

**Comments Submitted by**

**Presbyterian Medical Care Corp.**

**and**

**Novant Health, Inc.**

**In Opposition to**

**CON Project I.D. #F-12287-22**

**OrthoCarolina, P.A.**

**December 1, 2022**

## **I. Introduction**

Pursuant to N.C. Gen. Stat. § 131E-185, Presbyterian Medical Care Corp. d/b/a Novant Health Matthews Medical Center (“NH Matthews”) and Novant Health, Inc. submit the following comments in opposition to the application filed by OrthoCarolina, P.A. (“OrthoCarolina”) seeking the state's approval for one new fixed MRI scanner to be located at the OrthoCarolina University clinical practice (“University”) location in Mecklenburg County. For the reasons stated in these Comments, OrthoCarolina’s application does not conform with multiple CON review criteria and is a less effective alternative than the NH Matthews application. The NH Matthews application fully conforms to all applicable review criteria and should be approved.

## **II. CON Application**

OrthoCarolina plans to acquire a 1.5T wide bore MRI scanner for the University office to provide outpatient MRI scans. The proposed OrthoCarolina MRI scanner will provide the same types of MRI procedures as the mobile MRI scanner that currently serves University. OrthoCarolina plans to modify the University facility to accommodate the MRI scanner in a 637 square foot modular structure. OrthoCarolina indicates that the modular structure will be located adjacent to space to be renovated to accommodate MRI waiting, registration, and support spaces within the office. A canopy will cover the space between the office and the modular structure. As such, OrthoCarolina’s project is no different than the mobile service it is currently using at University.

## **III. CON Review Criteria**

The following comments are submitted based upon the CON Review Criteria found at N.C. Gen. Stat. § 131E-183.

**N.C. Gen. Stat. § 131E-183(a)(1)**

*The proposed project shall be consistent with the applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, facility beds, dialysis stations, ambulatory surgical operating rooms or home health offices that may be approved.*

OrthoCarolina owns two fixed MRI scanners (Project I.D. No. F-010287-14 and Project I.D. No. J-6698-02) and one mobile MRI scanner (Project No. F-7987-07). OrthoCarolina’s application proposes to install a fixed MRI scanner at its University location where it has been offering mobile MRI services using a grandfathered mobile MRI scanner provided by Alliance HealthCare Services. OrthoCarolina describes University as “a physician office location and currently a host site for a leased mobile MRI scanner<sup>1</sup>.” According to OrthoCarolina, the mobile MRI scanner at University is sub-optimal because it is a closed bore machine which causes some patients to be referred elsewhere.<sup>2</sup>

Later, OrthoCarolina states<sup>3</sup>:

OrthoCarolina conservatively projected flat utilization on its owned mobile MRI scanner. Late in 2021 OrthoCarolina added its Indian Land, South Carolina medical clinic as a mobile host site. Because OrthoCarolina anticipates that this mobile site will grow in volume, effective December 2021 OrthoCarolina discontinued sending its owned mobile MRI scanner to Spine Center where it was supplementing the busy fixed MRI scanner. Beginning in 2022, OrthoCarolina began contracting a leased mobile MRI scanner to provide supplemental MRI service at Spine Center. During CY 2021, OrthoCarolina’s owned mobile MRI scanner performed 2,104 unweighted MRI scans at Spine Center.

Elimination of Spine Center as a host site for the owned mobile MRI scanner, along with the yet growing MRI scan volume at the new Indian Land mobile host site, is the reason the CY2022 utilization for the owned mobile MRI scanner appears to be lower than CY2021.

Criterion (1) requires an applicant to conform with all applicable policies and need determinations in the SMFP. One of the applicable policies is Policy GEN-3, which requires the applicant to demonstrate that its project promotes quality, access and value. OrthoCarolina’s project fails to meet Policy GEN-3 primarily

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<sup>1</sup> OrthoCarolina CON Application, Page 18.

<sup>2</sup> OrthoCarolina CON Application, Page 40.

<sup>3</sup> OrthoCarolina CON Application, Pages 134 and 135.

because there is no need for the project OrthoCarolina proposes.

As explained in these comments, OrthoCarolina's application relies upon unreasonable and unsupported volume assumptions, including a shift of patients from both its Ballantyne and Spine Center locations. Further, the need OrthoCarolina claims to have for a fixed MRI scanner at University is artificial because, rather than use its existing and owned mobile MRI scanner to serve University, OrthoCarolina has chosen to deploy its owned mobile MRI scanner to its Indian Land, South Carolina site to serve South Carolina patients. Apparently, this arrangement has been going on for the last year<sup>4</sup>. OrthoCarolina's choice to deploy its mobile MRI scanner to South Carolina has consequences for the current CON application. OrthoCarolina's mobile MRI scanner operates in South Carolina every Wednesday and Thursday for a total of 104 days per year or nearly nine days per month.<sup>5</sup> This number of days represents 28.6% of the North Carolina CON-approved mobile MRI scanner's capacity. The number of mobile MRI days in the month in operation in South Carolina would immediately benefit the northern Mecklenburg County patients of OrthoCarolina, if the mobile MRI scanner was operated at its University location, rather than in South Carolina.

As discussed in the following pages in CON Review Criterion (3), OrthoCarolina fails to demonstrate the need the population has for the proposed new fixed MRI scanner at University, especially considering it is not utilizing all of its North Carolina CON-approved mobile MRI scanner capacity in North Carolina, specifically in Mecklenburg County. Further, the application is non-conforming with Criterion (4), because OrthoCarolina has not chosen the least costly or most effective alternative. Rather than use its existing mobile scanner to serve University, OrthoCarolina chose to deploy it to South Carolina.

In addition, as explained in the comments regarding Criterion (7), OrthoCarolina's staffing is deficient. Staffing has a direct relationship to quality, access and value. The deficient staffing is another reason why OrthoCarolina's project fails to meet Criterion (1).

Accordingly, for the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (1) and should be disapproved.

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<sup>4</sup> OrthoCarolina CON Application, Page 135.

<sup>5</sup> OrthoCarolina CON Application, Page 64.

**N.C. Gen. Stat. § 131E-183(a)(3)**

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

None of the four main reasons OrthoCarolina presents justify approval of the application. NH Matthews addresses three of the factors:

1. Improve Mecklenburg County residents' geographic access to local value based fixed MRI services.

OrthoCarolina has chosen to limit geographic access by restricting the utilization of its North Carolina CON-approved mobile MRI scanner's capacity by operating it in South Carolina.

Further, OrthoCarolina's assertion that its mobile solution at University is sub-optimal lacks merit. The proposed fixed MRI scanner is actually a mobile MRI scanner in disguise. In Exhibit F.1, the GE Healthcare quote, page 3 of 16, identifies a "US Lamboo Medical **Mobile** Unit powered by SVSR" and a "SIGNA Voyager 1.5T 33 Channel 29.1 **Mobile** MRI System." The only "fixed" part of the entire MRI scanner proposed by OrthoCarolina is the "Fixed Table." As such, the MRI scanner is designed as a mobile MRI scanner to be located in a mobile MRI trailer, however in this project it is a modular structure that will house the mobile MRI system, as shown in the structure layout in the Lamboo Medical quote<sup>6</sup>.

2. Help to address the continuing and growing demand for MRI services at OrthoCarolina by decompressing the busy Ballantyne and Spine Center MRI service locations.

As previously discussed, OrthoCarolina's North Carolina CON-approved mobile MRI scanner capacity is not entirely being used to the benefit of North Carolinians. OrthoCarolina nevertheless believes that it should be awarded a fixed MRI scanner to increase its MRI capacity lost to its mobile MRI scanner serving a South Carolina site.

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<sup>6</sup> OrthoCarolina CON Application, Exhibit F.1.

OrthoCarolina is proposing to “decompress” its Ballantyne and Spine Center MRI service locations by shifting 993 MRI procedures in Year 3 of the project. This assumption is not adequately supported for several reasons. First, the Ballantyne location is at the southern tip of Mecklenburg County, approximately 32 miles and 33 minutes from the University location in northeastern Mecklenburg County.<sup>7</sup> The Application does not explain why patients who receive scans now at Ballantyne would switch to University, given the distance between these locations. The application contains no information about the number of patients from the University area (or more generically, “northeastern Mecklenburg County”) who now go to Ballantyne for MRI scans. Spine Center is located in central Charlotte, and as the name “spine center” suggests, many of the patients treated at this location have spinal conditions. As stated on OrthoCarolina’s website:

At OrthoCarolina’s Spine Center, our fellowship-trained orthopedic surgeons specialize – and excel – in one area. Nationally recognized for spinal care, we lead the field in research and in the number of procedures performed, including minimally invasive surgery (MIS). Our physician staff, comprised of eight dedicated spine surgeons and three physiatrists, is committed to providing the highest level of care to patients suffering from pain, numbness or weakness anywhere from the neck to the lower back. Many of the procedures performed are outpatient procedures or allow the patient to go home the following morning. Our spectrum of care ranges from nonsurgical management of spinal disorders to the most complex reconstructive procedures for patients with debilitating conditions making us the best spine care center in the region.

We perform more than 2,000 spine surgeries and nearly 4,000 interventional spine procedures each year.

At OrthoCarolina, we make it our goal to only hire the best spine physicians to care for our patients. In addition to regularly seeing patients, our current physicians are actively involved in research, including the development of spinal implants and bone substitutes, and they are instrumental in teaching these latest techniques to other physicians. Additionally, our physicians often serve as a 2nd opinion option for many patients.

<https://www.orthocarolina.com/locations/spine-center-charlotte>. (visited November 28, 2022)

OrthoCarolina’s application fails to explain why patients who receive spinal care at the Spine Center would shift to the University location, which is not a spine center. There is no information in the application substantiating the statement that “some patients from zip codes 28025, 28027, 28075, 28213, 28215,

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<sup>7</sup> OrthoCarolina CON Application, Page 54.

28262, and 28269 will shift to OrthoCarolina University<sup>8</sup>.” Similarly, there is no substantiation for the charts contained on page 141. Notably, the application does not provide historical numbers of patients from these zip codes who received MRI scans at Ballantyne or Spine Center and who would be appropriate candidates to shift to University.

Next, with a nearly 1:1 MRI scan<sup>9</sup> to weighted MRI scan ratio, the vast majority of MRI scans are assumed to be outpatient scans with no contrast. The 2022 SMFP identifies a procedure time for outpatient with no contrast MRI scans of 30 minutes. This calculates to 496.5 hours [(993 x 30 minutes) / 60 minutes = 496.5 hours]. OrthoCarolina states that it will operate for at least 60 hours per week, throughout the year, excluding holidays, which averages 10 hours per day Monday through Saturday. The following table highlights the number of mobile MRI days per month necessary in 2024 through 2026 to accommodate the “decompression” at the Ballantyne and Spine Center MRI service locations as projected in the CON application:

<b>Year</b>	<b>Hours per Day</b>	<b>Decompressed Hours</b>	<b>Required Mobile MRI Days</b>	<b>Mobile MRI Days per Month</b>
2024	10	317	31.7	2.6
2025	10	421	42.1	3.5
2026	10	496.5	49.6	4.1

As the previous table indicates, OrthoCarolina would only need 2.6 to 4.1 mobile MRI days per month to “decompress” its Ballantyne and Spine Center MRI service locations as projected, which it could accommodate by moving its mobile MRI scanner back to North Carolina. Merely relocating its own mobile MRI scanner from Spine Center to University just three times per month would benefit OrthoCarolina MRI patients from northern Mecklenburg County by eliminating their 30-minute drive to Spine Center.

Finally, OrthoCarolina’s decompression argument is not adequately supported. OrthoCarolina actually projects an increase in MRI scans at Spine Center from 8,004 unweighted MRI scans in 2022 to 8,059 unweighted MRI scans in 2026.<sup>10</sup> At Ballantyne, OrthoCarolina projects a decrease of a mere 32 MRI scans

<sup>8</sup> OrthoCarolina CON Application, Page 140.

<sup>9</sup> OrthoCarolina CON Application, Page 142.

<sup>10</sup> OrthoCarolina CON Application, Page 142.

at Ballantyne from 8,620 MRI scans in 2022 to 8,588 MRI scans, which is a decrease of 0.4% in 2026.<sup>11</sup> Thus, to the extent either location needs to be decompressed, the proposed project will not provide an effective solution.

3. Offer access to modern and patient-friendly MRI scanner technology and maintain a high standard of quality care.

While the Agency typically accepts at face value an applicant's representations about its proposed equipment, the Agency should not have the mistaken impression that OrthoCarolina's proposed Voyager scanner is top of the line equipment. It is not. Rather, Voyager is designed as a mobile MRI scanner and as a 1.5T MRI scanner produced by GE Healthcare has fewer channel coils than the GE Artist 1.5T MRI scanner, which increases scan time and also increases noise and decreases signal. The 1.5T MRI scanner has fewer channel coils and a lower Tesla rating than the NH Matthews proposed 3.0T Hero MRI scanner, which increases scan time, increases noise and decreases signal, and decreases imaging quality. The Voyager is marketed by GE Healthcare as "SIGNA Voyager is designed to multiply your ROI to remarkable levels."<sup>12</sup>

Ironically, one of the main reasons that OrthoCarolina's 2014 MRI CON Application, CON Project #F-10287-14, was approved was because OrthoCarolina proposed to locate the fixed MRI scanner at Ballantyne, which as a mobile MRI site had performed the most MRI scans of any other OrthoCarolina mobile MRI site at 4,006 MRI scans. Now, however, OrthoCarolina proposes to locate a fixed MRI scanner at University, which performed the *lowest* number of MRI scans of any OrthoCarolina mobile MRI site at just 1,325 MRI scans.

OrthoCarolina assumes that the 671 MRI patients who will shift from Spine Center to University will not affect the utilization of the mobile MRI scanner located at Spine Center.<sup>13</sup> The mobile MRI scanner is projected to have a constant MRI scan volume of 6,274 MRI scans from 2022 through 2026.<sup>14</sup> This is not a reasonable or supported assumption. If indeed these 671 MRI patients shift, then mobile scan volume should also be impacted. It should not remain constant for four years.

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<sup>11</sup> OrthoCarolina CON Application, Page 143.

<sup>12</sup> <https://www.gehealthcare.com/products/magnetic-resonance-imaging/1-5t/signa-voyager>

<sup>13</sup> OrthoCarolina CON Application, Page 33.

<sup>14</sup> OrthoCarolina CON Application, Page 132.



OrthoCarolina projects that the fixed MRI scanner will cause a “shift” from Ballantyne and Spine Center to University by 50% in 2024, 65% in 2025, and 75% in 2026 from seven zip codes. The factors for this shift are identified as:

- Full time MRI scanner
- Convenient northeast Mecklenburg County location
- Reduced travel time
- More timely access
- Proximity to referring physicians

However, OrthoCarolina did not explain how these factors impact the “shift” percentage and why they increase over three years if the MRI scanner will have the same operating hours from Year 1. OrthoCarolina identifies an average OrthoCarolina Mecklenburg County MRI wait time of 12.81 days but does not identify how that wait time will change for any OrthoCarolina MRI patients if the proposed University MRI scanner is approved. As previously discussed, the Ballantyne location is more than 30 miles from University. The Spine Center focuses on spinal problems. Even assuming for the sake of argument that University’s scan volume is weighted toward orthopedic scans, that still fails to explain why volume will shift from Spine Center to University. Orthopedic scans take many forms other than scans of the spine, such as scans of the hips, knees, wrist, shoulder and elbow. There is no information in the application demonstrating, with reasonable and supported assumptions, that the projected volume shifts are realistic.

OrthoCarolina projects that the fixed MRI scanner will cause an “organic MRI growth” due to the OrthoCarolina provider letters of support included in Exhibit I.2. In other words, “if you build it, [they] will come.”<sup>15</sup> This “organic MRI growth” totals 0.25% in 2024, 0.50% in 2025, and 0.75% in 2026. These percentages are offered because they are small percentages but that are multiplied by a large number of projected Mecklenburg MRI scans.

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<sup>15</sup> *Field of Dreams* (Phil Alden Robinson dir., 1989)

The following table shows the number of “organic MRI growth” scans and calculates the percentage increase needed at University to achieve these “organic MRI growth” volumes:

	<b>2024</b>	<b>2025</b>	<b>2026</b>
Projected Mecklenburg County MRI Scans	138,461	140,762	142,929
“Organic MRI Growth” %	0.25%	0.50%	0.75%
“Organic MRI Growth” Scans	346	704	1,072
Projected OrthoCarolina MRI Scans	1,535	1,548	1,562
<b>% Increase of MRI Scans</b>	<b>22.5%</b>	<b>45.5%</b>	<b>68.6%</b>

OrthoCarolina is projecting its MRI scans will increase by nearly 70% in Year 3, which is unreasonable.

OrthoCarolina proposes a wide bore MRI scanner to accommodate claustrophobic and obese patients requiring an MRI scan. Although the proposed wide bore MRI scanner is wider than a “closed bore” MRI scanner, most orthopedic patients needing an MRI scan can be inserted into the bore “feet first,” so OrthoCarolina’s wide bore 1.5T MRI scanner should not be considered a material factor that increases patient volume. Additionally, OrthoCarolina does not substantiate its statement on page 40 that it is “unable to accommodate some patients because the leased MRI scanner has a closed bore.” The application does not reveal how many patients OrthoCarolina is “unable to accommodate” or how often this happens.

OrthoCarolina’s projections are not supported by reasonable and supported assumptions. Accordingly, for the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (3) and should be disapproved.

**N.C. Gen. Stat. § 131E-183(a)(4)**

*Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed*

The Application fails to conform with Criterion (4). First, an application that fails to demonstrate the need the population has for the services proposed is, by definition, not the least costly or most effective alternative. The same facts that cause the Application to be non-conforming with Criterion (3) also cause it to be non-conforming with Criterion (4).

Second, apart from its failure to demonstrate the need the population has for the services proposed, OrthoCarolina's application fails to identify the least costly or most effective alternative to meet the need of the population it proposes to serve. The least costly or most effective alternative is to relocate OrthoCarolina's North Carolina CON-approved mobile MRI scanner from South Carolina to its University location. OrthoCarolina has its mobile MRI scanner operating in South Carolina for 104 days per year, as calculated in the Criterion (3) discussion. It would only take 49.6 days of mobile MRI service to "decompress" the Ballantyne and Spine Center MRI service locations, as projected by OrthoCarolina. This also avoids a capital expenditure of nearly \$2.2 million. Ironically, OrthoCarolina's proposal is essentially a "fixed" mobile in that patients will need to exit the main building, walk under a canopy and enter a modular structure.<sup>16</sup> This is exactly the set up for mobile MRI scanners, so OrthoCarolina's critiques of mobile MRI scanners are not persuasive.<sup>17</sup>

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (4) and should be disapproved.

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<sup>16</sup> OrthoCarolina CON Application, Page 27.

<sup>17</sup> OrthoCarolina CON Application, Page 73.

**N.C. Gen. Stat. § 131E-183(a)(5)**

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

OrthoCarolina's application fails to demonstrate the financial feasibility of the proposed MRI scanner for the following reasons:

First, an application that fails to demonstrate the need the population has for the services proposed is not, by definition, a financially feasible project. The same facts that make the application non-conforming under Criterion (3) also make it non-conforming with Criterion (5).

Second, the application omits an essential cost, a required chiller. Exhibit F.1 contains two quotes, a GE Healthcare quote, and a Lamboo Medical quote.<sup>18</sup> The Lamboo Medical quote **specifically excludes** the cost for a chiller unit. Specifically, on the Lamboo Medical quote, page 11 of 16, it states the Basic Modular MRI Unit (excl chiller – to be supplied by OEM) Price is \$420,000. The customer added options **do not include** the chiller. The Modular MRI Unit with Customer Added Options totals \$510,900. This amount is supposedly included in the GE Healthcare quote on Line 20. Neither the GE Healthcare nor the Keach Construction estimate in Exhibit K.3 includes a chiller. The Lamboo Medical quote on page 12 of 16 includes a list of Available Options **Not Included** in Basic Modular Price. This list includes the cost for the chiller at \$39,800. But as page 11 of 16 shows, OrthoCarolina did not choose this option. The chiller is required for the MRI scanner to operate. The chiller circulates water through coils inside the MRI machine to keep it at a consistent temperature. Without a chiller, the MRI machine would heat up and could be damaged. Further, if the machine gets too hot, it can be dangerous for patients.<sup>19</sup> Since the cost of a chiller has not been included in the Form F.1a Capital Cost, then the project is, at a minimum, \$39,800 short from the Form F.1a Capital Cost identified project total of \$2,158,108. Notably, the "other" category

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<sup>18</sup> Line 20 in the GE Healthcare quote states, "\$510,900 applied for SVSR quote #233-2." If the Lamboo Medical quote is included in the GE Healthcare quote, then the proposed Voyager 1.5T mobile MRI system is only priced \$700,000 lower than NH Matthews proposed state-of-the-art Hero 3.0T MRI system with the added breast imaging package.

<sup>19</sup> See, e.g., <https://www.kkt-chillersusa.com/how-do-mri-chiller-systems-work/#:~:text=What%20is%20an%20MRI%20Chiller,up%20and%20could%20be%20damaged.> (visited Nov. 30, 2022)

on Form F.1a includes \$25,000 for IT, rigging/installation, contingency and miscellaneous sales tax. Even if “other” were exclusively for contingency, it is inadequate to cover the expense of the chiller.<sup>20</sup>

Third, OrthoCarolina projects the Utilities expense by multiplying \$8.20 per square feet by 1,764 square feet in Year 3 for a total of \$14,458. However, OrthoCarolina fails to include the square footage of the primary source of Utility expenses, the modular structure with the mobile MRI scanner, that has an estimated total square footage of 637 square feet. This alone is a shortfall of \$5,223 [ $\$8.20 \times 637$  square feet]. More importantly, OrthoCarolina identifies a Utilities expense in FY2021 of \$12,624 for the entire year at University. OrthoCarolina reports that the mobile MRI scanner is only available at University six days per month or 72 days per year. This would equal a Utilities expense rate of \$175 per day [ $\$12,624 / 72$  days]. At a minimum of six days per week or 312 days per year, the Utilities expense should be at least \$54,600 [ $\$175$  per day  $\times$  312 days], or more than 4x the OrthoCarolina projected Utilities expense. Additionally, OrthoCarolina did not indicate if it “leased” the mobile MRI scanner through a flat fee or a “click” fee and whether or not the utility expenses related to the chiller were even included in its existing \$8.20 per square feet Utilities rate. If the chiller’s energy consumption was not included in its existing \$8.20 per square feet Utilities rate, then Utilities expense could be dramatically higher.

Fourth, in Year 1, based on a 60-hour week, 52 weeks per year or 3,120 hours per year.<sup>21</sup> OrthoCarolina does not provide enough Radiology Technologists (MRI) or Other (MRI Tech Asst) to cover the hours of operation [ $3,120$  hours /  $2,080$  hours per FTE = 1.50 FTEs]. OrthoCarolina only proposes to hire 1.25 Radiology Technologists (MRI) and 1.25 Other (MRI Tech Asst). Thus, staffing expense is understated.

Fifth, per the American Hospital Association Estimated Useful Lives of Depreciable Hospital Expenses publication, the depreciable life of an MRI scanner is 5 years not 6 years, as shown on the following figure.

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<sup>20</sup> OrthoCarolina may claim that Truist Bank is willing to loan more money for this project. The bank’s potential willingness to loan OrthoCarolina more money does not change the fact that the application omits an essential cost. The CON filing fee was premised on a capital cost of \$2,158,108, which does not include the chiller. See CON Filing Fee Sheet for OrthoCarolina application. The application can only be reviewed if the entire required filing fee has been paid when the application is submitted. See N.C. Gen. Stat. § 131E-182(c); 10A NCAC 14C.0203(e). Assuming a cost of \$39,800 for the chiller, the filing fee is understated by approximately \$119. The filing fee is set by statute, and the Agency cannot waive or change the fee. Nor can the Agency require the applicant to pay any filing fee shortfall after the fact.

<sup>21</sup> OrthoCarolina CON Application, Page 27.

## Diagnostic and Treatment Departments (continued)

<i>Item</i>	<i>Years</i>	<i>Item</i>	<i>Years</i>
Laparoscope	3	Nebulizer	
Laryngoscope	3	Pneumatic	10
Laser		Ultrasonic	10
Coronary	2	Nephroscope	7
Surgical	5	Neurological surgical	
Laser positioner	5	table headrest	10
Laser smoke evacuator	5	Neutron beam accelerator	8
Lesion generator	5	Noninvasive CO <sub>2</sub> monitor	7
Lifter, patient	10	Optical coherence tomography	5
Linear accelerator	7	Optical imaging systems	5
Liver dialysis device	7	Optical mammography	5
Lithotripter		Optical readers	5
Extracorporeal shock-wave		Orthotron system	10
(ESWL)	5	Orthourological instruments	10
Renal	5	Oscilloscope	7
Magnetic resonance imaging		Oven	
(MRI) equipment	5	Paraffin	10
3T MRI	5	Sterilizing	10
7T MRI	5	Oximeter	10
Intra-operative MRI (iMRI)	5	Oxygen analyzer	7
Intra-operative MRI for		Oxygen blender	8
neurosurgery	5	Oxygen tank, motor, and	

If a depreciable life of 5 years was used, then the equipment depreciation would be \$374,156 [\$1,870,779 / 5 years] or \$61,610 more than OrthoCarolina projected equipment depreciation.

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (5) and should be disapproved.

**N.C. Gen. Stat. § 131E-183(a)(6)**

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

As discussed in the context of CON Review Criteria (1) and (3), OrthoCarolina fails to demonstrate a need by the identified population for the services proposed. Consequently, OrthoCarolina did not demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (6) and should be disapproved.

**N.C. Gen. Stat. § 131E-183(a)(7)**

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

As discussed in Criterion (5), in Year 1, MRI scanner staffing is based on a 60-hour week, 52 weeks per year or 3,120 hours per year. OrthoCarolina does not provide enough Radiology Technologists (MRI) or Other (MRI Tech Asst) to cover the hours of operation [3,120 hours / 2,080 hours per FTE = 1.50 FTEs]. OrthoCarolina only proposes to hire 1.25 Radiology Technologists (MRI) and 1.25 Other (MRI Tech Asst). Thus, the staffing is deficient.

As a result, OrthoCarolina did not demonstrate that the proposed project will have the necessary manpower to provide the MRI service.

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (7) and should be disapproved.



**N.C. Gen. Stat. § 131E-183(a)(12)**

*Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.*

As discussed in Criterion (5), Exhibit F.1 contains two quotes, a GE Healthcare quote, and a Lamboo Medical quote. Line 20 in the GE Healthcare quote states, “\$510,900 applied for SVSR quote #233-2.” If the Lamboo Medical quote is included in the GE Healthcare quote, then the proposed Voyager 1.5T mobile MRI system is only priced \$700,000 lower than NH Matthews proposed state-of-the-art Hero 3.0T MRI system with the added breast imaging package. The Lamboo Medical quote specifically excludes the cost for a chiller unit. Specifically, on the Lamboo Medical quote, page 11 of 16, it states the Basic Modular MRI Unit (excl chiller – to be supplied by OEM) Price is \$420,000. The customer added options do not include the chiller and the Modular MRI Unit with Customer Added Options totals \$510,900. This amount is supposedly included in the GE Healthcare quote on Line 20. Neither the GE Healthcare nor the Keach Construction estimate in Exhibit K.3 includes a chiller. The Lamboo Medical quote on page 12 of 16 includes a list of Available Options Not Included in Basic Modular Price. This list includes the cost for the chiller at \$39,800. Since the chiller is required for the MRI scanner to operate and the cost has not been included in the Form F.1a Capital Cost, then the project is at a minimum \$39,800 short from the Form F.1a Capital Cost identified project total of \$2,158,108.

As a result, OrthoCarolina did not demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative to provide the MRI service.

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (12) and should be disapproved.

**N.C. Gen. Stat. § 131E-183(a)(13)**

*The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:*

- a. The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;*
- b. Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;*
- c. That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and*
- d. That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.*

OrthoCarolina identifies that charity care/indigent care are combined in the Self-Pay payor category. In Year 3, the Self-Pay percentage is 3.16%, down from the 3.44% prior to the initiation of fixed MRI services. A Self-Pay percentage of 3.16% is equal to 115 patients in Year 3. In Year 3, Self-Pay gross revenue equals \$161,276 and Self-Pay write off equals \$85,927. As a result, on average each charity care/indigent care patient has \$747 written off [ $\$85,927 / 115$ ] but must still pay on average \$655 [ $(\$161,276 - \$85,927) / 115$ ]. Having a lower gross charge is meaningless if charity care patients must still make an out-of-pocket payment.

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (13) and should be disapproved.

**N.C. Gen. Stat. § 131E-183(a)(18a)**

*The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.*

As discussed above, OrthoCarolina fails to demonstrate conformity with CON Review Criteria (1), (3), (4), (5), (6), (7), and (12). Consequently, OrthoCarolina fails to demonstrate that its CON Application is conforming to CON Review Criterion (18a).

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with Criterion (18a) and should be disapproved.

#### **IV. North Carolina Criteria and Standards for CON Criteria and Standards**

##### **10A NCAC 14C .2703 Performance Standard**

As discussed in the context of CON Criterion (3), OrthoCarolina uses an unreasonable need methodology and assumptions, which result in overstated projected utilization for the new proposed fixed MRI scanner. For that reason, OrthoCarolina does not demonstrate a need for the new fixed MRI scanner as required by the performance standard.

For the reasons stated in these Comments and any additional reasons the Agency may discern, the OrthoCarolina application does not conform with 10A NCAC 14C .2703 and should be disapproved.

## **V. Comparative Analysis**

### **Conformity with Review Criteria**

Only the NH Matthews application conforms with all applicable review criteria and rules. Accordingly, NH Matthews is comparatively superior with respect to this factor.

### **Scope of Services**

OrthoCarolina is proposing to place the fixed MRI scanner adjacent to their University office, for the convenience of orthopedic and rehabilitation outpatients cared for by OrthoCarolina physicians. The proposed MRI scanner at University will only be able to offer contrasted and non-contrasted MRI scans to outpatients, primarily orthopedic, spine and rehabilitation patients seen by OrthoCarolina physicians and not to inpatients who are admitted to a hospital. Only the fixed MRI scanner proposed by NH Matthews will locate the new fixed MRI scanner where it can be accessed by multiple types of patients including inpatients, outpatients, and Emergency Department patients. In addition, the performance of MRI studies at NH Matthews will not be concentrated on only outpatient orthopedic MRI scans from one physician group, unlike at OrthoCarolina which is overwhelmingly outpatient orthopedic MRI scans referred largely by OrthoCarolina physicians. Rather, MRI patients will come from multiple physician specialties including Emergency Medicine, ENT, Family Medicine, Hematology/Oncology, Internal Medicine, Inpatient Care Specialists (Hospitalists), Neurology, Ophthalmology, Pediatric Oncology, Psychiatry, Sleep Medicine Specialists, as well as Orthopedics. NH Matthews also proposes to offer breast MRI scans. NH Matthews is the superior applicant in terms of access to inpatient and outpatient MRI scans and the enhanced accessibility created by MRI scan referrals from multiple physician specialties rather than from a single physician specialty or group.

NH Matthews is comparatively superior with respect to this factor.

**Historical Utilization**

The following table highlights utilization of the existing fixed MRI scanners for Novant Health and OrthoCarolina provided in the 2022 SMFP, representing FY2020 utilization and the 2023 SMFP representing FY2021 utilization.

	# of Fixed MRI Scanners		Total Weighted Procedures		Weighted Procedures per Scanner	
	FY2020	FY2021	FY2020	FY2021	FY2020	FY2021
Novant Health	10	12	50,264	56,564	5,026	4,714
OrthoCarolina	2	2	14,204	14,082	7,102	7,014

OrthoCarolina is comparatively superior with respect to this factor.

**Geographic Accessibility**

The following table highlights the site locations for the NH Matthews and OrthoCarolina proposed fixed MRI scanner:

	# of Fixed MRI Scanners Currently	Locations
NH Matthews	1	Matthews, NC
OrthoCarolina University	8	Charlotte, NC

NH Matthews proposes to locate a hospital-based MRI scanner in Matthews which currently has one hospital-based MRI scanner. OrthoCarolina proposed to locate a freestanding MRI scanner in Charlotte which currently has eight freestanding MRI scanners.

NH Matthews is comparatively superior with respect to this factor.

**Access by Service Area Residents**

NH Matthews indicates that the scheduled hours of operation for the proposed MRI scanner will be at least 107.5 hours per week. In addition, since the hospital is in operation 24 hours per day, 7 days per week, on call coverage is available for any MRI scans needed outside of these hours<sup>22</sup>. The OrthoCarolina CON Application proposes that scheduled hours of operation will be 60 hours per week. However, the OrthoCarolina MRI scanner project does not propose to offer on call coverage for MRI scans to be performed overnight during the weekdays or weekends. Thus, overall superior access is provided to all patients in need of an MRI scan at the NH Matthews MRI scanner.

Additionally, the following table highlights the projected patient origin for MRI patient at NH Matthews compared to OrthoCarolina, as projected in response to Section C.3.a:

**Year 3 Projected Patient Origin**

Counties	NH Matthews		OrthoCarolina University	
	Number of Patients	% of Total	Number of Patients	% of Total
Mecklenburg	5,477	60.4%	2,610	71.9%
Cabarrus			648	17.9%
Iredell			44	1.2%
Union	2,603	28.7%	38	1.0%
Gaston			36	1.0%
Rowan			34	0.9%
Stanly			30	0.8%
Other NC Counties	988	10.9%	81	2.2%
Other States			107	3.0%
<b>Total</b>	<b>9,069</b>	<b>100.0%</b>	<b>3,627</b>	<b>100.0%</b>

Although OrthoCarolina proposes a higher percentage of Mecklenburg County MRI patients, NH Matthews’ lower percentage of Mecklenburg County MRI patients is actually more than double the number of Mecklenburg County MRI patients served as compared to OrthoCarolina. NH Matthews projects to serve 2.5 times the number of MRI patients as compared to OrthoCarolina.

NH Matthews is the comparatively superior applicant with respect to this factor.

<sup>22</sup> NH Matthews CON Application, Page 39.

### Access by Underserved Groups

While OrthoCarolina may claim to have an advantage due to its supposedly lower prices as a non-hospital based provider, this perceived advantage must be considered in the broader context of access by medically underserved populations. A so-called lower price is not beneficial for patients who have no insurance and cannot afford to pay for their care. Novant Health has among the most generous charity and related policies in North Carolina. A family of four with household income up to 300% of the Federal Poverty Level and no insurance does not receive a bill for any care by Novant Health facilities or physicians. OrthoCarolina's charity care is simply not comparable.

As posed in the CON application form at Section C.6.a., the State asks the applicant to "briefly describe how the groups listed below will access the service components proposed in this application form: low-income persons; racial and ethnic minorities; women; persons with disabilities; persons 65 and older; Medicare beneficiaries; and Medicaid recipients."

Thus, in a comparative analysis of competing applications it is useful to compare the projected MRI scanner payor mix information for Self-Pay/Charity/Indigent, Medicare, and Medicaid populations, in response to CON Application Section L.3.b. That comparison is included in the following table.

<b>Payor Categories</b>	<b>NH Matthews</b>	<b>OrthoCarolina University</b>	<b>NH Matthews Difference</b>
Self-Pay/Charity/Indigent	3.00%	3.16%	- 0.16%
Medicare	42.90%	24.82%	+ 18.08%
Medicaid	5.20%	5.04%	+ 0.16%
<b>Total Medically Underserved</b>	<b>51.1%</b>	<b>33.02%</b>	<b>+ 18.08%</b>

Source: NH Matthews CON Application, page 99, and OrthoCarolina CON Application, page 108.

The previous table shows that the NH Matthews MRI scanner will provide more than half of its MRI scans to patients who are considered to be medically underserved populations. In contrast, University will provide 33% of its outpatient-only MRI scans to medically underserved populations. Based on the above percentages in the table NH Matthews will provide 18.08 percentage points more of MRI scans to medically underserved populations compared to University. Thus, NH Matthews is clearly the comparatively superior applicant in service to Medicare, Medicaid, and Self-Pay/Indigent/Charity Care



populations and to the total medically underserved populations.

NH Matthews is the comparatively superior applicant with respect to this factor.

### **Competition**

Both NH Matthews and OrthoCarolina are existing providers of fixed and mobile MRI services in Mecklenburg County. NH Matthews proposes to increase the number of fixed MRI scanners available within NH Matthews, serving both inpatient and outpatient. OrthoCarolina proposes to shift existing OrthoCarolina outpatients from Ballantyne and Spine Center to University, which is currently served by a mobile MRI scanner.

As neither applicant is a new fixed MRI provider, both applicants are equally effective with respect to competition.

### **Projected Average Net Revenue per MRI Scan for PYs 1-2-3**

The difference in the average annual net revenue per MRI Scan for the first three years of operation favors OrthoCarolina because it offers limited MRI scans, only to outpatients and primarily to orthopedic patients, whereas NH Matthews is offering MRI scans to inpatients, outpatients, and Emergency Department patients on an around the clock basis, if necessary.

The following table highlights the Net Revenue per MRI Scan and is based on the data included in the CON Applications, Section Q, for each applicant.

<b>MRI Scanner</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>
NH Matthews	\$1,078	\$1,110	\$1,144
OrthoCarolina University	\$513	\$518	\$524

Source: NH Matthews and OrthoCarolina University CON Applications, Forms F.2b and Forms C.2.b.

Based on the difference in MRI scans performed at each location, it is inconclusive as to which applicant is comparatively superior with respect to this factor.

**Projected Average Operating Expense per MRI Scan for PYs 1-2-3**

The difference in the average annual operating expense per MRI Scan for the first three years of operation highly favors NH Matthews even though University is offering only outpatient MRI scans primarily to orthopedic patients and NH Matthews is offering MRI scans to inpatients, outpatients, and Emergency Department patients on an around the clock basis, if necessary.

The following table highlights the Operating Expense per MRI Scan and is based on the data included in the CON Applications, Section Q, for each applicant.

<b>MRI Scanner</b>	<b>2024</b>	<b>2025</b>	<b>2026</b>
NH Matthews	\$345	\$322	\$301
OrthoCarolina University	\$470	\$482	\$442

Source: NH Matthews and OrthoCarolina University CON Applications, Forms F.2b and Forms C.2.b.

Note that in each of the three project years, the difference in the annual average cost per MRI scan, favors NH Matthews by a considerable amount due to volume efficiencies.

NH Matthews is the comparatively superior applicant with respect to this factor.

## Summary

The following table highlights the comparative factors and indicates that NH Matthew is the more comparatively superior applicant in this review.

<b>Comparative Factor</b>	<b>NH Matthews</b>	<b>OrthoCarolina</b>
Conformity with Review Criteria	<b>More Effective</b>	Less Effective
Scope of Services	<b>More Effective</b>	Less Effective
Historical Utilization	Less Effective	<b>More Effective</b>
Geographical Accessibility	<b>More Effective</b>	Less Effective
Access by Service Area Residents	<b>More Effective</b>	Less Effective
Access by Underserved Groups	<b>More Effective</b>	Less Effective
Competition	Equally Effective	Equally Effective
Projected AVG Net Revenue per Scan	Inconclusive	Inconclusive
Projected AVG Operating Expense per Scan	<b>More Effective</b>	Less Effective

## VI. Conclusion

Based on the analysis of the OrthoCarolina University MRI scanner project using the CON statutory review criteria, the requirements of the CON MRI Scanner Regulations, and the comparative analysis, the NH Matthews MRI scanner proposal is the superior project and should be approved. The OrthoCarolina University MRI scanner CON Application is not approvable for the previously stated reasons.