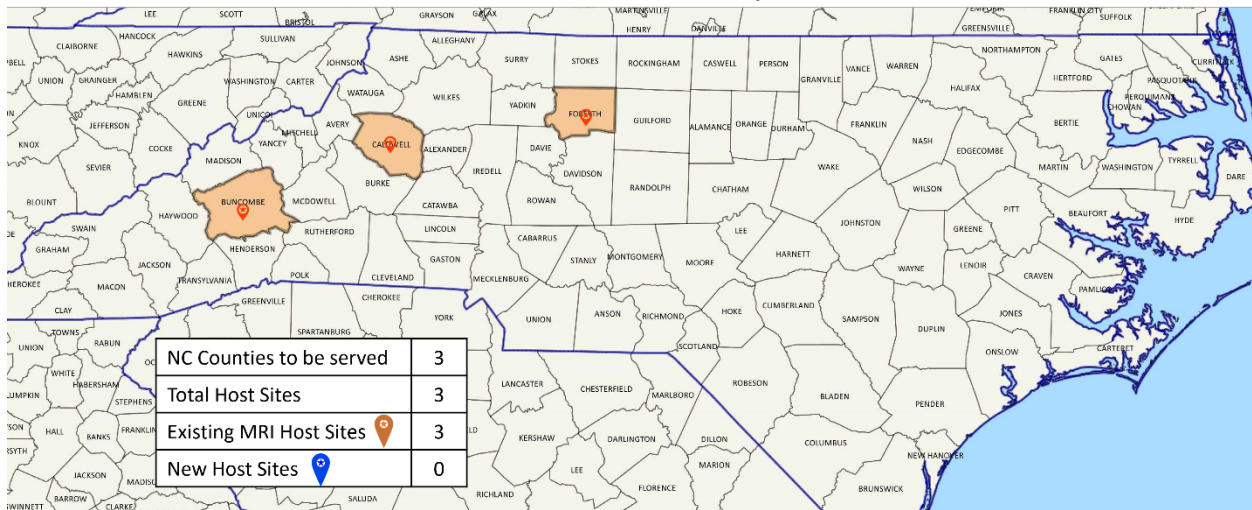
ATTACHMENT B

Comparison of Proposed NC Counties to be Served, New and Existing Host Sites by Applicant; Statewide Mobile MRI 2023

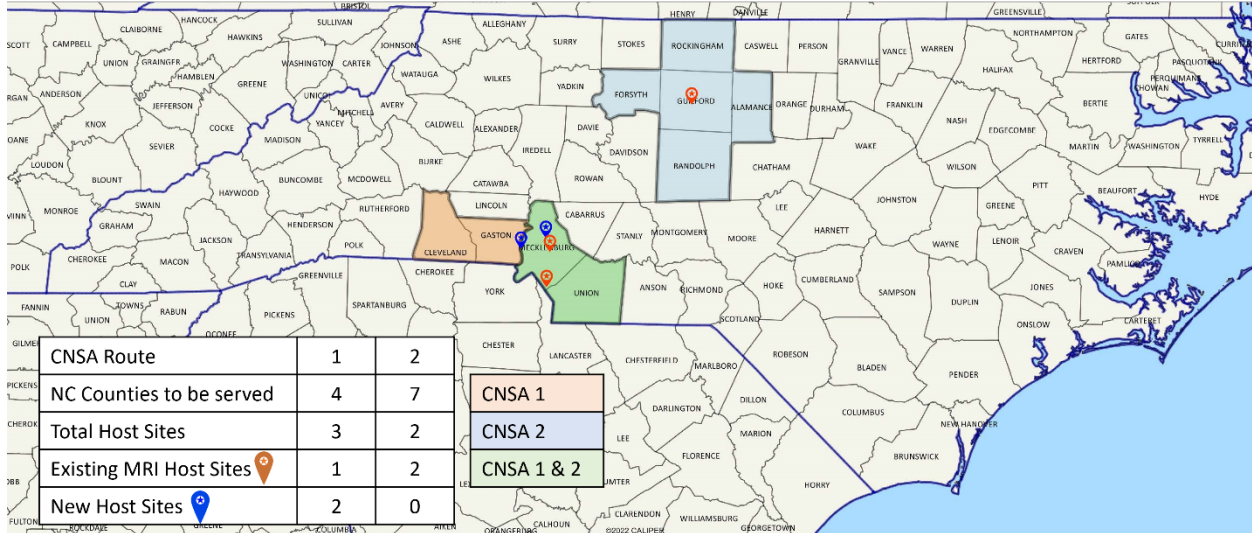
EmergeOrtho, PA



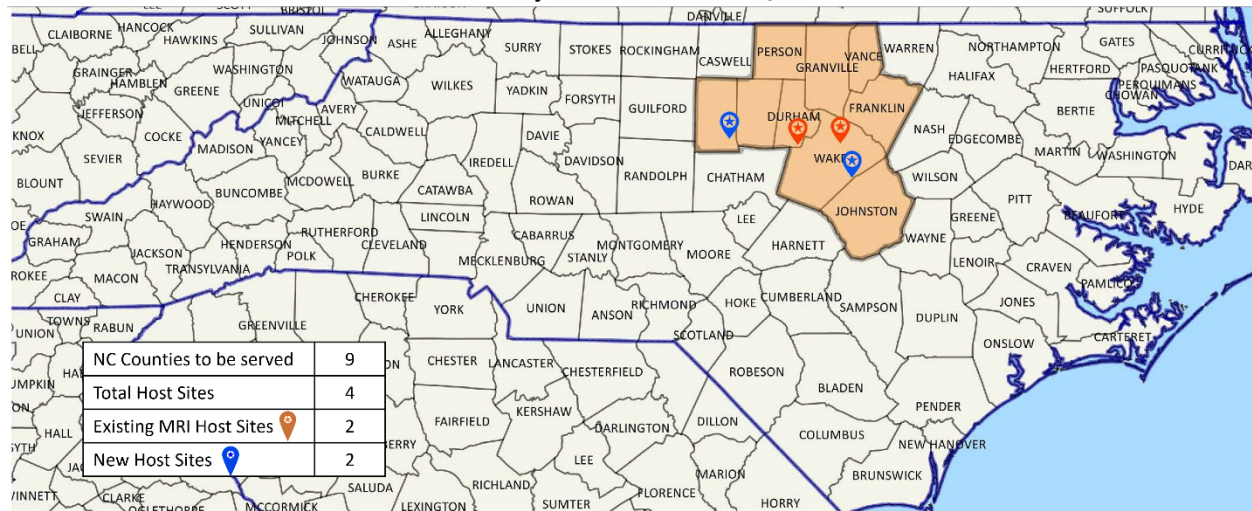
Alliance Healthcare Services, Inc.



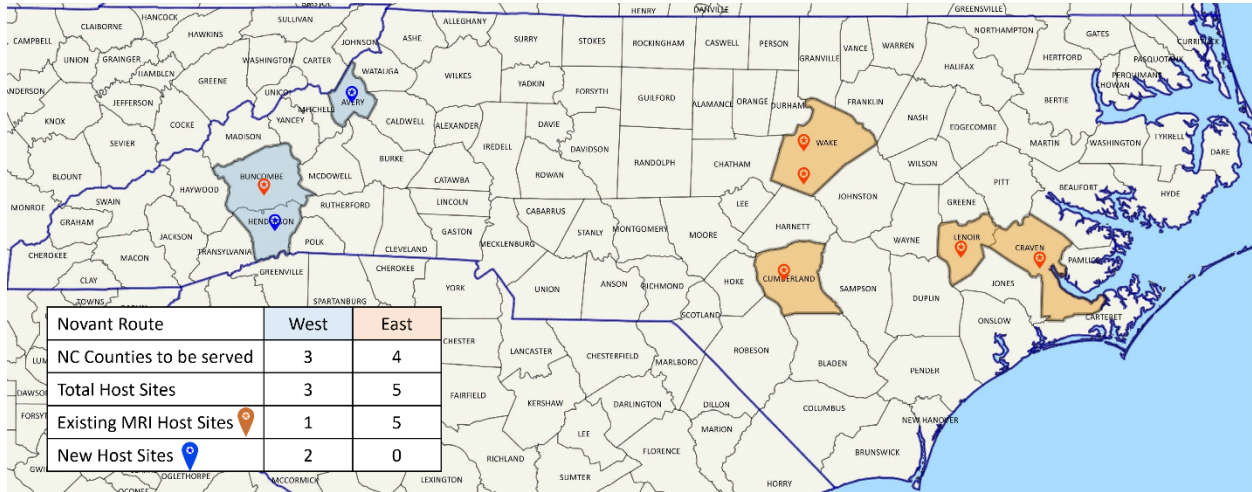
Carolina Neurosurgery & Spine, PA



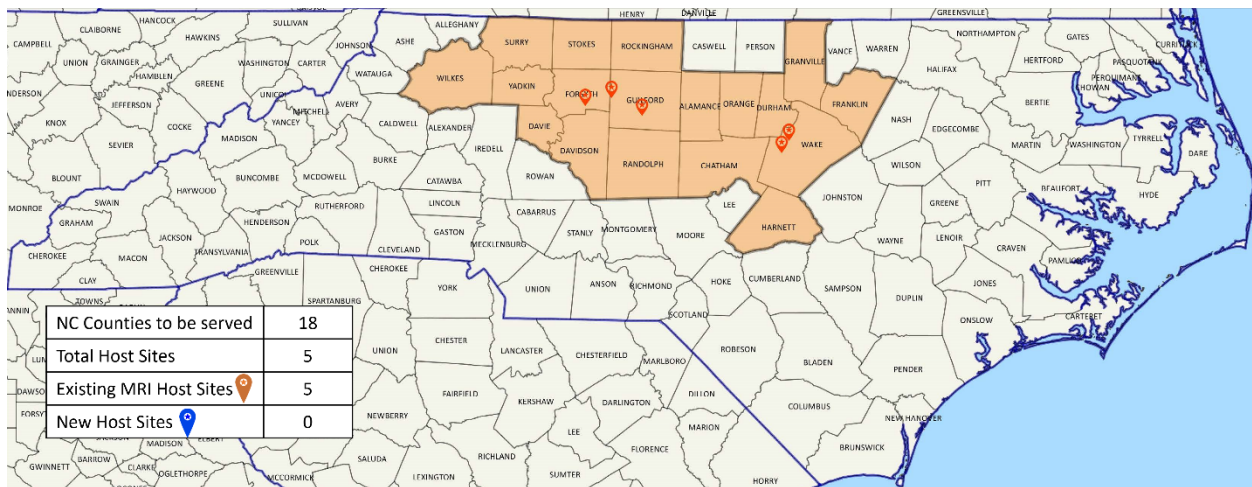
Duke University Health Services, Inc.



Novant Health-Norfolk, LLC



Pinnacle Health Services of North Carolina, LLC



**Competitive Review of –
Alliance Healthcare Services, Inc., G-12365-23**

Overview

Alliance Healthcare Services, Inc. (“Alliance”) submitted an application to acquire one new mobile Magnetic Resonance Imaging scanner (“MRI”) in response to the 2023 SMFP need determinations for three new statewide mobile MRIs.

The application proposes to acquire a mobile GE Signa Voyager 1.5 Tesla (“1.5T”) MRI scanner in a mobile trailer. Alliance proposes three stops: UNC Caldwell Memorial Hospital in Hickory, Caldwell County; Southeastern Sports Medicine in Asheville, Buncombe County; and Wake Forest Outpatient in Winston-Salem, Forsyth County.

As illustrated in the following discussion, the Alliance application is non-conforming with statutory review criteria 1, 3, 5, and 6.

CON Review Criteria

- 1. 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.**

As described in Criterion 3 below, Alliance does not demonstrate that its proposal’s, “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.” Alliance should therefore be found non-conforming to Criterion 1.

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.

Alliance makes no attempt to demonstrate that the proposed population to be served has a need for additional MRI services. Section C of the application offers no analysis of the population of its proposed three host site counties. The entire “demonstration of need” in response to Section C.4 is in the first paragraph on page 36: “Alliance proposes to acquire a mobile MRI scanner to respond to the need for additional mobile capacity that is identified in the 2023 State Medical Facilities Plan. The table on the following page provides the list of the mobile MRI host sites for the proposed project.” There is no table on the following page. There is a table on page 28.

The implicit assumption is that agreement from a host site to accept service from Alliance is sufficient demonstration of need. This is not true. In fact, one host site, UNC Caldwell Memorial Hospital (“Caldwell Memorial”), may actually be over-served if it adds service from this proposed mobile MRI.

Caldwell Memorial is in Caldwell County, for which the *2023 State Medical Facilities Plan* (“SMFP”) includes a need determination for one additional fixed MRI scanner. On page 30, the application reports the use of the fixed MRI scanner at Caldwell Memorial as 2,646 scans, which is far short of the 6,240-scan capacity listed on page 332 of the *2023 SMFP*.

On page 30, the application says it will provide total scans at Southeastern Sports Medicine, but there is nothing on pages 30-32. The application also lacks the referenced information for Southeastern Sports Medicine.

Because the application provides no projected patient origin for the proposed mobile the reader is left to assume that Caldwell Memorial patients follow the hospital’s historical pattern and 85 percent will come from Caldwell County. The application makes no attempt to explain why a population of just over 80,000 residents will need both a new fixed and the proposed mobile MRI scanners.

For reference, the Commenter used MRI Adjusted Scan Use Rate for both Caldwell County and the State for FY2021. Admittedly, Caldwell County has a low use rate compared to the State. However, even at the state average, which is almost twice that of Caldwell County, there will still be a surplus capacity of MRI scanners with the proposed mobile unit alone.

The application makes no attempt to define the need at either Wake Forest Outpatient in Forsyth County or Southeastern Sports Medicine in Buncombe County.

Because it failed to clearly identify the population to be served and did not demonstrate the need that this population has for the proposed mobile MRI services, Alliance should be found non-conforming to Criterion 3.

Finally, it is curious to note that Alliance does not propose service to Carolina Neurosurgery & Spine Associates, PA, another applicant in this batch who indicates in its CON applications that it has reached out to Alliance numerous times, asking for more MRI scanner time.

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.

On page 56 and in the letter in Exhibit F.2 states as “documented in the application, Alliance has been acquired by Akumin Inc.” Exhibit A.1 does not include anything related to Akumin. There is no organizational chart to explain what, if any, authority Alliance and/or Akumin have to commit funds to the proposed project.

The letter in Exhibit F.2 is also written for funds related to acquiring a mobile PET/CT scanner, not a mobile MRI. The letter goes on to quote costs related to a project that does not match those in Section F of the application.

Regardless of the actual funds available, it raises questions whether people with the authority to commit funds have actual knowledge of the proposed mobile MRI project.

Because it fails to clearly demonstrate that funds are available to the proposed mobile MRI project, Alliance should be found non-conforming to Criterion 5.

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

On page 62, the Alliance application acknowledges the 2023 SMFP special need Fixed MRI for Caldwell County but does not address why the proposed additional mobile service would not represent unnecessary duplication.

In light of the data presented in Criterion 3, Alliance should be found non-conforming to Criterion 6. Because it failed to justify the need in its host counties, specifically in Caldwell, it also failed to demonstrate how provision of services in any of the host counties would not result in duplication of existing services or facilities.

**Competitive Review of –
Carolina Neurosurgery & Spine Associates, PA
F-12368-23 and F-12381-23**

Overview

Carolina Neurosurgery & Spine Associates, PA (“CNSA”) submitted two applications for acquisition of mobile Magnetic Resonance Imaging scanners (“MRI”) in response to the 2023 SMFP need determinations for three new statewide mobile MRIs. These applications show costs and charges associated with only the technical component of MRI services. Footnotes to Form F.3 indicate that professional fees are billed separately by physicians and practices.

Each application proposes to acquire a mobile GE Signa Voyager 1.5 Tesla (“1.5T”) MRI scanner in a mobile trailer produced by Lamboo Medical. CNSA #1 proposes three stops: two in Mecklenburg County – Ballantyne and Huntersville – and one in Mount Holly, Gaston County. CNSA #2 proposes two stops, Charlotte, Mecklenburg County, and Greensboro, Guilford County (page 7 of methodology).

As demonstrated in the following paragraphs, both CNSA applications are non-conforming with statutory review criteria 1, 3, 5, and 18a.

CON Review Criteria

- 1. 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.**

CNSA #1 and #2 applications are very similar, with minor customizations related to each proposed mobile MRI service area. As described in Criteria 3, 5, and 18a below, CNSA does not demonstrate that “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” or that it will “maximiz[e] healthcare value for resources expended.”

CNSA #1 and #2 should be found non-conforming to Criterion 1.

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.**

Both applications present almost identical demonstrations of need. However, even with the limited amount of customization for each proposed service area, CNSA fails to demonstrate that any of its counties to be served **need** additional access to MRI services.

The Applicant very briefly notes that Mecklenburg and Guilford Counties, as well as a handful of neighboring counties, have growing populations over age 65. Then, both applications attribute the population's need for additional MRI services to one specific disease of elderly residents, Normal Pressure Hydrocephalus. CNSA makes no attempt to show what other trends or health needs these counties may have that would warrant additional services from a mobile MRI operated by a provider so limited in its scope of services. Later, the application speaks to increased use of MRI in Mecklenburg County (p46). However, it also notes that Mecklenburg County has received more fixed MRI allocations than any other County.

On page 43, the application argues that its fixed and mobile MRI units, owned and leased, are at capacity. This is incorrect. The table on page 42 compares procedure volume to regulatory performance thresholds, not to capacity. The 2023 SMFP defines capacity as 6,240 procedures.

Application Section C is confusing. It implies that the proposed MRI would add to, not replace existing vendor-provided MRI service. However, page 7 of the Charlotte/ Greensboro application notes, "[a]dditionally, as CNSA's proposed routes assume that contracted services with Alliance will end, as detailed in Section C.4."

An indirect and unclear connection between elderly residents and one disease type does not fully demonstrate the need of these populations to be served for the services proposed. References to continued presence of the Alliance vendor-provided scanner are unclear and the application bases need on CNSA's desire for MRI presence at all of its offices, **and not the capacity of its MRI scanners**. Therefore, both CNSA #1 and #2 should be found non-conforming to Criterion 3.

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.**

Both CNSA #1 and #2 indicate that acquisition of the proposed mobile MRI will negate need for continued lease of the Alliance operated third-party scanner which currently serves its Charlotte, Concord, and Greensboro locations (Section B.20.c page 28 and pages 4-5 and 7 of CNSA 2 methodology). However, the Applicant has provided no evidence that the Alliance contract can be terminated, nor does it account for any potential termination fees in its financial projections.

Finally, CNSA 1 proposes service to two new CNSA locations - Huntersville and Mount Holly. Neither location is operational, but the Applicant indicates “both of which **will have** mobile pads capable of hosting an MRI unit,” (Section C.1 page 30). CNSA states in several parts of its application that despite its best efforts, Alliance is unable to provide the Applicant with additional time on any of its mobile MRIs (Section C.4 pages 43-44). Logic would assume this extends to new locations as well. Therefore, its new locations in Huntersville and Mount Holly will only be able to provide MRI services if the CNSA mobile MRI application is approved. To that end, the Applicant should have included costs of installing mobile pads as part of the project costs. **The Applicant does not include the cost of installing mobile MRI pads at either location in its Form F.1a capital costs.**

Because neither application accounts for all financial and operational expenses, CNSA 1 and CNSA2 should be found non-conforming to Criterion 5.

- 18 a. 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.**

Cost Effectiveness

Section B.20.c simply asserts that ownership of its own scanner is more cost effective than its lease, but the Applicant provides no support for this assertion. Furthermore, these applications are presented as “complementary” to each other, which assumes that CNSA plans to operate both mobile MRIs (see Section C.1, page 30 in both applications). Nowhere in either application does CNSA demonstrate that ownership and operation of two additional mobile MRIs is a more cost-effective alternative to the CNSA current lease of one. Moreover, as noted above, the applications indicate intent to terminate the Alliance contract, suggesting that the addition of one mobile MRI to the applicant’s resources would make no change at all in availability of MRI services.

Because it did not clearly demonstrate the expected effects of the proposed services on cost-effectiveness, CNSA #1 and #2 should be found non-conforming to Criterion 18a.

Competitive Review of – Duke University Health System, Inc., J-12378-23

Overview

Duke University Health System, Inc. (“DUHS”) submitted an application to acquire one new mobile Magnetic Resonance Imaging scanner (“MRI”) in response to the 2023 SMFP need determinations for three new statewide mobile MRIs.

The application proposes to acquire a mobile Siemens Magnetom Aera 1.5 Tesla (“1.5T”) MRI scanner in a mobile trailer. DUHS proposes four stops: Duke Imaging Mebane Duke Orthopedics Practice (“Mebane”), Alamance County, Duke Imaging Knightdale (“Knightdale”) Duke Orthopedics Practice, Wake County, Duke Imaging Heritage (“Heritage”) Wake Forest, Wake County, and Duke Regional Hospital (“DRH”), Durham County. The mobile unit will supplement and/or replace existing mobile MRI access at DRH and Duke Heritage (p 30)

The DUHS application is non-conforming with statutory review criteria 1, 3, 5, and 6.

CON Review Criteria

- 1. 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.**

As described in Criterion 3 below, DUHS does not demonstrate that its proposal’s, “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.” DUHS should therefore be found non-conforming to Criterion 1.

- 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.**

DUHS fails to demonstrate that the proposed population has a need for additional mobile MRI services. Instead, it describes the need for the project in terms of its own desire for additional capacity. The application suggests that additional capacity at DUHS sites is demonstration enough that the proposed service project is in need.

However, DUHS has no existing MRI service in either Mebane or Knightdale, two of the proposed host sites. Although the application talks about the growth of Duke primary care and Alamance-based Kernodle Clinic practices, the application indicates that the mobile MRI will serve Orthopedic practices in both Mebane and Knightdale. The application says nothing about the need for orthopedic MRI scans.

Utilization forecasts in the Methodology, page 112, are based on growth of Outpatient MRI at DUHS from 2019 to 2023. The Applicant refers to Section C.4, where the only data are in a summary graphic and summary Table on pages 27 and 28. There are no data to tie projected utilization CAGRs used in the methodology to the table and graph. In fact, the graph shows that growth in Outpatient MRI use at DUHS facilities slowed down from FY21 to FY23. The CAGRs are inflated by using FY2019 as the starting point. (CAGR is calculated from two points, the beginning and the end).

The application provides no specific foundation for the CAGRs used on page 113 to forecast growth in MRI patients served at DUHS facilities. This is important because that table is the foundation for the Projected Shift to the mobile locations.

Moreover, Section C.1 indicates that the host site will be orthopedic practices, but the shift is applied to all patients.

On page 116, the application indicates that MRI scans will shift from DRH to Heritage in Wake County and Mebane in Alamance County. This is not explained.

As is their practice, DUHS does not demonstrate growth of patients or scans, nor does it explain why certain patients would receive care at one Duke location versus another. Specifically in the case of Mebane and Knightdale, neither locations' volume is a result of growth or need of the population served, but instead, 100 percent is a result of proposed "shift" of increased patients at existing DUHS locations. This is true for the proposed DRH site as well. DUHS proposes minimal growth – with no explanation as to where that will come from – and then shifts a percentage to the proposed mobile MRI. See pages 113, 115, and 117 of the DUHS application for detail.

Even if DUHS accounts for "net new" patients at Mebane, Knightdale, and DRH, that means DUHS will only capture 279 new patients by 2028, less than 20 percent of the projected patients at these three locations ($279 / 1,658 = 0.17$). See Table 3 below.

Table 3: Shifted Patients Compared to Net New, FY28

Site	FY22 Scans	FY28 Scans	Net New	% Shift	Projected Scans at Site	Net New to Site	Total Shift to Site
a	b	c	d	e	f	g	h
Mebane	1,485	1,780	295	25.0%	445	74	371
Knightdale	1,012	1,155	143	35.0%	404	50	354
DRH	3,270	4,045	775	20.0%	809	155	654
Total	5,767	6,980	1,213		1,658	279	1,379

Notes and Sources:

- a. *Proposed sites, DUHS application*
- b. *FY2022 patients served by DUHS deemed available for shift, pp 112, 114, 116.*
- c. *Growth of FY2022 shift patients at site of service, pp 113, 115, 117.*
- d. *c - b*
- e. *Percent of growth patients applied to shift, pp 113, 115, 117.*
- f. *e * f*
- g. *e * d*
- h. *f - g*

DUHS fails to explain how these 279 patients could not be absorbed at one of the existing 17 fixed MRIs it owns. Its only foundation is the fact that procedures at an IDTF cost less than procedures at a hospital.

Because DUHS provides no quantitative data to tie the needs of the population to the need of the service it should be found non-conforming to Criterion 3.

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.

On page 30 of its application, DUHS indicates that it will “supplement and/or replace existing mobile MRI access at Duke Regional Hospital (Durham) and Duke Heritage Medical (Wake Forest).” However, the application fails to demonstrate how DUHS will continue to pay the cost of its obligated lease to Alliance at other sites. Nor does it provide any documentation that Alliance is willing or able to change its contracts with DUHS to accommodate elimination and/or relocation of services.

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

According to Table 17E-1 in the 2023 SMFP, DUHS owns and operates 13 fixed MRI scanners in Durham County and four in Wake County. Of these **17 MRI scanners**, four reported less than 2,000 annual weighted scans in FY21. In fact, Duke Health Arrington Radiology in Wake County reported **zero weighted scans**, indicating it is not yet operational. This count does not include the approved fixed MRI scanner at Duke Imaging North Raleigh which is currently under appeal. Even without the North Raleigh scanner, DUHS seems to have abundant and dispersed MRI capacity in Wake and Durham Counties.

The premise of the Applicant’s need analysis is that DUHS needs more dispersed capacity to serve its patients; and, as explained in Criterion 3 above, the majority of DUHS’s projected utilization is a result an assumed shift of patients who would otherwise continue to increase at inflated rates at existing DUHS locations. However, DUHS fails to explain why existing patients could not be shifted to and/or new patients served at one of the four lower-volume fixed scanners in Durham or Wake Counties, many of which operate as IDTFs. See details in Table 4 below.

Table 4: DUHS Owned and Operated Scanners and FY21 Volume, Durham and Wake Counties

County	Service Type	CON#	Service Site	Fixed Magnet	Total Wtd. Scans	Wtd. Scans / Scanner
Durham	Hospital Fixed	Legacy; J-006207-00	Duke Regional Hospital	2.00	12,452	6,226
Durham	Hospital Fixed	J-005589-97; J-006109- 99; J-008030-07; J-008275-08; J-008466-10; J-008663-11; J-001112-	Duke University Hospital - Main	9.00	57,190	6,354
Durham	Hospital Fixed		Duke University Hospital - Southpoint Clinic	1.00	1,916	1,196
Durham	Freestanding Fixed	J-011913-20	Duke Imaging Arrington	1.00	1,113	1,113
Wake	Hospital Fixed	Legacy; J-008529-10	Duke Raleigh Hospital	2.00	13,139	6,570
Wake	Freestanding Fixed	J-011913-20	Duke Health Arrington Radiology	1.00	0	0
Wake	Freestanding Fixed	J-011167-16	Duke Imaging Holly Springs	1.00	1,938	1,938
Wake	Freestanding Fixed	J-012073-21 **under appeal**	Duke Imaging North Raleigh	0.00	0	0

Source: Table 17E-1, 2023 SMFP

Because DUHS failed to demonstrate why the proposed mobile MRI would not unnecessarily duplicate its own services, it should be found non-conforming to Criterion 6.

Competitive Review of – Novant Health-Norfolk, LLC, G-12372-23

Overview

Novant Health-Norfolk, LLC (“Novant East”) submitted an application for acquisition of a mobile Magnetic Resonance Imaging scanner (“MRI”) in response to the 2023 SMFP need determinations for three new statewide mobile MRIs.

The application proposes to acquire a mobile GE 1.5 Tesla (“1.5T”) MRI scanner in a mobile trailer. Novant East proposes five host sites: Carolinas East Medical Center (“CEMC”), Carolina Imaging, UNC Lenoir Healthcare (“UNC Lenoir”), Orthopedic Specialists of North Carolina (“OSNC”), and UNC Orthopedics Holly Springs (“UNC Ortho”).

Novant East’s application is non-conforming with statutory review Criterion 8 and the Performance Standard in 10A NCAC 14C .2703(b)(8).

CON Review Criteria

- 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.**

The proposed service is for a **mobile** MRI scanner. As such, a key ancillary service needed for this project is **availability of a host site**. Novant East proposes five host sites: CEMC in Craven County, Carolina Imaging in Cumberland County, UNC Lenoir in Lenoir County, and two Wake County locations – OSNC and UNC Ortho. As stated in the criterion, applicants must “demonstrate that the provider will ... make arrangements for, the provision of necessary ancillary and support services.”

Exhibit C, pages 153-159, provides “evidence” that Novant East has secured access to host sites. However, it is unclear whether all sites are in fact available. **There is no correspondence at all – not even a support letter for the project – provided in the application or exhibits from Carolina Imaging or UNC Lenoir.**

Novant East explains on page 77 of its application that it will continue to provide service three days per week to OSNC on existing mobile MRI MQ-17. The proposed mobile will add one day of service to this host site per week. **However, there is nothing directly from OSNC supporting the project or detailing its interest in or need for additional days of service at any of its locations.**

Because Novant East failed to demonstrate that it has arranged for the availability of ancillary services, it should be found non-conforming to Criterion 8. The absence of such an agreement would make financial projections unsupportable and the project would also be non-conforming to Criterion 5.

CON Rules

10A NCAC 14C .2703(b)(8) Performance Standard

Project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and . . .

As detailed in Criterion 8 above, Novant East did not demonstrate the availability of three of its proposed five host sites. With that in mind, Novant East cannot reasonably claim any of the scans proposed at those locations.

Without inclusion of the scans projected at CEMC, Carolina Imaging, and OSNC, Novant East does not meet the performance standard required for mobile MRIs. Table 5 below demonstrates this.

Table 5: Novant East Projected Utilization Compared to Performance Standard, FY27

Metric	Proposed Utilization PY3	Supported Utilization	Sources / Notes
Carolina Imaging (Cumberland)	1,460	-	<i>Page 69, No host site evidence</i>
OSNC (Wake)	725	-	<i>Page 69, No correspondence asking for additional service.</i>
UNC Ortho (Wake)	1,232	1,232	<i>Page 69</i>
CEMC (Craven)	624	624	<i>Page 69</i>
UNC Lenoir (Lenoir)	527	-	<i>Page 69, No host site evidence</i>
Existing MQ-17	3,717	3,717	<i>Page 82</i>
Existing MQ-23	3,392	3,392	<i>Page 82</i>
Total Weighted Scans	11,677	8,965	
Total Units	3	3	<i>Proposed Novant East + 2 Existing</i>
Weighted Scans / Unit	3,892	2,988	<i>Does not meet performance standard</i>

Because it fails to meet the performance standard, Novant East should be found non-conforming.

**Competitive Review of –
Novant Health-Norfolk, LLC, G-12373-23**

Overview

Novant Health-Norfolk, LLC (“Novant West”) submitted an application for acquisition of a mobile Magnetic Resonance Imaging scanner (“MRI”) in response to the 2023 SMFP need determinations for three new statewide mobile MRIs.

The application proposes to acquire a mobile GE 1.5 Tesla (“1.5T”) MRI scanner in a mobile trailer. Novant West proposes three host sites: Cannon Memorial Hospital (“Cannon Memorial”), Providence Imaging Center (“Providence”), and Open MRI & Imaging of Asheville (“Open MRI”).

Novant West’s application is non-conforming with statutory review Criterion 8 and the Performance Standard in 10A NCAC 14C .2703(b)(8).

CON Review Criteria

- 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.**

The proposed service is for a **mobile** MRI scanner. As such, a key ancillary service needed for this project is **availability of a host site**. As listed above, Novant West proposes three host sites: Cannon Memorial in Avery County; Providence in Henderson County; and Open MRI in Buncombe County. As stated in the criterion applicants must “demonstrate that the provider will ... make arrangements for, the provision of necessary ancillary and support services.”

Exhibit C, pages 162-168 provide “evidence” that Novant West has secured access to host sites. However, it is unclear whether all sites are in fact available. Beginning on page 163, is not a letter of support or interest from Appalachian Regional Healthcare System (“ARHS”), it is, in fact, a Request for Proposal (“RFP”). This indicates that while the proposed host site Cannon Memorial **may** be in search of additional MRI services, Novant West is not secured as a provider. Page 2 of the RFP begins a long list of questions and requirements from ARHS that Novant West must meet before being **considered** as a candidate to provide services at Cannon Memorial. Novant does not provide its response to the RFP, nor does ARHS provide any clear support for the proposed project. There is no indication whether Cannon Memorial will secure another MRI vendor before approval of this project.

There is no correspondence at all – not even a support letter for the project – provided in the application or exhibits from Providence Imaging.

Because Novant West failed to demonstrate that it has arranged for the availability of ancillary services, it should be found non-conforming to Criterion 8.

CON Rules

10A NCAC 14C .2703(b)(8) Performance Standard

Project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and

As detailed in Criterion 8 above, Novant West did not demonstrate availability of two host sites, Cannon Memorial and Providence. With that in mind, Novant West cannot reasonably claim any of the scans proposed to be performed at either location.

Furthermore, the State Health Coordinating Council defined the service area for the mobile MRIs as “Statewide.” According to Team Leader, Michael McKillip, applicants can interpret this to mean that the applicant can propose its own service area. Based on the table in Section C.3 of the Novant West application, its defined service area is Avery, Buncombe, and Henderson Counties. According to page 64 of its application, **Novant West is in the process of acquiring a legacy mobile MRI owned by Kings Medical Group.** This unit (“Kings Mobile”) provided services to Open MRI in the 12 months preceding this application. As a result, Novant West must include projected volumes for that scanner as part of the performance standard requirements. The application further explains that Novant West proposes to move all services from Kings Mobile at Open MRI to the proposed unit. That means, future projected volumes performed on the Kings Mobile unit will occur solely in Mecklenburg County (see page 72), thus offering no benefit to residents of the proposed service area counties.

Without inclusion of the scans projected at Cannon Memorial and Providence, Table 6 below demonstrates that Novant West **needs** the projected scans of the Kings Mobile unit to – just barely – meet the performance standard. This is not possible because **none** of the projected volumes of the Kings Mobile unit will benefit the patients of Avery, Buncombe, or Henderson Counties. Projected scans at Open MRI alone do not meet the performance standard.

Table 6: Novant West Projected Utilization Compared to Performance Standard, FY27

Metric	Proposed Utilization PY3	Actual Utilization	Sources / Notes
Open MRI (Buncombe)	3,061	3,061	Page 69
Cannon Memorial Hospital (Avery)	635	-	Page 66, no host site evidence
Providence Imaging (Henderson)	670	-	Page 66, no host site evidence
Existing King Mobile (Mecklenburg)	3,417	3,417	Page 72, all PY3 projected scans occur in Meck
Total Weighted Scans	7,783	6,478	
Total Units	2	2	Proposed Novant West + Existing Kings Mobile
Weighted Scans / Unit	3,892	3,239	

Because it fails to meet the performance standard, Novant West should be found non-conforming to Statutory requirements in GS 131E1-18(3b)

Competitive Review of – Pinnacle Health Services of NC, LLC, J-12375-23

Overview

Pinnacle Health Services of NC, LLC (“PHSNC”) submitted an application to acquire one new mobile Magnetic Resonance Imaging scanner (“MRI”) in response to the 2023 SMFP need determinations for three new statewide mobile MRIs.

The application proposes to acquire a mobile Siemens Magnetom Aera 1.5 Tesla (“1.5T”) MRI scanner in a mobile trailer. PHSNC proposes five stops: Cardinal Points Imaging in Brier Creek and Cary; and Atrium Health Wake Forest Baptist Outpatient Imaging in Greensboro, Winston-Salem, and Kernersville.

The PHSNC application is non-conforming with statutory review criteria 5, 6, 8 and the Performance Standard in 10A NCAC 14C .2703(b)(8).

CON Review Criteria

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.**

On page 29 of its application, PHSNC indicates that **it will have a continuing obligation to lease scanners from MedQuest and Alliance**. It indicates that “PHSNC will coordinate to relocate to other locations” which currently serve Brier Creek and Atrium Wake Forest Baptist Outpatient Imaging Winston-Salem. The application fails to demonstrate how PHSNC will continue to pay the cost of its obligated lease to Alliance at other sites. This should be included in the projected financials because it is an essential part of the assumptions supporting the use of the proposed new mobile scanner.

PHSNC proposes to locate the mobile MRI at three host sites that are owned by Atrium Healthcare. Those sites account for 68 percent of the total procedures proposed. The pro forma Form F.2b shows no income from site leases. It presents information as if PHSNC will bill for all services provided at the Atrium host sites. The letter from Atrium in Exhibit I.2 does not indicate Atrium’s willingness to contract PHSNC for mobile MRI services at any specific Atrium host site. **It is simply a letter of support for the concept of more mobile MRI capacity in North Carolina.** The application contains no information about arrangements between PHSNC and Atrium at the Wake Forest or Greensboro location.

Yet, assumptions for Form F.3b on PHSNC application page 135 indicate that all charges and payments are based on PHSNC history, presumably indicating that PHSNC will be the direct care provider and Atrium Wake Forest physicians will refer to them. However, PHSNC does not control the real estate.

There is no information about who will actually have authority to bill for services provided at Atrium locations. Therefore, it is impossible to determine the reasonableness of costs at the host sites or charges.

The application contains no information about how patient support services, e.g., registration, recovery, or toilet, would be provided at the Atrium sites. Because the application contains no information about the cost of using the host site, the expense projections in Form F.3b are not based on reasonable projections of costs by the person proposing the service.

In the methodology in Section Q, page 128, PHSNC indicates that the proposed mobile MRI will “locate” at three Atrium sites a total of four days per week. Neither the application nor exhibits provide evidence that the host sites can accommodate the proposed scanner. The payor mix in Section L and Form F.2b are based on PHSNC payor mix. PHSNC has no sites in either Forsyth or Guilford Counties, and no sites at Atrium facilities. **Because most (68 percent)** of the proposed procedures would be “shifted” from Atrium locations, the payor mix should represent history of these Atrium patients, **not** history of PHSNC (see detail in Table 7 below). Therefore, the revenue projections in Form F.2b are not based on reasonable projection of the charges for providing health services.

Table 7: Percent Distribution of Proposed PHSNC Mobile MRI Patients by Host Site, 2027

Host Site	Weighted Scans	Percent of Total Scans	Subtotal by Provider
CPIC Brier Creek	1,205	24.6%	
CPIC Cary	360	7.4%	32.0%
Atrium Greensboro	345	7.0%	
Atrium Kernersville	927	18.9%	
Atrium Winston-Salem	2,060	42.1%	68.0%
Total Weighted Scans	4,897	100.0%	100.0%

Source: page 130, PHSNC application

There is no agreement from Atrium or Wake Forest Baptist to refer patients to PHSNC rather than to Atrium-owned MRI scanners. Although the application includes a number of letters from physicians on Atrium Wake Forest Baptist letterhead, none refer to a specific location, and every letter indicates intent to refer only “as appropriate.”

Finally, capital costs are not supported. The medical equipment line shows a cost of \$2.2M, which is supported by a vendor quote from Siemens in Exhibit F.1. However, Exhibit F.1 **also** contains a separate quote from AMST of \$629,793 for costs related to the basic coach with some additional options. The additional cost of the coach is not included in Form F.1a. Also missing from Form F.1a and all included quotes is the cost of installing the proposed MRI on the coach.

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

According to Table 17E-1 in the 2023 SMFP, Atrium Health / Wake Forest Baptist owns two fixed MRI scanners at its Kernersville outpatient imaging center (G-011798-19 and G-007780-07). It appears in Table 17E-1 that one is not yet operational, and the other operates only part-time. Together, these scanners completed **less than 600** weighted scans in FY21. By comparison, the full-time freestanding fixed 3T MRI at the Winston-Salem outpatient imaging center completed over 7,000 weighted scans in the same year. See Table ## below.

Table 8: Wake Forest Baptist Imaging Owned and Operated Scanners and FY21 Volume, Forsyth County

County	Service Type	CON#	Service Site	Fixed Magnet	Fixed Equiv	Total Wtd. Scans	Wtd. Scans / Scanner
Forsyth	Freestanding Fixed	G-011798-19	Wake Forest Baptist Imaging - Kernersville	1	1.00	0	0
Forsyth	Freestanding Fixed	G-007780-07	Wake Forest Baptist Imaging Kernersville (Wake Forest Baptist, LLC)	0	0.11	566	592
Forsyth	Freestanding Fixed	G-007780-07	Wake Forest Baptist Imaging (Wake Forest Baptist Imaging, LLC)	1	1.00	6,401	7,218

Source: Table 17E-1, 2023 SMFP

A web search confirms that the Kernersville Outpatient Imaging location has offers MRI services three days a week, on a “**new** 3T MRI ... [with] state-of-the-art technology placed within a calm, serene environment.”¹ The Winston-Salem location appears to offer MRI services seven days per week.² This suggests that the Kernersville location is wisely operating according to volume but can increase as demand needs it. Using Winston-Salem as a benchmark, together these locations could perform up to 15,000 weighted scans annually.

PHSNC fails to explain why existing patients could not be shifted to and/or new patients served at the lower-volume scanner, nor does it explain why its presence at these two locations a total of three days per week will not duplicate services. It should therefore be found non-conforming to Criterion 6.

¹ <https://www.wakehealth.edu/locations/labs-and-imaging/i/imaging-kernersville>

² <https://www.wakehealth.edu/locations/labs-and-imaging/i/imaging>

- 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.**

The proposed service is for a **mobile** MRI scanner. As such, a key ancillary service needed for this project is **availability of a host site**. PHSNC provides no evidence that Atrium Healthcare is willing to host PHSNC at the specific host sites listed. Without access to power, water, registration, and/or toilets, PHSNC is not able to provide mobile MRI services.

Because PHSNC failed to clearly demonstrate it made “arrangements for... the provision of necessary ancillary and support services,” it should be found non-conforming to Criterion 8.

CON Rules

10A NCAC 14C .2703(b)(8) Performance Standard

Project that the mobile MRI scanners identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile MRI scanner shall perform 3,120 or more adjusted MRI procedures per MRI scanner during the third full fiscal year of operations following completion of the project; and . . .

As detailed in Criterion 8 above, PHSNC did not demonstrate the availability of three of its proposed five host sites. With that in mind, PHSNC cannot reasonably claim any of the scans proposed at those locations.

Furthermore, the State Health Coordinating Council defined the service area for the mobile MRIs as “Statewide.” According to Team Leader, Michael McKillip, applicants can interpret this to mean that the applicant can propose its own service area. Based on the table in Section C.3 of the PHSNC application, its defined service area includes Wake County. As a result, PHSNC must include projected volumes for its existing mobile scanner as part of the performance standard requirements. However, as explained in Criterion 5 above, most of the scans for the proposed MRI are expected to occur at Atrium host site locations.

Without inclusion of the scans projected at the three Atrium host sites, Table 6 below demonstrates that PHSNC **needs** the projected scans of the existing mobile MRI to meet the performance standard.

Projected scans at CPIC Brier Creek and Cary alone do not meet the performance standard.

Table 9: PHSNC Projected Utilization Compared to Performance Standard, FY27

Metric	Proposed Utilization PY3	Supported Utilization	Sources / Notes
CPIC Brier Creek	1,205	1,205	Page 130
CPIC Cary	360	360	Page 130
Atrium Greensboro	345	-	Page 130, No host site evidence
Atrium Kernersville	927	-	Page 130, No host site evidence
Atrium Winston-Salem	2,060	-	Page 130, No host site evidence
Existing PHSNC Mobile Scanner	5,489	5,489	Page 126
Total Weighted Scans	10,386	7,054	
Total Units	2	2	Proposed PHSNC + Existing
Weighted Scans / Unit	5,193	3,527	

Because it fails to meet the performance standard, PHSNC should be found non-conforming.

EO Mobile MRI Final Comments

Final Audit Report

2023-05-26

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