



**Comments on Competing Applications for  
Statewide Mobile MRI Scanners**

**May 31, 2023**

## Competitive Comments on Statewide Mobile MRI Applications

*Submitted by*

**Carolina Neurosurgery & Spine Associates (CNSA)**

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Carolina Neurosurgery & Spine Associates, P.A. (CNSA) hereby submits the following comments related to competing applications filed to acquire and develop a mobile MRI scanner based on the statewide need for three mobile MRI scanners identified in the *2023 State Medical Facilities Plan (SMFP)*. “discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards.” See N.C. GEN. STAT. § 131E-185(a1)(1)(c).<sup>1</sup> In order to facilitate the Agency’s ease in reviewing these comments, CNSA has organized its discussion by issue, specifically noting the general Certificate of Need (CON) statutory review criteria and regulations creation the non-conformity relative to each issue as they relate to the competing applications. CNSA’s comments relate to the following applications proposing to acquire and develop a mobile MRI scanner:

- **Alliance Healthcare Services Mobile MRI 2023 (Alliance), Project ID # G-012365-23**
- **Duke Imaging Mobile MRI (Duke), Project ID # J-012378-23**
- **EmergeOrtho Mobile MRI Blue Ridge/Foothills Route (EmergeOrtho), Project ID # J-012357-23**
- **EmergeOrtho Mobile MRI Triad Route (EmergeOrtho), Project ID # J-012358-23**
- **EmergeOrtho Mobile MRI Triangle Route (EmergeOrtho), Project ID # J-012359-23**
- **Novant Health-Norfolk, LLC (1) (Novant), Project ID # G-012372-23**
- **Novant Health-Norfolk, LLC (2) (Novant), Project ID # G-012373-23**
- **PHSNC Mobile MRI Scanner (PHSNC), Project ID # J-012375-23**

Given that the state determined a statewide need for three mobile MRI scanners, and given that a total of ten applications – the eight listed above plus CNSA’s two complementary applications – were filed for that need, not all applications can be approved. The comments below include substantial issues that CNSA believes render the competing applications non-conforming with applicable statutory and regulatory review criteria.

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<sup>1</sup> CNSA is providing comments consistent with this statute; as such, none of the comments should be interpreted as an amendment to its complementary applications filed on April 17, 2023 (Project ID # F-12368-23 and Project ID # F-012381-23).

## GENERAL COMMENTS

The 2023 SMFP identifies a statewide need for three additional mobile MRI scanners. The following section outlines general comments related to the applications for these three mobile MRI scanners.

### Competition (Access to a New or Alternate Provider)

Historically, with regards to this comparative factor, the Agency has stated that the introduction of a new provider in the proposed service area is the most effective alternative. In this instance, all six applicants are existing providers of mobile MRI services in the service area; i.e., statewide.

When comparing *existing* providers, however, the Agency has instead found the applicant with the fewest of the proposed service components to be the most effective alternative. For example, in its 2022 Mecklenburg County Acute Care Bed Review, in which both Atrium Health and Novant were applicants, the Agency found Novant to be the more effective alternative with regards to patient access to a new or alternate provider, as Atrium Health controlled 63.8 percent of Mecklenburg County beds while Novant controlled the remaining 36.2 percent.<sup>2</sup> Likewise, in its 2021 Mecklenburg County MRI Review, the Agency found Novant to be the more effective alternative with regards to the same competitive factor as it controlled only 11 MRI scanners in Mecklenburg County, while the other applicant, Atrium Health, controlled 12.<sup>3</sup>

Given this precedent, it should be noted that CNSA, along with PHSNC, controls the fewest combined fixed and mobile MRI scanners amongst all six applicants for the 2023 SMFP statewide mobile MRI need, as noted in the table below.

**Existing Total MRI Scanners by Applicant  
FY 2021**

<b>Applicant</b>	<b>Mobile</b>	<b>Fixed</b>	<b>Total</b>
CNSA	1	1	2
Alliance	30		30
Duke	1	16	17
EmergeOrtho	2	5	7
Novant	10	30	40
PHSNC	1	1	2

Source: Respective applications.

Based on the above, PHSNC and CNSA are the most effective applicants with regards to the access to a new or alternate provider comparative factor.

### Performance Standard

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

<sup>2</sup> As noted in the Required State Agency Findings – 2022 Mecklenburg Acute Care Bed Review.

<sup>3</sup> As noted in the Required State Agency Findings – 2021 Mecklenburg County MRI Review.

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

As noted in the 2023 SMFP, the service area for the mobile MRI scanner need determination is “Statewide.”<sup>4</sup> As such, with regards to 10A NCAC 14C .2703 (b)(1), it is necessary for each applicant for that subsequent need to include all scanners they own and operate for the “proposed mobile MRI scanner service area,” which, in the case, would be statewide. Alliance, Duke, EmmergeOrtho, and Novant do not include this information, instead only including the scanners they own and operate from the counties in which their proposed mobile MRI scanner(s) will operate. This omission clearly violates the performance standards cited above, and it is particularly problematic for the mobile MRI scanners operated by these applicants, as they fail to demonstrate the need for another mobile scanner when they have existing mobile scanners that could potentially be relocated to serve their proposed host sites.

Given this issue, these applicants should be found non-conforming, as will be discussed further in the comments specific to each application.

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<sup>4</sup> 2023 SMFP, p. 359.

### **General Comments**

As the Agency is likely aware, Alliance is one of the dominant providers of mobile MRI services in the state of North Carolina, owning and operating 30 mobile MRI scanners statewide. Although it is an experienced operator, the application that Alliance has submitted for the statewide need determination for one mobile MRI scanner is simply unapprovable, as apparent from even a cursory review. As will be detailed in CNSA's comments below, large swaths of the application are non-conforming with the North Carolina general statutory criteria, either because the evidence and data Alliance has provided is insufficient or because that data is missing entirely. Further, Alliance's demonstration of need for its proposed project – in which an applicant must justify their need to provide accessible, cost-effective, and quality care for its patients and their proposed service area – is inadequately brief at only 193 words and is not in the spirit of CON law or the regulatory criteria of the State of North Carolina.

Given the issues with the application, it is all but certain that Alliance has only applied for a mobile MRI scanner in order to ensure that it may have standing to appeal other applications for that need. As the Agency is aware, appeals of approved applications filed by non-applicants have repeatedly been dismissed for lack of substantial prejudice as a non-applicant. However, the courts have found that applicants that are non-conforming with statutory and regulatory review criteria have also failed to demonstrate substantial prejudice. Moreover, Alliance has a record of opposing petitions and applications that would result in the development of additional MRI scanners—effectively opposing enhanced competition for this service. Given the numerous issues with the Alliance application, as well as its history of opposing other applications for MRI scanners, CNSA urges the Agency to find it non-conforming with multiple review criteria.

Clearly, the Alliance application is a wholly unserious one. As such, Alliance should be found non-conforming with multiple statutory and regulatory review criteria. Issue-specific comments related to Alliance's application can be found below.

### **Issue-Specific Comments**

1. Alliance does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*

- (3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;
- ...
- (6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;
- (7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;

According to Section A.6 and Form O of its application, Alliance owns and operates 30 existing mobile MRI scanners across the state of North Carolina. Additionally, Alliance identifies the service area for its proposed mobile scanner as “Statewide” in Section A.4.a, Section A.5.a, and Section B.1.a. However, in response to Section C.7, Alliance only provides volume assumptions for its proposed mobile MRI scanner. Given this, Alliance is unable to adequately assess whether the statewide population it proposes to serve has a need for the services provided, whether its proposed scanner is a duplication of existing services, whether these existing scanners meet the needs of underserved groups, or whether these scanners will impact competition statewide. Further, by excluding projections and assumptions for its existing scanners, Alliance fails to meet performance standards.

**As such, Alliance’s application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), and (6), as well as the performance standards in the rules for MRI scanners.**

2. Alliance does not demonstrate a need for the proposed project.

As mentioned in CNSA’s general comments towards Alliance’s application, Alliance’s demonstration of need, detailed in Section C.4, is simply inadequate.<sup>5</sup> It notes a reference to a table “on the following page”<sup>6</sup> that lists the mobile MRI host sites for the proposed project;<sup>7</sup> a statement that Alliance “continues to have requests for additional days of service from numerous entities including those in the western most part of the state” with no evidence to support this claim; and a quote from Nathan Nipper, the COO of Appalachian Regional Healthcare System (a healthcare entity unrelated to Alliance), attesting to a general patient need in the western part of the state due to “inclement weather; high elevation; and a lack of an interstate.”

None of the aspects of this truncated statement on need supports the necessity of Alliance specifically to provide mobile MRI services to the patient population that it projects to serve. Moreover, Mr. Nipper’s comments were written in support of a petition for a new policy in the SMFP to allow the conversion of fixed MRI scanners to mobile, not in support of Alliance’s application to develop another mobile MRI scanner. In addition, Alliance’s proposed scanner does not even include any counties in the High Country in its projected route; thus, the need for additional MRI services in the High Country is not relevant to Alliance’s proposed project.

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<sup>5</sup> Project ID # G-012365-23, p. 36.

<sup>6</sup> Ibid.

<sup>7</sup> Table found on p. 44.

Furthermore, Alliance has included no letters of support for its application, from any part of the state, which certainly undermines its purported need for the proposed project.

In fact, it is questionable whether the counties that Alliance has identified as its proposed service area – Caldwell, Buncombe, and Forsyth counties – are in need of MRI services at all; indeed, Alliance does not explain why these counties in particular demonstrate a need for mobile MRI services. According to the *2023 SMFP*, all three of the MRI service areas that Alliance will serve with its proposed project were below their respective need determination thresholds, thereby demonstrating a lack of necessity for additional MRI services for any of those services areas or host sites.

**Average Scans for Proposed Alliance Mobile MRI Service Area Counties  
FY 2021**

<i>Service Area</i>	<i>Average Scans</i>	<i>Threshold</i>	<i>Difference</i>	<i>MRI Need</i>
Buncombe/Graham/Madison/Yancey	4,172	4,992	(820)	0
Caldwell	3,720	4,368	(639)	0
Forsyth	4,730	4,992	(262)	0

Source: *2023 SMFP*, p. 354.

While there may be other factors beyond the *SMFP* need methodology driving need for a mobile MRI scanner in that area, Alliance has failed to provide any evidence of the need for its project. Of note, the *2023 SMFP* includes an adjusted need determination for another fixed MRI scanner in Caldwell County, which will certainly obviate the need for any additional MRI capacity in that rural county for the foreseeable future. Alliance failed to address this issue in its application.

**As a result of these issues, Alliance is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), and (6), as well as the performance standards for MRI scanners.**

3. Alliance fails to provide projected payor mix or payor mix assumptions.

In Section L.3.a, applicants are required to provide projected payor sources during the third full fiscal year of operation following completion of the proposed project; in section L.3.b, applicants must describe any assumptions used to project each payor source. Alliance does neither of these things.<sup>8</sup>

**As such, Alliance is non-conforming to N.C. Gen. Stat. § 131E-183(a)(13)(c).**

4. Alliance does not provide reasonable and supported assumptions for its utilization projections.

In its “Form Q,” which contains Alliance’s utilization projections for its proposed mobile MRI scanner for the first three years of the proposed project, Alliance provides a list of “Assumptions” that largely base its projections on the number of scans per day performed and

<sup>8</sup> Seen in Project ID # G-012365-23, pp. 76-77.

“historical knowledge of the sites and experience operating mobile MRI throughout the state.”<sup>9</sup> However, this is not sufficient analytical support for the volume projections that Alliance has provided, and is not adequate to justify or validate the projections that Alliance has made through its project year three.

In addition, Alliance states that it has projected MRI procedures “based on the following weights: one outpatient MRI procedure without contrast or sedation is valued at 1.0 weighted MRI procedure, one outpatient MRI procedure MRI with contrast or sedation is valued at 1.4 weighted MRI procedures, one inpatient MRI procedure without contrast or sedation is valued at 1.4 weighted MRI procedures, and one inpatient MRI procedure with contrast or sedation is valued at 1.8 weighted MRI procedures.”<sup>10</sup> These are not the weights utilized by the performance standards in the CON rules, which refer to the weighting in the current *SMFP*. The weighting values for MRI procedures were updated for the *2023 SMFP*, and have been replicated below:

The following table shows the calculations for the weighting values to be assigned based on the complexity of the procedure type. For example, a base outpatient scan is not weighted; in other words, its weight is “1.” To calculate the weight for a complex outpatient scan, divide its procedure time (40) by the procedure time for a base outpatient scan (33).

Procedure Type	Procedure Time in Minutes	Weight
Base Outpatient	33	1.0
Complex Outpatient	40	40/33
Base Inpatient	60	60/33
Complex Inpatient	70	70/33

Source: *2023 SMFP*, p. 333.

**Given this, Alliance is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), and (6), and the performance standards in the CON rules for MRI scanners.**

5. Alliance does not provide assumptions for any of its financial projections.

In Section F.4.a, applicants are required to “[d]escribe the assumptions and methodology used to complete each form in 4.b.”<sup>11</sup> Alliance has provided projected revenues and net income upon project completion in Form F.2b, as well as projected operating costs upon project completion in Form F.3b;<sup>12</sup> however, Alliance has not provided the assumptions and methodology for either of these projections. As such, it has failed to meet the requirements of Criterion 5, which states that applicants must demonstrate financial feasibility based on “reasonable projections of the costs and charges.” Without any assumptions or basis, the financial projections cannot be found to be reasonable.

**As such, Alliance is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

<sup>9</sup> Ibid, p. 87.

<sup>10</sup> Ibid.

<sup>11</sup> Seen in Project ID # G-012365-23, p. 58.

<sup>12</sup> Ibid, pp. 92-93.



**In summary, based on the issues detailed above, the Alliance application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), and (13)(c), as well as the performance standards in the CON rules for MRI services.**

Issue-Specific Comments

1. Duke does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

According to Section A.6, Duke owns and operates four existing or approved diagnostic centers across the state of North Carolina, which it further confirms in its Form O.<sup>13</sup> Duke identifies the service area for its proposed mobile scanner as “Statewide” in Section B.1.a. However, in its Form C, Duke does not provide projected data for its Coley Hall location, which is approved to provide MRI services. As such, it does not follow the requisite instructions in the performance standards listed above. Furthermore, without projections of volume for the approved Coley Hall location in Orange County, the utilization projections for the proposed mobile MRI scanner, which also projected to serve patients from Alamance and Durham counties, among others, cannot be determined to be reasonable.

**Therefore, the Duke application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), (13), and (18a), as well as the criteria and standards for magnetic resonance imaging scanners.**

2. Duke does not appropriately identify the health facility and provider of the proposed project.

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<sup>13</sup> Project ID # J-012378-23, p. 23.

Duke makes a number of errors with regards to the classification and identification of its proposed mobile MRI scanner. In Section A.4.b and A.5.b, Duke states that the health service facility will be a diagnostic center; however, the total projected capital costs for the proposed project are under \$3 million,<sup>14</sup> and as such, the proposed mobile service will not meet the criteria to be a health service facility or a diagnostic center, as defined in N.C. Gen. Stat. § 131E-176(7a).

Additionally, Duke states that “[u]pon receipt of the CON, DUHS intends to operate this service under a controlled affiliate to be formed for this purpose. This Duke affiliate (“Duke”) will staff the mobile MRI service and all staff will be dedicated to providing MRI services.”<sup>15</sup> Despite stating that an affiliate will co-operate the proposed project, only one applicant has been listed in Section A.1. This ambiguity in the service provider is also relevant to Section I, where Duke states that “support and ancillary services are provided by the service provider.”<sup>16</sup> As Duke has not specifically identified the service provider, Duke has not sufficiently demonstrated that all ancillary and support services will be available for the proposed project. Since the proposed project will not constitute a health service facility, the actual operator of the equipment—the entity that will offer the MRI service—will be unable to acquire the unit through an exemption. As such, it is unclear how the other entity will be able to provide MRI services without a CON. At a minimum, an entity that intends to offer the service should be an applicant, as defined in the definitions section of the application form.

**Given this issue, the Duke application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3) and (8).**

**In summary, based on the issues detailed above, the Duke application is non-conforming with N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), (8), (13), and (18a), as well as the performance standards for MRI scanners.**

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<sup>14</sup> Ibid, pp. 18-20.

<sup>15</sup> Ibid. p. 30.

<sup>16</sup> Ibid, p. 76.

**EMERGEORTHO MOBILE MRI BLUE RIDGE/FOOTHILLS ROUTE, PROJECT ID # J-012357-23**

**Issue-Specific Comments**

1. EmergeOrtho’s utilization and methodology is unreasonable and based on inconsistent data and assumptions.

In “Section Q: EmERGEOrtho Need and Utilization Methodology for Section C Blue Ridge / Foothills,” EmERGEOrtho provides utilization projections for the first three years of the proposed mobile MRI scanner. To do so, EmERGEOrtho makes a series of projections that are inconsistent and unsupported by external data and its own evidence.

First, in Step 6, in order to estimate the unmet need for MRI services in its proposed service area, EmERGEOrtho provides an estimate of the adjusted North Carolina MRI scans by county for fiscal year (FY) 2021. It ultimately reaches an estimate of 947,966 adjusted total scans for FY 2021, as seen in the table below, which has been partially replicated:

County	FY21 Est. Reported Scans	FY21 Est. Unreported Scans	FY21 Est. Adjusted Total Scan
Surry	8,295		8,295
Swain	1,258		1,258
Transylvania	3,788		3,788
Tyrrell	273		273
Union	20,588	1,191	21,779
Vance	4,308		4,308
Wake	70,523	9,291	79,814
Warren	905		905
Washington	1,065		1,065
Watauga	3,236		3,236
Wayne	10,097		10,097
Wilkes	6,093		6,093
Wilson	7,275	66	7,342
Yadkin	4,344		4,344
Yancey	1,890		1,890
NC State Total	916,897	31,069	947,966

*Notes: total estimated scans Step 5 + estimated unreported scan by county, Exhibit C.5*

Source: Project ID # J-012357-23, p. 142.

However, this understates the true number of total MRI scans as reported in the 2023 SMFP for FY 2021, which totaled 975,892.<sup>17</sup> EmERGEOrtho itself states that this estimate “[is] within 97% of the scans reported in Table 17E-1 in the 2023 SMFP (947,966 / 975,892 = 0.971);”<sup>18</sup> in short, EmERGEOrtho validates that its own estimate is an underestimate of the true MRI scan total, by approximately 28,000 scans.

<sup>17</sup> 2023 SMFP, p. 353.

<sup>18</sup> Project ID # J-012357-23, p. 142.

EmergeOrtho further estimates, in step 8, the number of unserved MRI scans by county through FY 2027, in order to approximate unmet need at the county level. It concludes that, in FY 2027, there will be an estimated unmet need for 93,953 adjusted MRI scans in North Carolina, shown below.

Wayne	769	760	753	747	742	737
Wilkes	-	-	-	-	-	-
Wilson	-	-	-	-	-	-
Yadkin	-	-	-	-	-	-
Yancey	-	-	-	-	-	-
<b>NC State Total</b>	<b>38,241</b>	<b>49,943</b>	<b>61,450</b>	<b>72,534</b>	<b>83,245</b>	<b>93,953</b>

Notes: projected county scans Step 7, Table 6 – adjusted FY21 scans, Step 6, Table 5

Source: Project ID # J-012357-23, p. 148.

However, in Step 10, EmmergeOrtho accounts for the calculated surplus of MRI scans to be captured by new and not yet operational MRI scanners by cluster for FY 2027. While EmmergeOrtho does not sum the total of these scans, the summation across all clusters, as seen in the table below, is 87,120 scans.

**Surplus of MRI Scans to be Captured by New/Not Yet Operational MRI Scanners  
FY 2027**

<b>Cluster</b>	<b>MRI Scans</b>
Cluster 1	2,904
Cluster 2	5,808
Cluster 3	17,424
Cluster 4	7,260
Cluster 5	15,972
Cluster 6	8,712
Cluster 7	7,260
Cluster 8	4,356
Cluster 9	8,712
No Cluster	8,712
<b>Total</b>	<b>87,120</b>

Source: Project ID # J-012357-23, pp. 151-154.

This means that, when accounting for this met need, EmmergeOrtho projects an unmet need of 6,833 scans for North Carolina (93,953 scans – 87,120 scans = 6,833 scans). As noted above, EmmergeOrtho understated the actual number of scans provided in the state in 2021 by 28,000; when this figure is subtracted from the applicant’s projected unmet need of 6,833 scans, the methodology fails to demonstrate any unmet need for additional MRI scanners in the state. While there is a need determination for three additional mobile MRI scanners, this error is

carried through the remainder of the utilization methodology, resulting in unreasonable projections.

Despite these adjustments, EmergeOrtho provides conflicting information against this calculation in step 11, which shows net unserved MRI scans by cluster for 2027.

**Table 10: Summary of Net Unserved MRI Scans by Cluster, 2027**

Cluster Number	Cluster Name	Net Unmet Scans
1	Western NC	2,264
2	Foothills NC	1,200
3	Southwestern NC	18,401
4	Triad NC	5,327
5	Triangle NC	55,792
6	Southeastern NC	695
7	Eastern NC	113
8	Northeastern NC	2,930
9	Coastal	1,439
0	Other Not Included Counties	0

Source: Project ID # J-012357-23, p. 158.

These figures, however, are overstated, given the currently approved MRI scanners as well as the additional analysis shown above. As such, EmergeOrtho’s volume projections are unsupported.

Interestingly, following this table, EmergeOrtho states that “EmergeOrtho is proposing to serve Cluster 1 / Western NC. Again, one mobile MRI scanner cannot service the entire state...It is therefore necessary to narrow the need to one Cluster.”<sup>19</sup> Given the unmet need figures provided above, however, the choice of “Western NC” for this scanner is not supported; there are other clusters with higher unmet need in which EmergeOrtho could choose to develop a mobile MRI scanner.

EmergeOrtho further provides a calculation for the number of unserved orthopedic MRI scans by county through project year three. It assumes that “it is reasonable and conservative...[that] 50 percent of MRI scans will be spine or musculoskeletal (orthopedic-related).”<sup>20</sup> CNSA does not question the validity of this assumption or the use of this figure as a means of estimation; however, there is nothing that correlates the need calculated in the previous steps of EmergeOrtho’s methodology to orthopedic MRI services specifically. In other words, 52 percent of all MRI services being orthopedic scans does not mean that that same ratio will hold for the population that EmergeOrtho projects are not being served.

**Given these factors, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards in the MRI rules.**

<sup>19</sup> Ibid, p. 158.

<sup>20</sup> Ibid, p. 159.

2. EmergeOrtho does not provide evidence of the availability of its proposed equipment.

In Form F.1a Capital Cost and Form F.1a Capital Cost Assumptions, EmERGEOrtho provides a cost estimate for the medical equipment for its proposed project, and states that the proposed cost for the MRI magnet are quoted in Exhibit F.1.<sup>21</sup> However, the equipment quote that EmERGEOrtho provides in Exhibit F.1 uses the same purchase agreement identifying number – NIS-002169 – for all three of EmERGEOrtho’s applications.<sup>22</sup>

Given that EmERGEOrtho has submitted more than one application for a statewide need for three mobile MRI scanners, and given that EmERGEOrtho could in theory be approved for more than one mobile MRI scanner following Agency review, it would be impossible for EmERGEOrtho to utilize the same purchase agreement for each approved application, as it would ultimately require the purchase of more than one mobile MRI scanner. Further, the purchase agreement is for a refurbished mobile MRI scanner, which further adds to the scarcity of the equipment; it would be tangibly impossible, therefore, for EmERGEOrtho to acquire more than one of the proposed MRI scanners following the approval of more than one of its applications. Given this, the capital costs that EmERGEOrtho provides in Form F.1a cannot be considered reasonable without unique equipment quotes for each of its mobile MRI applications.

**EmERGEOrtho’s application, therefore, is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

3. EmergeOrtho does not include working capital in its financial projections.

In Section F.3, EmERGEOrtho omits all answers related to working capital and the availability of funds for working capital, stating that it “proposes to utilize its own office locations as host sites for the mobile MRI scanner. These are ongoing operations and will not require working capital.”<sup>23</sup> However, the financial projections EmERGEOrtho provides in Section Q, Forms F.2a, F.2b, F.3a, and F.3b are *not* for the entirety of its office locations, but *only* for its individual existing and proposed MRI scanners.<sup>24</sup> As such, the financials that EmERGEOrtho provides do not fully support the financial feasibility of the proposed project as suggested by EmERGEOrtho itself in its application.

As such, the application fails to demonstrate that the practice can support the start-up and initial operating expenses of the proposed project, and it has failed to demonstrate the availability of funds for capital and operating needs.

**The EmERGEOrtho application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

4. EmergeOrtho does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

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<sup>21</sup> Ibid, pp. 172-173.

<sup>22</sup> See Exhibit F.1 in Project ID # J-012357-23, Project ID # J-012358-23, and Project ID # J-012359-23.

<sup>23</sup> Project ID # J-012357-23, p. 79.

<sup>24</sup> Ibid, pp. 174-184.

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

In Section B.1.a, EmergeOrtho acknowledges that the need determination for which it is applying is a statewide one; yet in Section C.7, EmergeOrtho only lists its existing scanners that it owns and operates in the counties it proposes to serve – *not* all MRI scanners it owns and operates statewide. In reality, EmergeOrtho owns and operates two mobile MRI scanners and five fixed MRI scanners across the state of North Carolina, as detailed in its Form O Facilities.<sup>25</sup> As such, it does not follow the requisite instructions in the performance standards listed above.

EmergeOrtho does provide a statement regarding the need to project volume across all of its MRI scanners in its Section Q, quoted at length below:

*The SHCC 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. One single mobile MRI unit cannot reasonably serve the entire state of North Carolina. However, it is reasonable to determine a service area that could reach most patients in need of access to additional MRI services. The following methodology evaluates MRI need by county and narrows the statewide need to a cluster of counties that could be served efficiently with a mobile route. It then provides a methodology for this proposed project...<sup>26</sup>*

EmergeOrtho is misinterpreting and misrepresenting Mr. McKillip’s statement. Mr. McKillip’s point of clarity is to state that an applicant does not have to project its proposed mobile MRI scanner to serve the entire state. However, that applicant *does* still have to meet the

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<sup>25</sup> Ibid, p. 189.

<sup>26</sup> Ibid, p. 128.



performance standards as defined in 10A NCAC 14C .2703. If an applicant has multiple MRI scanners statewide, this would mean that that applicant would have to project volume for the entirety of those scanners, and project that those scanners meet the necessary performance standard. Given the ability of mobile MRI scanners to move and serve other areas of the state, this is clearly the only rational interpretation of the rule.

Given that EmergeOrtho does not provide volume projections for any of its other MRI scanners, it therefore also does not provide assumptions for those scanners, as well, thereby failing to demonstrate conformity with 10A NCAC 14C .2703(b) (6) and (7). The only assumptions that EmergeOrtho does provide are for the proposed mobile MRI scanner, which are given in Section Q.

**As such, EmergeOrtho is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards in the MRI rules.**

5. EmergeOrtho does not sufficiently document the need for the proposed project.

In “Section Q: EmergeOrtho Need and Utilization Methodology for Section C Blue Ridge / Foothills,” EmergeOrtho proceeds to forecast the number of MRI scans by county by year by using a static use rate; mainly, the North Carolina MRI scan use rate per 1,000 population of 92.4.<sup>27</sup>

The use of this use rate, however, is flawed, given that different counties in the state of North Carolina have largely varying health profiles that will drastically affect whether or not this use rate will accurately capture their true utilization of MRI services. For example, in the data set that EmergeOrtho presents, Johnston County residents would be expected to receive 21,580 MRI scans in 2022; meanwhile, as presented, Johnston County residents only received 13,719 scans in 2021.<sup>28</sup> While EmergeOrtho claims that using a single MRI use rate is reasonable because it “provides uniform forecasts,”<sup>29</sup> it is questionable whether an applicant would want to use a use rate that is uniform in order to project MRI use rate across disparate, distinct North Carolina counties. In particular, this single statewide use rate is problematic considering the example of Johnston County, which would be expected to increase its volume by over 57 percent in a single year, if the application’s projections were reasonable.

Further, and as mentioned above, EmergeOrtho submitted three applications – one to serve the Blue Ridge/Foothills area of western North Carolina, one to serve the Triad counties, and a final application to serve the Triangle counties. However, curiously, none of the three EmergeOrtho applications makes any mention of any other application. As EmergeOrtho would presumably have to coordinate care between multiple mobile MRI scanners if more than one of its applications were to be approved by the Agency, some consideration would be necessary as to how this coordination would be performed by the applicant.

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<sup>27</sup> Ibid, p. 142.

<sup>28</sup> Ibid, pp. 141, 144. Of note, the patient origin data from DHSR reports that 11,256 Johnston County residents had MRI scans in 2021. [https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/30-PatientOrigin\\_MRI-2022.pdf](https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/30-PatientOrigin_MRI-2022.pdf).

<sup>29</sup> Ibid, p. 135.

**As such, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4) (6), (13), and (18a), as well as the performance standards in the MRI rules.**

6. EmergeOrtho includes several inconsistencies regarding the proposed routing for its mobile MRI scanner.

In its response to Policy GEN-3, EmergeOrtho lists four proposed host sites for its mobile MRI scanner to serve the “Blue Ridge / Foothills” service area as well as the days per month that its proposed mobile MRI scanner will serve each location.<sup>30</sup> For the host site at 129 McDowell St in Asheville, EmergeOrtho lists the total days per month as eight; for the host site at 503 E Parker Rd in Morganton, in lists the total days per month as six. However, on page 28 in the same section, it later claims that the proposed mobile MRI scanner will serve the 129 McDowell St location nine days per month, and 503 E Parker Rd location five days per month.<sup>31</sup>

Further, in Section E, EmergeOrtho states that “[t]he Applicant selected the following three physician office locations as the most effective host sites,” then lists four host sites: Asheville, Hendersonville and Waynesville, and Morganton.<sup>32</sup> Further, the tables cited above on pages 25 and 28 both list four locations, as well. These inconsistencies are particularly problematic for the utilization projections as the volume of a mobile MRI scanner is dependent on the number of days it will serve various sites.

**As such, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6) and the performance standards in the MRI rules.**

7. EmergeOrtho’s forecasted patient information is not consistent across its application.

In Section C.7, EmergeOrtho forecasts patient and unweighted and weighted volume for both its existing and proposed MRI scanners through 2027:

Table 13: EmergeOrtho Existing and Proposed Owned and Operated Fixed and Mobile MRI Forecast Patients, 2023-2027

Scanner	CY23	Jan-Mar CY24	Apr-Dec CY24	CY25	CY26	CY27
BRFH Mobile 2	5,515	1,383	4,149	5,548	5,565	5,582
BRFH Mobile 6			2,772	3,699	3,705	3,710

Table 14: EmergeOrtho Existing and Proposed Owned and Operated Mobile and Fixed MRI Scanner Unweighted Scan Projections, 2023-2027

Scanner	CY23	Jan-Mar CY24	Apr-Dec CY24	CY25	CY26	CY27
BRFH Mobile 2	5,864	1,471	4,412	5,900	5,918	5,936
BRFH Mobile 6			2,947	3,934	3,940	3,945

Table 15: EmergeOrtho Existing and Proposed Owned and Operated Mobile and Fixed MRI Scanner Weighted Scan Projections, 2023-2027

Scanner	CY23	Jan-Mar CY24	Apr-Dec CY24	CY25	CY26	CY27
BRFH Mobile 2	5,935	1,488	4,464	5,970	5,989	6,007
BRFH Mobile 6			2,983	3,981	3,987	3,993

<sup>30</sup> Ibid, p. 25.

<sup>31</sup> Ibid, p. 28.

<sup>32</sup> Ibid, p. 74.

Source: Project ID # J-012357-23, p. 61

However, this projected volume is inconsistent with the volume reported in EmergeOrtho’s Form C.2b, specifically for the projected weighted procedures for “BRFH Mobile MRI 6.”

Form C.2b Projected Medical Equipment Utilization upon Project Completion ^  EmergeOrtho - BRFH Mobile MRI 6	Partial FY	1st Full FY	2nd Full FY	3rd Full FY
	F: 04/01/2024	F: 01/01/2025	F: 01/01/2026	F: 01/01/2027
	T: 12/31/2024	T: 12/31/2025	T: 12/31/2026	T: 12/31/2027
MRI Scanner (see Tab C)				
# of Units	1	1	1	1
# of Procedures	3,084	4,023	4,028	4,034
# of Weighted Procedures	3,121	4,071	4,077	4,083

Source: Project ID # J-012357-23, p. 127.

Based on these inconsistencies, the actual projected utilization of the mobile MRI scanner is unclear, and the application should be found **non-conforming to N.C. Gen. Stat. § 131E-183(a)(3) (5), (6), and (18a), as well as the performance standards for MRI scanners.**

8. EmergeOrtho does not demonstrate that its proposed service area has a need for the proposed project.

In Section C.4, EmergeOrtho outlines the need for the proposed project, which includes “population growth and age of the service area counties” and “need for additional access to MRI in Blue Ridge / Foothills Route,”<sup>33</sup> amongst other points. However, the data that EmergeOrtho presents in its application does not support or confirm these reasons as driving patient need for the proposed mobile MRI scanner in the counties it proposes to serve.

First, EmergeOrtho provides the population by age in the Blue Ridge / Foothills Route communities for 2023 and projected for 2027, along with the compound annual growth rate (CAGR) for each of those age demographics. That table is replicated below.

**Table 5: Population by Age Group in the Blue Ridge / Foothills Route Counties, 2023 and 2027**

Blue Ridge / Foothills Route	<18	18-44	45-64	65+
2023	140,303	219,924	202,758	193,422
2027	139,059	226,125	204,190	207,982
Growth	(1,244)	6,201	1,432	14,560
CAGR	-0.2%	0.7%	0.2%	1.8%

*Source: NCOSBM population by age, sex, and race, 2000-2050*

Source: Project ID # J-012357-23, p. 43.

However, EmergeOrtho does not provide the total CAGR for the entirety of the service area population across all age groups. This CAGR is 0.69 percent. This growth rate is in fact *lower*

<sup>33</sup> Ibid, p. 41.

than the CAGR of the state of North Carolina over that same period, using data sourced from the North Carolina Office of State Budget and Management (NC OSBM).

**Total Population CAGR for Proposed Service Area and Stat  
FY 2023 – FY 2027**

<i>Service Area</i>	<i>2023</i>	<i>2027</i>	<i>CAGR</i>
Blue Ridge / Foothills Route	756,407	777,356	0.69%
<b>North Carolina</b>	<b>10,794,463</b>	<b>11,270,518</b>	<b>1.08%</b>

Source: Project ID # J-012357-23, p. 43; NC OSBM.

Given this relatively low overall growth rate, the population that EmergeOrtho purports to serve does not demonstrate a need for further medical services based on demographic growth alone.

Second, in Step 12 of its “Section Q: EmergeOrtho Need and Utilization Methodology for Section C Blue Ridge / Foothills,” EmergeOrtho details the estimated number for orthopedic MRI scans within the “cluster” of counties it will serve through the proposed project through the year 2027. However, as seen below, it only estimates that there will be 1,132 ortho-only MRI scans within that service area by 2027.

**Table 11: Estimated Number of Ortho-Only MRI Scans by County by Cluster, 2022-2027**

Cluster	County	2022	2023	2024	2025	2026	2027
1	Buncombe	-	-	15	-	-	-
1	Burke	45	69	76	-	-	-
1	Cherokee	234	244	253	208	215	222
1	Clay	201	209	214	197	201	206
1	Graham	78	79	79	64	64	64
1	Haywood	-	-	-	-	-	-
1	Henderson	-	-	-	-	-	-
1	Jackson	358	374	391	327	339	351
1	Macon	-	-	7	-	-	-
1	Rutherford	366	374	382	271	273	275
1	Swain	33	35	38	13	14	14
1	Transylvania	-	-	-	-	-	-
1	<b>Summary</b>	<b>1,315</b>	<b>1,383</b>	<b>1,454</b>	<b>1,082</b>	<b>1,107</b>	<b>1,132</b>

*Note: unserved patients by county Step 11 \* 50%*

Source: Project ID # J-012357-23, p. 159.

The counties in which EmergeOrtho proposes hosting its proposed mobile MRI scanner are Buncombe, Burke, Henderson, and Haywood counties. EmergeOrtho projects that none of these counties will have a need for ortho-only MRI scans by the year 2027. All scans originate from counties outside of EmergeOrtho’s selected host counties, thereby not justifying the need for EmergeOrtho’s services at its proposed host sites.

EmergeOrtho further forecasts the number of unserved orthopedic MRI scans within the cluster of counties it will serve through the proposed project through the year 2027. It only estimates providing 296 new scans within that service area by 2027.

**Table 15: Forecast New Ortho-Only Scans by Patient County Served at EmmergeOrtho Cluster 1 Blue Ridge/Foothills Route Host Sites, 2024-2027**

Cluster	Patient County	2024	2025	2026	2027
1	Buncombe	-	-	-	-
1	Burke	-	-	-	-
1	Cherokee	25	21	22	22
1	Clay	21	20	20	21
1	Graham	8	6	6	6
1	Haywood	-	-	-	-
1	Henderson	-	-	-	-
1	Jackson	117	98	102	105
1	Macon	-	-	-	-
1	McDowell	-	-	-	-
1	Rutherford	191	136	137	138
1	Swain	11	4	4	4
<b>Total New</b>		<b>374</b>	<b>285</b>	<b>290</b>	<b>296</b>

*Notes: total patients by year Step 12, Table 11 \* market share column Step 15, Table 14*

Source: Project ID # J-012357-23, p. 164.

In order to ensure it meets the performance standard for a mobile MRI scanner by its project year three, EmmergeOrtho claims that the rest of its scans will originate from recaptured patients currently referred out of the counties within Cluster 1. Those recapture rates are provided below.

**Table 16: EmergeOrtho Ortho-Only MRI Patients Referred Out by County, 2021, and Estimated Percent Recapture, 2024-2027**

Cluster	Patient County	Referred Out Patients FY21	Est. Referred Out Scans FY21	Percent Recapture	Total Recapture Scans by Year
		a	b	c	d
1	Buncombe	2,296	2,442	60.0%	1,465
1	Burke	839	892	55.0%	491
1	Cherokee	14	15	50.0%	7
1	Clay	-	-	50.0%	-
1	Graham	17	18	50.0%	9
1	Haywood	195	207	95.0%	197
1	Henderson	845	899	95.0%	854
1	Jackson	91	97	50.0%	48
1	Macon	57	61	50.0%	30
1	McDowell	531	565	95.0%	536
1	Rutherford	70	74	95.0%	71
1	Swain	29	31	95.0%	29
<i>Total Recapture</i>					<b>3,738</b>

*Sources and Notes:*

- a. EmergeOrtho internal patient data, provided February 2023; EmergeOrtho patients referred to other providers by Blue Ridge / Foothills Route County
- b.  $a * 1.06$ , EmergeOrtho average scans per patient
- c. Estimated percent of MRI scans Applicant expects to recapture on the proposed new mobile MRI
- d.  $b * c$

Source: Project ID # J-012357-23, p. 165.

These provided recapture rates are inconsistent. For example, EmergeOrtho projects to recapture 95 percent of patients from Henderson County, despite that county having two existing MRI scanners in its service area; however, it only projects to recapture 55 percent of patients from Burke County, despite that county having four MRI scanners in its service area. EmergeOrtho does not provide supported justification for the variance in these recapture rates, only stating that they are based on “drive times and other providers in the proposed counties.”<sup>34</sup>

**Therefore, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and the performance standards for MRI scanners.**

9. EmergeOrtho does not select the most effective alternative for the proposed project based on its own analysis.

In Section E.3.b, EmergeOrtho outlines the alternatives considered instead of the proposed project. One such alternative is to “Choose Other Clusters to Serve.” EmergeOrtho identifies nine clusters of counties to which its proposed mobile MRI scanner could possibly be routed, as well as counties that EmergeOrtho did not group into any such cluster. It also includes its projected number of unserved MRI scans for the year 2027, using its own methodology as outlined in Section Q. That table is replicated below.

<sup>34</sup> Ibid, p. 165.

**Table 17: NC Counties by Mobile MRI Cluster**

Cluster	Counties	Est. Unserved MRI Scans 2027
1: West	Buncombe, Burke, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Rutherford, Swain, Transylvania	2,264
2: Foothills	Alexander, Alleghany, Ashe, Avery, Caldwell, Catawba, Iredell, Watauga, Wilkes	1,200
3: South	Cabarrus, Cleveland, Gaston, Lincoln, Mecklenburg, Union	18,401
4: Triad	Alamance, Caswell, Chatham, Davidson, Guilford, Randolph, Rockingham	5,327
5: Triangle	Durham, Franklin, Granville, Harnett, Johnston, Nash, Orange, Person, Vance, Wake, Warren	55,792
6: Southeast	Bladen, Cumberland, Hoke, Lee, Moore, Richmond, Robeson, Sampson, Scotland	695

Cluster	Counties	Est. Unserved MRI Scans 2027
7: East	Craven, Duplin, Greene, Jones, Lenoir, Pitt, Wayne	113
8: Northeast	Beaufort, Bertie, Camden, Chowan, Currituck, Dare, Gates, Hertford, Hyde, Martin, Northampton, Pasquotank, Perquimans, Tyrrell, Washington	2,930
9: Coastal	Brunswick, Columbus, New Hanover, Onslow, Pender	1,439
0: Other counties not included in a Cluster	Anson, Carteret, Davie, Edgecombe, Forsyth, Halifax, Madison, McDowell, Mitchell, Montgomery, Pamlico, Polk, Rowan, Stanly, Stokes, Surry, Wilson, Yadkin, Yancey	0

Source: Project ID # J-012357-23, pp. 70-71.

The three clusters with the highest number of unserved MRI scans in the state, according to EmergeOrtho’s own analysis, are “Triangle,” “South,” and “Triad,” in that order. While two of EmergeOrtho’s applications for the statewide need for three mobile MRI scanners *do* propose to serve two of the highest unserved clusters identified in the table above (the Triangle and Triad clusters, ranking first and third in terms of most unserved MRI scans by 2027, respectively), EmergeOrtho does *not* propose to serve the South cluster of counties, which shows a need for 18,401 unserved MRI scans by 2027. Nowhere in Section E – or elsewhere in its application – does EmergeOrtho explain its decision to not serve this cluster of counties.

In fact, the “Northeast” cluster of counties is *also* projected to have a higher number of unmet unserved MRI scans by 2027 than the West cluster, at 2,930 scans versus 2,264 scans. EmergeOrtho also does not explain its decision to not serve this cluster of counties, despite, according to its own methodology, a higher need existing there.

**The EmergeOrtho application is as such non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4), (5), and (6) and the performance standards in the rules for MRI scanners.**

**In summary, based on the issues detailed above, the EmergeOrtho application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (4), (5), (6), (13), and (18a), and the performance standards in the MRI rules.**



**EMERGEORTHO MOBILE MRI TRIAD ROUTE, PROJECT ID # J-012358-23**

**Issue-Specific Comments**

1. EmergeOrtho’s utilization and methodology is unreasonable and based on inconsistent data and assumptions.

In “Section Q: EmERGEOrtho Need and Utilization Methodology for Section C Triad,” EmERGEOrtho provides utilization projections for the first three years of the proposed mobile MRI scanner. To do so, EmERGEOrtho makes a series of projections that are inconsistent and unsupported by external data and its own evidence.

First, in Step 6, in order to estimate the unmet need for MRI services in its proposed service area, EmERGEOrtho provides an estimate of the adjusted North Carolina MRI scans by county for fiscal year (FY) 2021. It ultimately reaches an estimate of 947,966 adjusted total scans for FY 2021, as seen in the table below, which has been partially replicated:

County	FY21 Est. Reported Scans	FY21 Est. Unreported Scans	FY21 Est. Adjusted Total Scan
Surry	8,295		8,295
Swain	1,258		1,258
Transylvania	3,788		3,788
Tyrrell	273		273
Union	20,588	1,191	21,779
Vance	4,308		4,308
Wake	70,523	9,291	79,814
Warren	905		905
Washington	1,065		1,065
Watauga	3,236		3,236
Wayne	10,097		10,097
Wilkes	6,093		6,093
Wilson	7,275	66	7,342
Yadkin	4,344		4,344
Yancey	1,890		1,890
NC State Total	916,897	31,069	947,966

*Notes: total estimated scans Step 5 + estimated unreported scan by county, Exhibit C.5*

Source: Project ID # J-012358-23, p. 140.

However, this understates the true number of total MRI scans as reported in the 2023 SMFP for FY 2021, which totaled 975,892.<sup>35</sup> EmERGEOrtho itself states that this estimate “[is] within 97% of the scans reported in Table 17E-1 in the 2023 SMFP (947,966 / 975,892 = 0.971);”<sup>36</sup> in short, EmERGEOrtho validates that its own estimate is an underestimate of the true MRI scan total, by approximately 28,000 scans.

<sup>35</sup> 2023 SMFP, p. 353.

<sup>36</sup> Project ID # J-012358-23, p. 140.

EmergeOrtho further estimates, in step 8, the number of unserved MRI scans by county through FY 2027, in order to approximate unmet need at the county level. It concludes that, in FY 2027, there will be an estimated unmet need for 93,953 adjusted MRI scans in North Carolina, shown below.

Wayne	769	760	753	747	742	737
Wilkes	-	-	-	-	-	-
Wilson	-	-	-	-	-	-
Yadkin	-	-	-	-	-	-
Yancey	-	-	-	-	-	-
<b>NC State Total</b>	<b>38,241</b>	<b>49,943</b>	<b>61,450</b>	<b>72,534</b>	<b>83,245</b>	<b>93,953</b>

Notes: projected county scans Step 7, Table 6 – adjusted FY21 scans, Step 6, Table 5

Source: Project ID # J-012358-23, p. 146.

However, in Step 10, EmmergeOrtho accounts for the calculated surplus of MRI scans to be captured by new and not yet operational MRI scanners by cluster for FY 2027. While EmmergeOrtho does not sum the total of these scans, the summation across all clusters, as seen in the table below, is 87,120 scans.

**Surplus of MRI Scans to be Captured by New/Not Yet Operational MRI Scanners  
FY 2027**

<b>Cluster</b>	<b>MRI Scans</b>
Cluster 1	2,904
Cluster 2	5,808
Cluster 3	17,424
Cluster 4	7,260
Cluster 5	15,972
Cluster 6	8,712
Cluster 7	7,260
Cluster 8	4,356
Cluster 9	8,712
No Cluster	8,712
<b>Total</b>	<b>87,120</b>

Source: Project ID # J-012358-23, pp. 149-152.

This means that, when accounting for this met need, EmmergeOrtho projects an unmet need of 6,833 scans for North Carolina (93,953 scans – 87,120 scans = 6,833 scans). As noted above, EmmergeOrtho understated the actual number of scans provided in the state in 2021 by 28,000; when this figure is subtracted from the applicant’s projected unmet need of 6,833 scans, the methodology fails to demonstrate any unmet need for additional MRI scanners in the state. While there is a need determination for three additional mobile MRI scanners, this error is

carried through the remainder of the utilization methodology, resulting in unreasonable projections.

Despite these adjustments, EmergeOrtho provides conflicting information against this calculation in step 11, which shows net unserved MRI scans by cluster for 2027.

**Table 10: Summary of Net Unserved MRI Scans by Cluster, 2027**

Cluster Number	Cluster Name	Net Unmet Scans
1	West	2,591
2	Foothills	1,200
3	Southwest	18,401
4	Triad	5,451
5	Triangle	55,557
6	Southeast	695
7	East	113
8	Northeast	2,930
9	Coastal	1,439

Source: Table 7

Source: Project ID # J-012358-23, p. 156.

These figures, however, are overstated, given the currently approved MRI scanners as well as the additional analysis shown above. As such, EmergeOrtho’s volume projections are unsupported.

Interestingly, following this table, EmergeOrtho states that “EmergeOrtho is proposing to serve Cluster 4 / Triad NC. Again, one mobile MRI scanner cannot service the entire state...It is therefore necessary to narrow the need to one Cluster.”<sup>37</sup> Given the unmet need figures provided above, however, the choice of “Triad NC” for this scanner is not supported; there are other clusters with higher unmet need in which EmergeOrtho could choose to develop a mobile MRI scanner.

EmergeOrtho further provides a calculation for the number of unserved orthopedic MRI scans by county through project year three. It assumes that “it is reasonable and conservative...[that] 50 percent of MRI scans will be spine or musculoskeletal (orthopedic-related).”<sup>38</sup> CNSA does not question the validity of this assumption or the use of this figure as a means of estimation; however, there is nothing that correlates the need calculated in the previous steps of EmergeOrtho’s methodology to orthopedic MRI services specifically. In other words, 52 percent of all MRI services being orthopedic scans does not mean that that same ratio will hold for the population that EmergeOrtho projects are not being served.

**Given these factors, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards in the MRI rules.**

<sup>37</sup> Ibid, p. 156.

<sup>38</sup> Ibid, p. 157.

2. EmergeOrtho does not provide evidence of the availability of its proposed equipment.

In Form F.1a Capital Cost and Form F.1a Capital Cost Assumptions, EmERGEOrtho provides a cost estimate for the medical equipment for its proposed project, and states that the proposed cost for the MRI magnet are quoted in Exhibit F.1.<sup>39</sup> However, the equipment quote that EmERGEOrtho provides in Exhibit F.1 uses the same purchase agreement identifying number – NIS-002169 – for all three of EmERGEOrtho’s applications.<sup>40</sup>

Given that EmERGEOrtho has submitted more than one application for a statewide need for three mobile MRI scanners, and given that EmERGEOrtho could in theory be approved for more than one mobile MRI scanner following Agency review, it would be impossible for EmERGEOrtho to utilize the same purchase agreement for each approved application, as it would ultimately require the purchase of more than one mobile MRI scanner. Further, the purchase agreement is for a refurbished mobile MRI scanner, which further adds to the scarcity of the equipment; it would be tangibly impossible, therefore, for EmERGEOrtho to acquire more than one of the proposed MRI scanners following the approval of more than one of its applications. Given this, the capital costs that EmERGEOrtho provides in Form F.1a cannot be considered reasonable without unique equipment quotes for each of its mobile MRI applications.

**EmerGEOrtho’s application, therefore, is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

3. EmerGEOrtho does not include working capital in its financial projections.

In Section F.3, EmERGEOrtho omits all answers related to working capital and the availability of funds for working capital, stating that it “proposes to utilize its own office locations as host sites for the mobile MRI scanner. These are ongoing operations and will not require working capital.”<sup>41</sup> However, the financial projections EmERGEOrtho provides in Section Q, Forms F.2a, F.2b, F.3a, and F.3b are *not* for the entirety of its office locations, but *only* for its individual existing and proposed MRI scanners.<sup>42</sup> As such, the financials that EmERGEOrtho provides do not fully support the financial feasibility of the proposed project as suggested by EmERGEOrtho itself in its application.

As such, the application fails to demonstrate that the practice can support the start-up and initial operating expenses of the proposed project, and it has failed to demonstrate the availability of funds for capital and operating needs.

**The EmERGEOrtho application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

4. EmerGEOrtho does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703 state the following:

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<sup>39</sup> Ibid, pp. 171-172.

<sup>40</sup> See Exhibit F.1 in Project ID # J-012357-23, Project ID # J-012358-23, and Project ID # J-012359-23.

<sup>41</sup> Project ID # J-012358-23, p. 77.

<sup>42</sup> Ibid, pp. 173-183.

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

In Section B.1.a, EmergeOrtho acknowledges that the need determination for which it is applying is a statewide one; yet in Section C.7, EmergeOrtho only lists its existing scanners that it owns and operates in the counties it proposes to serve – *not* all MRI scanners it owns and operates statewide. In reality, EmergeOrtho owns and operates two mobile MRI scanners and five fixed MRI scanners across the state of North Carolina, as detailed in its Form O Facilities.<sup>43</sup> As such, it does not follow the requisite instructions in the performance standards listed above.

EmergeOrtho does provide a statement regarding the need to project volume across all of its MRI scanners in its Section Q, quoted at length below:

*The SHCC 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. One single mobile MRI unit cannot reasonably serve the entire state of North Carolina. However, it is reasonable to determine a service area that could reach most patients in need of access to additional MRI services. The following methodology evaluates MRI need by county and narrows the statewide need to a cluster of counties that could be served efficiently with a mobile route. It then provides a methodology for this proposed project...<sup>44</sup>*

EmergeOrtho is misinterpreting and misrepresenting Mr. McKillip’s statement. Mr. McKillip’s point of clarity is to state that an applicant does not have to project its proposed mobile MRI

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<sup>43</sup> Ibid, p. 188.

<sup>44</sup> Ibid, p. 127.

scanner to serve the entire state. However, that applicant *does* still have to meet the performance standards as defined in 10A NCAC 14C .2703. If an applicant has multiple MRI scanners statewide, this would mean that that applicant would have to project volume for the entirety of those scanners, and project that those scanners meet the necessary performance standard. Given the ability of mobile MRI scanners to move and serve other areas of the state, this is clearly the only rational interpretation of the rule.

Given that EmergeOrtho does not provide volume projections for any of its other MRI scanners, it therefore also does not provide assumptions for those scanners, as well, thereby failing to demonstrate conformity with 10A NCAC 14C .2703(b) (6) and (7). The only assumptions that EmergeOrtho does provide are for the proposed mobile MRI scanner, which are given in Section Q.

**As such, EmergeOrtho is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards in the MRI rules.**

5. EmergeOrtho does not sufficiently document the need for the proposed project.

In “Section Q: EmergeOrtho Need and Utilization Methodology for Section C Triad,” EmergeOrtho proceeds to forecast the number of MRI scans by county by year by using a static use rate; mainly, the North Carolina MRI scan use rate per 1,000 population of 92.4.<sup>45</sup>

The use of this use rate, however, is flawed, given that different counties in the state of North Carolina have largely varying health profiles that will drastically affect whether or not this use rate will accurately capture their true utilization of MRI services. For example, in the data set that EmergeOrtho presents, Johnston County residents would be expected to receive 21,580 MRI scans in 2022; meanwhile, as presented, Johnston County residents only received 13,719 scans in 2021.<sup>46</sup> While EmergeOrtho claims that using a single MRI use rate is reasonable because it “provides uniform forecasts,”<sup>47</sup> it is questionable whether an applicant would want to use a use rate that is uniform in order to project MRI use rate across disparate, distinct North Carolina counties. In particular, this single statewide use rate is problematic considering the example of Johnston County, which would be expected to increase its volume by over 57 percent in a single year, if the application’s projections were reasonable.

Further, and as mentioned above, EmergeOrtho submitted three applications – one to serve the Blue Ridge/Foothills area of western North Carolina, one to serve the Triad counties, and a final application to serve the Triangle counties. However, curiously, none of the three EmergeOrtho applications makes any mention of any other application. As EmergeOrtho would presumably have to coordinate care between multiple mobile MRI scanners if more than one of its applications were to be approved by the Agency, some consideration would be necessary as to how this coordination would be performed by the applicant.

**As such, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4) (6), (13), and (18a), as well as the performance standards in the MRI rules.**

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<sup>45</sup> Ibid, p. 141.

<sup>46</sup> Ibid, pp. 139, 142.

<sup>47</sup> Ibid, p. 134.

6. EmergeOrtho includes several inconsistencies regarding the proposed routing for its mobile MRI scanner.

In its response to Policy GEN-3, EmERGEOrtho lists four proposed host sites for its mobile MRI scanner to serve the “Triad” service area as well as the days per month that its proposed mobile MRI scanner will serve each location.<sup>48</sup> For the host site at 4430 US Hwy 220 N in Summerfield, EmERGEOrtho lists the total days per month as eight; for the host site at 600 West Salisbury Street in Asheboro, it lists the total days per month as five. However, on page 29 in the same section, it later claims that the proposed mobile MRI scanner will serve the 4430 US Hwy 220 N location nine days per month, and 600 West Salisbury Street location four days per month.<sup>49</sup> These inconsistencies are particularly problematic for the utilization projections as the volume of a mobile MRI scanner is dependent on the number of days it will serve various sites.

Additionally, in Section C.3, EmERGEOrtho identifies its projected patient origin for the proposed project, noting 187, 184, and 181 patients in FY 2025, 2026 and 2027 respectively for Caswell County. EmERGEOrtho also shows 736, 728, and 720 patients across those same three years respectively for Rockingham County.

<Mobile MRI>	<Triad Route> *					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Alamance	1,008	24.8%	1,008	24.8%	1,015	24.8%
Caswell	187	4.6%	184	4.5%	181	4.4%
Chatham	362	8.9%	375	9.2%	386	9.5%
Davidson	22	0.6%	24	0.6%	26	0.6%
Guilford	1,579	38.9%	1,579	38.8%	1,579	38.6%
Randolph	164	4.0%	172	4.2%	179	4.4%
Rockingham	736	18.1%	728	17.9%	720	17.6%
<b>Total</b>	<b>4,059</b>	<b>100.0%</b>	<b>4,071</b>	<b>100.0%</b>	<b>4,087</b>	<b>100.0%</b>

\* This should match the name provided in Section A, Question 4.

\*\* Home health agencies should report the number of unduplicated clients.

Source: Project ID # J-012358-23, p. 38.

However, the patients that EmERGEOrtho projects for its Reidsville and Asheboro locations through FY 2027 do not sum to its total projected patients, as seen below. For example, based on its tables below, Caswell would have 362 patients in total and Rockingham would have 1,407.

<sup>48</sup> Ibid p. 26.

<sup>49</sup> Ibid, p. 29.

<Mobile MRI>	<EmergeOrtho Reidsville> *					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Alamance	-	0.0%	-	0.0%	-	0.0%
Caswell	187	21.1%	184	21.0%	181	20.9%
Chatham	-	0.0%	-	0.0%	-	0.0%
Davidson	-	0.0%	-	0.0%	-	0.0%
Guilford	-	0.0%	-	0.0%	-	0.0%
Randolph	-	0.0%	-	0.0%	-	0.0%
Rockingham	702	78.9%	694	79.0%	687	79.1%
<b>Total</b>	<b>890</b>	<b>100.0%</b>	<b>879</b>	<b>100.0%</b>	<b>867</b>	<b>100.0%</b>

<Mobile MRI>	<EmergeOrtho Asheboro> *					
	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	01/01/2025 to 12/31/2025		01/01/2026 to 12/31/2026		01/01/2027 to 12/31/2027	
County or other geographic area such as ZIP code	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of Patients **	% of Total
Alamance	-	0.0%	-	0.0%	-	0.0%
Caswell	187	20.3%	184	20.2%	181	20.1%
Chatham	-	0.0%	-	0.0%	-	0.0%
Davidson	-	0.0%	-	0.0%	-	0.0%
Guilford	-	0.0%	-	0.0%	-	0.0%
Randolph	-	0.0%	-	0.0%	-	0.0%
Rockingham	736	79.7%	728	79.8%	720	79.9%
<b>Total</b>	<b>923</b>	<b>100.0%</b>	<b>912</b>	<b>100.0%</b>	<b>901</b>	<b>100.0%</b>

Source: Project ID # J-012358-23, p. 39.

These irregularities in EmergeOrtho’s projections through project year three render those projections unreliable and inconsistent.

**The EmergeOrtho application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), (13), and the performance standards in the MRI rules.**

7. EmergeOrtho does not demonstrate that its proposed service area has a need for the proposed project.

In Section C.4, EmergeOrtho outlines the need for the proposed project, which includes “population growth and age of patients to be served in the Triad Route counties” and “need for additional access to MRI in low use rate counties,”<sup>50</sup> amongst other points. However, the data that EmergeOrtho presents in its application does not support or confirm these reasons as driving patient need for the proposed mobile MRI scanner in the counties it proposes to serve.

First, EmergeOrtho provides the population by age in the Triad Route communities for 2023 and projected for 2027, along with the compound annual growth rate (CAGR) for each of those age demographics. That table is replicated below.

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<sup>50</sup> Ibid, p. 42.



**Table 6: Population by Age Group in the Triad Route Counties, 2023 and 2027**

Triad Route	<18	18-44	45-64	65+
2023	247,815	124,646	318,452	237,723
2027	248,631	124,477	314,177	262,880
Growth	816	(169)	(4,275)	25,157
CAGR	0.1%	0.0%	-0.3%	2.5%

Source: NCOSBM population by age, sex, and race, 2000-2050

Source: Project ID # J-012358-23, p. 44.

However, EmergeOrtho does not provide the total CAGR for the entirety of the service area population across all age groups. This CAGR is 0.57 percent. This growth rate is nearly *half* of the CAGR of the state of North Carolina over that same period, using data sourced from the NC OSBM.

**Total Population CAGR for Proposed Service Area and State  
FY 2023 – FY 2027**

Service Area	2023	2027	CAGR
Triad Route	928,636	950,165	0.57%
<b>North Carolina</b>	<b>10,794,463</b>	<b>11,270,518</b>	<b>1.08%</b>

Source: Project ID # J-012358-23, p. 44; NC OSBM.

Given this relatively low overall growth rate, the population that EmergeOrtho purports to serve does not demonstrate a need for further medical services based on demographic growth alone.

Second, in Section E.3.b, EmergeOrtho outlines the alternatives considered instead of its proposed project. One such alternative is to “Propose a Different Service Geography.” EmergeOrtho identifies nine clusters of counties to which its proposed mobile MRI scanner could possibly be routed, as well as counties that EmergeOrtho did not group into any such cluster. It also includes its projected number of unserved MRI scans for the year 2027, using its own methodology as outlined in Section Q. That table is replicated below.

**Table 20: Unmet MRI Need by Mobile MRI Cluster, 2027**

Cluster	Counties	Est. Unserved MRI Scans 2027
1: West	Buncombe, Cherokee, Clay, Graham, Haywood, Henderson, Jackson, Macon, Rutherford, Swain, Transylvania	2,264
2: Foothills	Alexander, Alleghany, Ashe, Avery, Burke, Caldwell, Catawba, Iredell, Watauga, Wilkes	1,200
3: South	Cabarrus, Cleveland, Gaston, Lincoln, Mecklenburg, Union	18,401
4: Triad	Alamance, Caswell, Chatham, Davidson, Guilford, Randolph, Rockingham	5,327
5: Triangle	Durham, Franklin, Granville, Harnett, Johnston, Nash, Orange, Person, Vance, Wake, Warren	55,792
6: Southeast	Bladen, Cumberland, Hoke, Lee, Moore, Richmond, Robeson, Sampson, Scotland	695

Cluster	Counties	Est. Unserved MRI Scans 2027
7: East	Craven, Duplin, Greene, Jones, Lenoir, Pitt, Wayne	113
8: Northeast	Beaufort, Bertie, Camden, Chowan, Currituck, Dare, Gates, Hertford, Hyde, Martin, Northampton, Pasquotank, Perquimans, Tyrrell, Washington	2,930
9: Coastal	Brunswick, Columbus, New Hanover, Onslow, Pender	1,439
0: Other counties not included in a Cluster	Anson, Carteret, Davie, Edgecombe, Forsyth, Halifax, Madison, McDowell, Mitchell, Montgomery, Pamlico, Polk, Rowan, Stanly, Stokes, Surry, Wilson, Yadkin, Yancey	0

Source: Project ID # J-012358-23, pp. 67-68.

The three clusters with the highest number of unserved MRI scans in the state, according to EmergeOrtho’s own analysis, are “Triangle,” “South,” and “Triad,” in that order. EmergeOrtho does *not* propose to serve the South cluster of counties, which shows a need for 18,401 unserved MRI scans by 2027 – more than three times the total of the Triad cluster for 2027. Nowhere in Section E – or elsewhere in its application – does EmergeOrtho explain its decision to not serve the South cluster as opposed to Triad, or why Triad has need that precludes that of South’s supposed need.

**As such, the EmergeOrtho application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4), (5), (6), and the performance standards for MRI scanners.**

8. EmergeOrtho overstates its net income for partial FY 2024.

In Form F.2b, EmergeOrtho provides the projected revenues and net income for both its total facilities and the proposed project (“Triad Mobile MRI 5”). Notably, FY 2024 is a partial fiscal year, containing only 9 months of revenues. However, the revenues reported in Form F.2b for the proposed mobile MRI scanner are not appropriately scaled for a partial fiscal year; for example, EmergeOrtho reports \$5,116,042 in total gross revenue for partial FY 2024, yet reports \$5,227,445 for *full* FY 2025.<sup>51</sup> Conversely, the expenses reported in Form F.3b are appropriately scaled for a partial first year. As a result, net income in the partial fiscal year is overstated.

**Based on these errors and inconsistencies in EmergeOrtho’s financial projections, it has failed to demonstrate that its financial projections are based on reasonable assumptions; as such, its application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

**In summary, based on the issues detailed above, the EmergeOrtho application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (4), (5), (6), (13), and (18a), and the performance standards in the MRI rules.**

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<sup>51</sup> *Ibid*, p. 176.

**EMERGEORTHO MOBILE MRI TRIANGLE ROUTE, PROJECT ID # J-012359-23**

**Issue-Specific Comments**

1. EmergeOrtho’s utilization and methodology is unreasonable and based on inconsistent data and assumptions.

In “Section Q: EmERGEOrtho Need and Utilization Methodology for Section C Triangle” EmERGEOrtho provides utilization projections for the first three years of the proposed mobile MRI scanner. To do so, EmERGEOrtho makes a series of projections that are inconsistent and unsupported by external data and its own evidence.

First, in Step 6, in order to estimate the unmet need for MRI services in its proposed service area, EmERGEOrtho provides an estimate of the adjusted North Carolina MRI scans by county for fiscal year (FY) 2021. It ultimately reaches an estimate of 947,966 adjusted total scans for FY 2021, as seen in the table below, which has been partially replicated:

County	FY21 Est. Reported Scans	FY21 Est. Unreported Scans	FY21 Est. Adjusted Total Scan
Surry	8,295		8,295
Swain	1,258		1,258
Transylvania	3,788		3,788
Tyrrell	273		273
Union	20,588	1,191	21,779
Vance	4,308		4,308
Wake	70,523	9,291	79,814
Warren	905		905
Washington	1,065		1,065
Watauga	3,236		3,236
Wayne	10,097		10,097
Wilkes	6,093		6,093
Wilson	7,275	66	7,342
Yadkin	4,344		4,344
Yancey	1,890		1,890
NC State Total	916,897	31,069	947,966

*Notes: total estimated scans Step 5 + estimated unreported scan by county, Exhibit C.5*

Source: Project ID # J-012359-23, p. 143.

However, this understates the true number of total MRI scans as reported in the 2023 SMFP for FY 2021, which totaled 975,892.<sup>52</sup> EmERGEOrtho itself states that this estimate “[is] within 97% of the scans reported in Table 17E-1 in the 2023 SMFP (947,966 / 975,892 = 0.971);”<sup>53</sup> in short, EmERGEOrtho validates that its own estimate is an underestimate of the true MRI scan total, by approximately 28,000 scans.

<sup>52</sup> 2023 SMFP, p. 353.

<sup>53</sup> Project ID # J-012359-23, p. 143.

EmergeOrtho further estimates, in step 8, the number of unserved MRI scans by county through FY 2027, in order to approximate unmet need at the county level. It concludes that, in FY 2027, there will be an estimated unmet need for 93,953 adjusted MRI scans in North Carolina, shown below.

Wayne	769	760	753	747	742	737
Wilkes	-	-	-	-	-	-
Wilson	-	-	-	-	-	-
Yadkin	-	-	-	-	-	-
Yancey	-	-	-	-	-	-
<b>NC State Total</b>	<b>38,241</b>	<b>49,943</b>	<b>61,450</b>	<b>72,534</b>	<b>83,245</b>	<b>93,953</b>

Notes: projected county scans Step 7, Table 6 – adjusted FY21 scans, Step 6, Table 5

Source: Project ID # J-012359-23, p. 149.

However, in Step 10, EmmergeOrtho accounts for the calculated surplus of MRI scans to be captured by new and not yet operational MRI scanners by cluster for FY 2027. While EmmergeOrtho does not sum the total of these scans, the summation across all clusters, as seen in the table below, is 87,120 scans.

**Surplus of MRI Scans to be Captured by New/Not Yet Operational MRI Scanners  
FY 2027**

<b>Cluster</b>	<b>MRI Scans</b>
Cluster 1	2,904
Cluster 2	5,808
Cluster 3	17,424
Cluster 4	7,260
Cluster 5	15,972
Cluster 6	8,712
Cluster 7	7,260
Cluster 8	4,356
Cluster 9	8,712
No Cluster	8,712
<b>Total</b>	<b>87,120</b>

Source: Project ID # J-012359-23, pp. 152-155.

This means that, when accounting for this met need, EmmergeOrtho projects an unmet need of 6,833 scans for North Carolina (93,953 scans – 87,120 scans = 6,833 scans). As noted above, EmmergeOrtho understated the actual number of scans provided in the state in 2021 by 28,000; when this figure is subtracted from the applicant’s projected unmet need of 6,833 scans, the methodology fails to demonstrate any unmet need for additional MRI scanners in the state. While there is a need determination for three additional mobile MRI scanners, this error is

carried through the remainder of the utilization methodology, resulting in unreasonable projections.

Despite these adjustments, EmergeOrtho provides conflicting information against this calculation in step 11, which shows net unserved MRI scans by cluster for 2027.

**Table 10: Summary of Net Unserved MRI Scans by Cluster, 2027**

Cluster Number	Cluster Name	Net Unmet Scans
1	Western NC	2,264
2	Foothills NC	1,200
3	Southwestern NC	18,401
4	Triad NC	5,327
5	Triangle NC	55,792
6	Southeastern NC	695
7	Eastern NC	113
8	Northeastern NC	2,930
9	Coastal	1,439
0	Other Not Included Counties	0

Source: Project ID # J-012359-23, p. 159.

These figures, however, are overstated, given the currently approved MRI scanners as well as the additional analysis shown above. As such, EmergeOrtho’s volume projections are unsupported.

Interestingly, following this table, EmergeOrtho states that “EmergeOrtho is proposing to serve Cluster 5 / Triangle NC. Again, one mobile MRI scanner cannot service the entire state...It is therefore necessary to narrow the need to one Cluster.”<sup>54</sup> Given the unmet need figures provided above, however, the choice of “Triangle NC” for this scanner is not fully supported; the “Southwestern NC” cluster has a higher unmet need, yet EmergeOrtho has not chosen to develop a mobile MRI scanner at that location.

EmergeOrtho further provides a calculation for the number of unserved orthopedic MRI scans by county through project year three. It assumes that “it is reasonable and conservative...[that] 50 percent of MRI scans will be spine or musculoskeletal (orthopedic-related).”<sup>55</sup> CNSA does not question the validity of this assumption or the use of this figure as a means of estimation; however, there is nothing that correlates the need calculated in the previous steps of EmergeOrtho’s methodology to orthopedic MRI services specifically. In other words, 52 percent of all MRI services being orthopedic scans does not mean that that same ratio will hold for the population that EmergeOrtho projects are not being served.

**Given these factors, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards in the MRI rules.**

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<sup>54</sup> Ibid, p. 159.

<sup>55</sup> Ibid, p. 160.

2. EmergeOrtho does not provide evidence of the availability of its proposed equipment.

In Form F.1a Capital Cost and Form F.1a Capital Cost Assumptions, EmERGEOrtho provides a cost estimate for the medical equipment for its proposed project, and states that the proposed cost for the MRI magnet are quoted in Exhibit F.1.<sup>56</sup> However, the equipment quote that EmERGEOrtho provides in Exhibit F.1 uses the same purchase agreement identifying number – NIS-002169 – for all three of EmERGEOrtho’s applications.<sup>57</sup>

Given that EmERGEOrtho has submitted more than one application for a statewide need for three mobile MRI scanners, and given that EmERGEOrtho could in theory be approved for more than one mobile MRI scanner following Agency review, it would be impossible for EmERGEOrtho to utilize the same purchase agreement for each approved application, as it would ultimately require the purchase of more than one mobile MRI scanner. Further, the purchase agreement is for a refurbished mobile MRI scanner, which further adds to the scarcity of the equipment; it would be tangibly impossible, therefore, for EmERGEOrtho to acquire more than one of the proposed MRI scanners following the approval of more than one of its applications. Given this, the capital costs that EmERGEOrtho provides in Form F.1a cannot be considered reasonable without unique equipment quotes for each of its mobile MRI applications.

**EmERGEOrtho’s application, therefore, is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

3. EmergeOrtho does not include working capital in its financial projections.

In Section F.3, EmERGEOrtho omits all answers related to working capital and the availability of funds for working capital, stating that it “proposes to utilize its own office locations as host sites for the mobile MRI scanner. These are ongoing operations and will not require working capital.”<sup>58</sup> However, the financial projections EmERGEOrtho provides in Section Q, Forms F.2a, F.2b, F.3a, and F.3b are *not* for the entirety of its office locations, but *only* for its individual existing and proposed MRI scanners.<sup>59</sup> As such, the financials that EmERGEOrtho provides do not fully support the financial feasibility of the proposed project as suggested by EmERGEOrtho itself in its application.

As such, the application fails to demonstrate that the practice can support the start-up and initial operating expenses of the proposed project, and it has failed to demonstrate the availability of funds for capital and operating needs.

**The EmERGEOrtho application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

4. EmergeOrtho does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

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<sup>56</sup> Ibid, pp. 172-173.

<sup>57</sup> See Exhibit F.1 in Project ID # J-012357-23, Project ID # J-012358-23, and Project ID # J-012359-23.

<sup>58</sup> Project ID # J-012359-23, p. 78.

<sup>59</sup> Ibid, pp. 174-184.

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

In Section B.1.a, EmergeOrtho acknowledges that the need determination for which it is applying is a statewide one; yet in Section C.7, EmergeOrtho only lists its existing scanners that it owns and operates in the counties it proposes to serve – *not* all MRI scanners it owns and operates statewide. In reality, EmergeOrtho owns and operates two mobile MRI scanners and five fixed MRI scanners across the state of North Carolina, as detailed in its Form O Facilities.<sup>60</sup> As such, it does not follow the requisite instructions in the performance standards listed above.

EmergeOrtho does provide a statement regarding the need to project volume across all of its MRI scanners in its Section Q, quoted at length below:

*The SHCC 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. One single mobile MRI unit cannot reasonably serve the entire state of North Carolina. However, it is reasonable to determine a service area that could reach most patients in need of access to additional MRI services. The following methodology evaluates MRI need by county and narrows the statewide need to a cluster of counties that could be served efficiently with a mobile route. It then provides a methodology for this proposed project...<sup>61</sup>*

EmergeOrtho is misinterpreting and misrepresenting Mr. McKillip’s statement. Mr. McKillip’s point of clarity is to state that an applicant does not have to project its proposed mobile MRI scanner to serve the entire state. However, that applicant *does* still have to meet the

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<sup>60</sup> Ibid, p. 189.

<sup>61</sup> Ibid, p. 129.



performance standards as defined in 10A NCAC 14C .2703. If an applicant has multiple MRI scanners statewide, this would mean that that applicant would have to project volume for the entirety of those scanners, and project that those scanners meet the necessary performance standard. Given the ability of mobile MRI scanners to move to serve other areas of the state, this is clearly the only rational interpretation of the rule.

Given that EmergeOrtho does not provide volume projections for any of its other MRI scanners, it therefore also does not provide assumptions for those scanners, as well, thereby failing to demonstrate the conformity with 10A NCAC 14C .2703(b) (6) and (7). The only assumptions that EmergeOrtho does provide are for the proposed mobile MRI scanner, which are given in Section Q.

**As such, EmergeOrtho is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards in the MRI rules.**

5. EmergeOrtho does not sufficiently document the need for the proposed project.

In “Section Q: EmergeOrtho Need and Utilization Methodology for Section C Triangle,” EmergeOrtho proceeds to forecast the number of MRI scans by county by year by using a static use rate; mainly, the North Carolina MRI scan use rate per 1,000 population of 92.4.<sup>62</sup>

The use of this use rate, however, is flawed, given that different counties in the state of North Carolina have largely varying health profiles that will drastically affect whether or not this use rate will accurately capture their true utilization of MRI services. For example, in the data set that EmergeOrtho presents, Johnston County residents would be expected to receive 21,580 MRI scans in 2022; meanwhile, as presented, Johnston County residents only received 13,719 scans in 2021.<sup>63</sup> While EmergeOrtho claims that using a single MRI use rate is reasonable because it “provides uniform forecasts,”<sup>64</sup> it is questionable whether an applicant would want to use a use rate that is uniform in order to project MRI use rate across disparate, distinct North Carolina counties. In particular, this single statewide use rate is problematic considering the example of Johnston County, which would be expected to increase its volume by over 57 percent in a single year, if the application’s projections were reasonable.

Further, and as mentioned above, EmergeOrtho submitted three applications – one to serve the Blue Ridge/Foothills area of western North Carolina, one to serve the Triad counties, and a final application to serve the Triangle counties. However, curiously, none of the three EmergeOrtho applications makes any mention of any other application. As EmergeOrtho would presumably have to coordinate care between multiple mobile MRI scanners if more than one of its applications were to be approved by the Agency, some consideration would be necessary as to how this coordination would be performed by the applicant.

**As such, the EmergeOrtho application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4), (6), (13), and (18a), as well as the performance standards in the MRI rules.**

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<sup>62</sup> Ibid, p. 143.

<sup>63</sup> Ibid, pp. 142, 145.

<sup>64</sup> Ibid, p. 136.

6. EmergeOrtho does not discuss the unmet need in its proposed service area.

In its response to Policy GEN-3, EmERGEOrtho lists the counties in which it will host its proposed project as Granville, Harnett, Johnston, and Wake counties, all of which are located in or near the “Triangle” area of North Carolina.<sup>65</sup>

There are two underutilized fixed scanners that EmERGEOrtho owns and operates near the proposed service area – a freestanding fixed scanner in Durham County in SouthPoint, and a freestanding fixed scanner in Wilson County. While EmERGEOrtho does not identify either Durham or Wilson as counties potentially served by the proposed project, it nevertheless stands that both counties are contiguous to its proposed service area: Durham County to Granville and Wake counties; and Wilson County to Nash, Johnston, and Wayne counties. In Section E, EmERGEOrtho discusses the alternatives to the proposed project, and does *not* propose shifting volume to their underutilized scanners in adjacent counties.

In short, these underutilized scanners could potentially meet the unmet need discussed in EmERGEOrtho’s application; however, this alternative is never discussed.

**EmERGEOrtho’s application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (4), (6), (13), and (18a).**

7. EmergeOrtho’s utilization is overstated and unsupported for Johnston County.

EmERGEOrtho estimates in step 7 of its “Need and Utilization Methodology for Section C Triangle” that Johnston County will require 21,580 scans in 2022 based on the state FY 21 scan use rate.<sup>66</sup> As mentioned above, this calculation is overstated and unsupported.

In Step 6, EmERGEOrtho determined that Johnston County residents received 13,719 scans in FY 2021.<sup>67</sup> Given this, EmERGEOrtho assumes that Johnston County volume will grow by 57 percent in one year. This growth is unrealistic and is not explained.

EmERGEOrtho’s calculations imply major access challenges for residents of Johnston County. Historically, Johnston County residents seek care in Johnston County, Wake County, and other contiguous counties. An analysis of the 2023 SMFP, shown in the table below, highlights that existing Johnston County providers have capacity to serve additional MRI patients. If access was a major issue in Johnston County, these providers would be operating at or near max capacity.

**Johnston County Scanners with Capacity**

<i>Provider</i>	<i>County</i>	<i>Scanners</i>	<i>FY 2021 Adjusted Scans per Scanner</i>	<i>% of Capacity</i>
UNC Health Johnston – Clayton	Johnston	1	2,751	44.1%
UNC Health Johnston – Smithfield	Johnston	1	3,884	62.2%

<sup>65</sup> Ibid, p. 26.

<sup>66</sup> Ibid, p. 145.

<sup>67</sup> Ibid, p. 142.

Source: 2023 SMFP.

As a result of its overstatement of potential scans, EmergeOrtho calculates that there is a need of 9,327 scans for Johnston County residents in 2027. They half this to 4,664 patients to calculate ortho-only MRI scan needs, a methodology detailed above. In step 15, EmergeOrtho assumes that they will serve 50% of these scans which equates to 2,332 scans. Johnston County represents more than 50% of the mobile MRI scanner's volume. Given that EmergeOrtho overstated this need, its projected volume based on this need is also overstated. Thus, its volumes are unrealistic and unsupported.

**The EmergeOrtho application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (6), (13), (18a), as well as the performance standards for MRI scanners.**

**In summary, based on the issues detailed above, the EmergeOrtho application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (4), (5), (6), (13), and (18a), and the performance standards in the MRI rules.**

**Issue-Specific Comments**

1. Novant does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

According to Section A.6, Novant owns and operates 10 existing mobile MRI scanners across the state of North Carolina. Additionally, Novant operates 30 fixed MRI scanners, as noted in Form O.<sup>68</sup> Novant identifies the service area for its proposed mobile scanner as “Statewide” in Section B.1.a. However, in response to Section C.7, Novant only projects the volume for the existing and projected scanners that it owns and operates in the counties it proposes to serve – *not* all MRI scanners it owns and operates statewide. As such, it does not follow the requisite instructions in the performance standards listed above and fails to demonstrate that it meets the performance standards for all its existing fixed and mobile scanners in the statewide service area.

**Therefore, the Novant application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and the performance standards for magnetic resonance imaging scanners.**

2. Novant fails to provide a payor mix or payor mix assumptions.

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<sup>68</sup> Project ID # G-012372-23, p. 155 of PDF.

In Section L.3.a, applicants are required to provide projected payor sources during the third full fiscal year of operation following completion of the proposed project; in section L.3.b, applicants must describe any assumptions used to project each payor source. Novant does neither of these things.<sup>69</sup>

In explanation, Novant states that “[t]he proposed service involves the provision of mobile MRI service. Mobile MRI providers charge a per diem rate to each mobile MRI host site and as such, they do not bill patients directly.”<sup>70</sup> While Novant is choosing to utilize its proposed project as a contracted mobile MRI, as shown on page 81 of its application, each of the proposed host sites is already served by a Novant Health-owned mobile MRI scanner. As such, it follows that Novant could have requested payor mix data for the proposed sites, particularly to demonstrate that it would care for the underserved populations.

**As such, Novant is non-conforming to N.C. Gen. Stat. § 131E-183(a)(13)(a) and (c).**

3. Novant provides projected patient origin data that is inconsistent with its provided LRA data.

In Section C.3, Novant provides projected patient origin data for its proposed project, and estimates that the entirety of its proposed patient population will come from Craven, Cumberland, Lenoir, and Wake counties – the four counties that will serve as host sites for the proposed mobile MRI scanner, with no immigration from other counties to each respective host site.<sup>71</sup>

However, this projected patient origin is inconsistent with patient origin information as detailed in the license renewal applications or medical equipment inventory reports provided by Novant in its Exhibit C for each facility:

- CarolinaEast Health System, located in Craven County, reports 3,695 of its 5,939 total MRI patients, or 62.2 percent, as originating from Craven County in its 2023 License Renewal Application, with the rest originating from other counties or out of state.<sup>72</sup>
- Lenoir Memorial Hospital, Inc., located in Lenoir County, reports 2,293 of its 3,126 total MRI patients, or 73.4 percent, as originating from Lenoir County in its 2023 License Renewal Application, with the rest originating from other counties or out of state.<sup>73</sup>
- The other three locations – Carolina Imaging in Cumberland County; and Orthopedic Specialists of North Carolina and UNC Orthopedics Holly Springs, both in Wake County – report between 70.4 percent and 92.4 of their patients as originating from their home counties on their Medical Equipment Inventory Reports.<sup>74</sup>

There are no providers for which 100 percent of their patient origin derives solely from their home county; all providers have some patients originating from outside their county, as evidenced by the historical information provided alongside Novant’s application. The

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<sup>69</sup> Seen in Project ID # G-012372-23, p. 117.

<sup>70</sup> Ibid.

<sup>71</sup> Ibid, p.45.

<sup>72</sup> Exhibit G-012372-23, pp. 112-113 of PDF.

<sup>73</sup> Ibid, p. 121 of PDF.

<sup>74</sup> Ibid, pp. 122-151 of PDF.

assumption underlying Novant's patient origin projections, in other words – that patient origin is strictly and solely tied to the location of service – is incorrect and unsubstantiated.

**The Novant application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3).**

4. Novant fails to provide capital costs for the proposed project.

In Section F.1.b, Novant states that it “has included its [Capital Costs] Form F.1a in Section Q with assumptions.”<sup>75</sup> However, Form F.1a Capital Costs has not been included with Novant's application. While the application includes total projected capital costs, the reasonableness of these costs cannot be demonstrated without the requisite Form F.1a, including the assumptions for those costs.

**Based on this issue, the Novant application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(5).**

**In summary, based on the issues detailed above, the Novant application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), (13)(a) and (c), and the performance standards for MRI scanners.**

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<sup>75</sup> Project ID # G-012372-23, p. 94.

Issue-Specific Comments

1. Novant does not comply with all applicable performance standards.

The performance standards for magnetic resonance imaging scanners, as defined in 10A NCAC 14C .2703, state the following:

*An applicant proposing to acquire a mobile MRI scanner pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:*

- *(1) identify the existing mobile MRI scanners owned or operated by the applicant or a related entity that provided mobile MRI services at host sites located in the proposed mobile MRI scanner service area during the 12 months before the application deadline for the review period;*
- *(2) identify the approved mobile MRI scanners owned or operated by the applicant or a related entity that will provide mobile MRI services at host sites located in the proposed mobile MRI scanner service area;*
- *(3) identify the existing fixed MRI scanners owned or operated by the applicant or a related entity that are located in the proposed mobile MRI scanner service area;*
- *...*
- *(6) provide projected utilization of the MRI scanners identified in Subparagraphs (b)(1) through (b)(4) of this Paragraph and the proposed mobile MRI scanner during each of the first three fiscal years of operation following completion of the project;*
- *(7) provide the assumptions and methodology used to project the utilization required by Subparagraph (b)(6) of this Paragraph;*

According to Section A.6, Novant owns and operates 10 existing mobile MRI scanners across the state of North Carolina. Additionally, Novant operates 30 fixed MRI scanners, as noted in Form O.<sup>76</sup> Novant identifies the service area for its proposed mobile scanner as “Statewide” in Section B.1.a. However, in response to Section C.7, Novant only projects the volume for the existing and projected scanners that it owns and operates in the counties it proposes to serve – *not* all MRI scanners it owns and operates statewide. As such, it does not follow the requisite instructions in the performance standards listed above and fails to demonstrate that it meets the performance standards for all its existing fixed and mobile scanners in the statewide service area.

**Therefore, the Novant application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and the performance standards for magnetic resonance imaging scanners.**

2. Novant fails to provide a payor mix or payor mix assumptions.

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<sup>76</sup> Project ID # G-012373-23, p. 142 of PDF.

In Section L.3.a, applicants are required to provide projected payor sources during the third full fiscal year of operation following completion of the proposed project; in section L.3.b, applicants must describe any assumptions used to project each payor source. Novant does neither of these things.<sup>77</sup>

In explanation, Novant states that “[t]he proposed service involves the provision of mobile MRI service. Mobile MRI providers charge a per diem rate to each mobile MRI host site and as such, they do not bill patients directly.”<sup>78</sup> While Novant is choosing to utilize its proposed project as a contracted mobile MRI scanner, at least two of the proposed host sites have historically provided mobile MRI services, and thus have historical payor mix data. As such, it follows that Novant could have requested payor mix data for the proposed sites, particularly to demonstrate that it would care for the underserved populations.

**As such, Novant is non-conforming to N.C. Gen. Stat. § 131E-183(a)(13)(a) and (c).**

3. Novant does not demonstrate the need for the proposed project.

In Section C.1, Novant outlines its route for its proposed mobile MRI scanner, stating that it will host its scanner at facilities in Avery, Henderson, and Buncombe counties. However, according to MRI utilization figures in the 2023 SMFP, none of those counties demonstrates a need for additional MRI services at this time.

CNSA has replicated the average scans from FY 2021 (the most recent year from which data is available) for Avery and Henderson counties, as well as the Buncombe/Graham/Madison/Yancey MRI service area. Each is far below the threshold needed to trigger a need determination for each respective service area.

**Average Scans for Proposed Novant Mobile MRI Service Area Counties  
FY 2021**

<i>Service Area</i>	<i>Average Scans</i>	<i>Threshold</i>	<i>Difference</i>	<i>MRI Need</i>
Avery	0	1,872	(1,872)	0
Buncombe/Graham/Madison/Yancey	4,172	4,992	(820)	0
Henderson	3,970	4,992	(1,022)	0

Source: 2023 SMFP, pp. 354-355.

While there may be other factors beyond the SMFP need methodology driving need for a mobile MRI scanner in these areas, Novant has failed to provide sufficient evidence of the need for its project. This lack of need is further compounded by Novant projecting the entirety of its patient origin to originate from Avery, Henderson, and Buncombe counties, which will be discussed further below. Given this restrictiveness, along with the lack of evaluated need in the proposed host counties, Novant has not demonstrated that its proposed host sites have a need for the proposed MRI services.

<sup>77</sup> Seen in Project ID # G-012373-23, p. 107.

<sup>78</sup> Ibid.



**Novant's application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and the performance standards for MRI scanners.**

4. Novant provides projected patient origin data that is inconsistent with its provided LRA data.

In Section C.3, Novant provides projected patient origin data for its proposed project, and estimates that the entirety of its proposed patient population will come from Avery, Buncombe, and Henderson counties – the three counties that will serve as host sites for the proposed mobile MRI scanner.<sup>79</sup>

However, this projected patient origin is inconsistent with patient origin information as detailed in the license renewal applications or medical equipment inventory reports provided by Novant in its Exhibit C for each facility. For example, only 52 percent of patients who received MRI services from Asheville Open MRI – located in Buncombe County – originated from Buncombe County itself, according to its most recent Medical Equipment Inventory Report.<sup>80</sup>

In short, Novant's assumption that patient origin ties to the location of service is incorrect, thereby ensuring that its projected patient origin is flawed and unsupported.

**Novant's application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3).**

5. Novant fails to provide staffing information for the proposed project.

In Section H.1, applicants are required to “[c]omplete Form H Staffing, which is found in Section Q.” However, Novant has failed to include Form H Staffing with its application.

**Thus, Novant is non-conforming to N.C. Gen. Stat. § 131E-183(a)(7).**

**In summary, based on the issues detailed above, the Novant application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), (7), (13)(a) and (c), and the performance standards for MRI scanners.**

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<sup>79</sup> Ibid, p.44.

<sup>80</sup> Exhibit G-012373-23, p. 130 of PDF (3,532 / 6,780 = 52 percent of patients).

Issue-Specific Comments

1. PHSNC’s argument that MRI use rates in Forsyth, Guilford, and Wake counties indicate need is based on flawed assumptions.

In discussing the need for its proposed project in Section C.4, PHSNC relies on the North Carolina MRI Utilization rate, remarking that “while the North Carolina population increased 7.66% between 2013 and 2021, the number of MRI procedures performed in North Carolina increased 25.5%...As a result, the North Carolina MRI use rate increased to 92.4 scans per 1,000 population in FY2021, a 16.52% increase from the FY2013 MRI use rate of 79.3.”<sup>81</sup> In other words, PHSNC justifies the importance and significance of the increase of the North Carolina MRI use rate, before proceeding to utilize it to undergird the need for its proposed service area. It shows, for Forsyth, Guilford, and Wake counties, that the use rate per 1,000 MRI procedures was both significantly high and increased from FY 2017 through FY 2021, as seen in the table replicated below.

County MRI Use Rate  
FFY2017 – FFY2021

Forsyth County			Guilford County			Wake County		
County Population	Number of Procedures	Use Rate/1000	County Population	Number of Procedures	Use Rate/1000	County Population	Number of Procedures	Use Rate/1000
374,689	71,092	189.7	529,098	50,146	94.8	1,071,499	90,481	84.4
378,098	70,260	185.8	535,150	56,842	106.2	1,093,558	100,643	92.0
380,663	75,330	197.9	538,536	55,151	102.4	1,114,815	108,970	97.7
382,944	71,036	185.5*	541,685	53,165	98.1*	1,132,620	99,529	87.9*
384,063	73,782	192.1	542,451	59,577	109.8	1,150,722	118,165	102.7

Totals may not foot due to rounding.

\*This utilization data reflects the anomalous effect of the COVID-19 pandemic, which negatively impacted FFY2020 MRI utilization for all providers in Forsyth, Guilford and Wake counties, and throughout North Carolina and the United States.

Sources: Population data from NC OSBM, Vintage 2022. MRI volume data from 2019–2023 SMFPs

Source: Project ID # J-012375-23, p. 40.

However, the high MRI use rate of PHSNC’s proposed service area of Forsyth, Guilford, and Wake counties is not indicative of a need for MRI services *amongst the patients originating from those specific counties*. As PHSNC itself notes, “each of these three counties is among the major medical care referral counties in North Carolina, serving as a healthcare center for residents of many neighboring North Carolina counties.”<sup>82</sup> As such, comparing the volumes of procedures performed in PHSNC’s service area counties to each county’s population is inappropriate for the purposes of determining need for MRI services, as each county accounts for significant in-migration from other counties, thus inflating their MRI use rate above what their internal population alone would provide. To accurately reflect the use rate of *only* patients within each county – and therefore the need generated by patients within those counties – the number of MRI procedures would need to reflect the number of procedures received *only* by patients who originate from the applicable county, while excluding all in-migrating patients.

<sup>81</sup> Project ID #J-012375-23, p. 38.

<sup>82</sup> Ibid, p. 40.

Additionally, PHSNC further states that “of the approximately 172 mobile MRI host sites identified in the 2023 SMFP, approximately 53 sites (or 31%) are located in either Forsyth, Guilford, or Wake counties. This data is a further indication of the need for increased mobile MRI scanner capacity in these three counties.”<sup>83</sup> PHSNC also includes population data from the NC OSBM that shows that the three counties have a combined population of 2,125,004, as of 2023, or, as it identifies in the table below, 19.7 percent of North Carolina’s overall population.

**Projected Population Growth, 2023 – 2027**

Year	North Carolina	County				% of NC
		Forsyth	Guilford	Wake	Combined	
2023	10,794,463	388,365	546,934	1,189,705	2,125,004	19.7%
2024	10,918,935	390,943	550,216	1,213,138	2,154,297	19.7%
2025	11,038,826	393,717	553,974	1,237,890	2,185,581	19.8%
2026	11,154,686	396,647	558,089	1,263,294	2,218,030	19.9%
2027	11,270,518	399,693	562,482	1,288,980	2,251,155	20.0%
# Increase	476,055	11,328	15,548	99,275	126,151	
% Increase	4.41%	2.92%	2.84%	8.34%	5.94%	
<b>4-Yr CAGR</b>	<b>0.80%</b>	<b>0.55%</b>	<b>0.55%</b>	<b>1.53%</b>	<b>1.11%</b>	

Source: North Carolina Office of State Budget & Management, Vintage 2022

Source: Project ID # J-012375-23, p. 42.

Given that there are more mobile MRI sites (31 percent) than there are persons (19.7 percent) in the proposed service area by percentage, these ratios do not necessarily support the need for additional MRI capacity, as PHSNC suggests. In short, PHSNC’s arguments do not support the need for its proposed project.

**Therefore, PHSNC’s application is non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (6), and the performance standards for MRI scanners.**

2. PHSNC’s projected volume is overstated and duplicative.

PHSNC makes numerous errors with regards to its projections of the volume of its proposed mobile scanner that overstate the total utilization of the proposed project.

First, in its “Form C.2 Assumptions and Methodology,” PHSNC provides the historical MRI utilization for both its existing mobile MRI site (serving Cary, Clayton, Midtown, and Wake Forest), as well as its proposed mobile MRI site (serving Brier Creek, Cary, Greensboro, Kernersville, and Winston-Salem). For both mobile MRI scanners, PHSNC includes its existing 1,141 and 341 MRI scans at Brier Creek and Cary, respectively. PHSNC then projects MRI scans forward at Brier Creek and Cary for each mobile MRI scanner assuming the existing volume will

<sup>83</sup> Ibid.

continue at each site. As such, it duplicates volume across these two scanners, thereby overestimating volume.

Second, in determining the number of mobile MRI scans it will perform at its facilities currently housing fixed MRI scanners – i.e., Kernersville and Winston-Salem – PHSNC notes that, at those facilities, approximately 77.78 percent of scans performed were on fixed MRI scanners. As such, it concludes that the remaining ratio of procedures – i.e., 22.22 percent of its current MRI scanner volume at those sites – will be performed through the proposed project.<sup>84</sup>

This projection, however, is not sound. While PHSNC states that its projections are “reasonable because diagnostic MR imaging procedures on PHSNC’s mobile MRI scanner will continue to be necessary to aid referring physicians and other referring providers to diagnose and treat their patients in Forsyth, Guilford, and Wake counties,” PHSNC vastly overestimates the amount of volume that it can possibly capture of this potential pool of mobile MRI patients. Indeed, the Forsyth, Guilford, and Wake County service areas have a significant number of existing mobile MRI providers; according to the *2023 SMFP*, Forsyth County has six active mobile MRI scanners that performed procedures in FY 2021, Guilford County has nine active mobile MRI scanners that performed procedures in FY 2021, and Wake County has *thirty* active mobile MRI scanners that performed procedures in FY 2021.

Based on the goal to expand services, the proposed mobile MRI scanner would add to the services that already exist in PHSNC’s proposed service area. PHSNC fails to account for the existing mobile scanners that currently serve the volume that it projects at the Kernersville and Winston-Salem locations. As such, that volume is significantly overstated.

To test the potential overstatement at Kernersville and Winston-Salem, CNSA calculated each of PHSNC’s mobile MRI #2 host sites to perform the following number of scans per day in CY 2027, based on PHSNC’s own projections (assuming a 51-week year in order to account for time off for holidays).

**Projected Utilization for Mobile MRI Scanner #2 per Day per Host Site  
FY 2027**

<i>Host Site</i>	<i>Scans/Day*</i>
Brier Creek	11.8
Cary	7.1
Greensboro	6.7
Kernersville	18.2
Winston-Salem	20.2
<b>Total (Unweighted)</b>	<b>13.7</b>

Source: Project ID # J-012375-23, p. 130.

\* Scans/Day = 2027 Mobile MRI Procedures / 51 / 2

As shown above, the volumes at the Kernersville and Winston-Salem sites are considerably higher than the other sites which further validates that its volumes at those locations are overstated.

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<sup>84</sup> As calculated via tables on Project ID #J-012375-23, p. 130.

**The PHSNC application is therefore non-conforming to N.C. Gen. Stat. § 131E-183(a)(3), (5), (6), and (18a), as well as the performance standards for MRI scanners.**

**In summary, based on the issues detailed above, the PHSNC application is non-conforming with the review criteria established under N.C. Gen. Stat. § 131E-183, specifically Criteria (3), (5), (6), and (18a), and the performance standards for MRI scanners.**