

May 30, 2023

Tanya Saporito, Project Analyst Healthcare Planning and Certificate of Need Section Division of Health Service Regulation North Carolina Department of Health and Human Services 809 Ruggles Drive Raleigh, North Carolina 27603

RE: Comments regarding competing Novant Health New Hanover Regional Medical Center Fixed MRI Scanner CON Application

Dear Ms. Saporito:

Enclosed please find comments prepared by EmergeOrtho regarding the competing Novant Health New Hanover Regional Medical Center CON application to develop one fixed MRI scanner within New Hanover County, to meet the need identified in the 2023 State Medical Facilities Plan (SMFP). We appreciate your consideration of these comments regarding the Novant Health application during your review of the applications.

If you have any questions about the information presented here, please contact me at 910.332.1550 extension 31220 or Zachary.welch@emergeortho.com.

Sincerely,

Lachary Welch

Zachary Welch Executive Director, EmergeOrtho – Coastal Region

COMMENTS ABOUT COMPETING NOVANT HEALTH NEW HANOVER REGIONAL MEDICAL CENTER CERTIFICATE OF NEED APPLICATION

Submitted by EmergeOrtho May 31, 2023

In accordance with N.C.G.S. §131E-185(a.1)(1), EmergeOrtho (EO) submits these written comments regarding a competing application from Novant Health New Hanover Regional Medical Center, LLC (Novant Health) Project ID# O-12361-23, to develop another fixed MRI scanner to be located at the NHRMC main campus, in response to the need identified in the *2023 State Medical Facilities Plan (SMFP)* for New Hanover County. The discussion below describes how the Novant application does not conform to all the Certificate of Need review criteria and applicable MRI administrative rules. These comments also address the issue of how the EO application represents a comparatively more effective alternative than the Novant Health application for development of an additional fixed MRI scanner in New Hanover County.

EmergeOrtho acknowledges that two other organizations (Delaney Radiology and Wilmington Health) submitted applications in this batch review, and is confident in the Agency's due diligence process in reviewing those applications.

Specific comments regarding the Novant Health NHRMC application (O-12361-23)

Criterion (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

Novant Health does not adequately demonstrate the need for the proposed project, did not propose the least costly or most effective alternative, and did not show that its proposal is not unnecessarily duplicative of existing MRI resources. Therefore, Novant Health fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2023 SMFP. The discussions regarding analysis of need in Criterion (3), alternative methods in Criterion (4), unnecessary duplication in Criterion (6), and the applicable .2703 MRI Scanner administrative rules, are incorporated herein by reference. Therefore, the Novant Health application is not conforming to Criterion 1 because the applicant does not adequately demonstrate that the proposal is consistent with Policy GEN-3.

Criterion (3) "The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed."

The Novant Health application did not account for a mobile MRI scanner that is owned by a related entity, and which serves host sites in New Hanover County, specifically the mobile MRI scanner (CON #O-7254-05) owned by Porters Neck Imaging, LLC. As described in the Delaney Radiology application (pp. 57-58), this entity is owned by Delaney Radiology and by Novant Health New Hanover Regional Medical Center, and this mobile MRI scanner during the most recent 12 months has served the Delaney Radiology imaging centers at Medical Center Drive and at Ashton Drive in Wilmington. In its application Novant Health neither mentioned nor accounted for this MRI scanner, nor did Novant Health portray historical or projected MRI scans for the mobile scanner.

Novant Health failed to demonstrate the projected procedure volume for all of its existing and proposed MRI scanners. Therefore, the Novant Health application is nonconforming to Criterion 3.

Criterion (4) *"Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed."*

Novant Health does not adequately demonstrate that the alternative proposed in its application is the most effective to meet the need because the application is not conforming to all statutory and regulatory review criteria and administrative rules. An application that cannot be approved cannot be the most effective alternative.

Also, the Novant Health proposal is not the most effective or least costly option because Novant Health's capital cost of \$6.85M is by far the highest of the applicants. The Novant Health proposal represents a typically expensive hospital project. As shown in the table below, Novant projects that its project capital cost will exceed \$6.8 million, which is more than three times as expensive as the projected EmergeOrtho project capital cost of \$2.2 million.

Projected Capital Cost

EmergeOrtho	Novant Health
\$2,246,570	\$6,855,305
	F F4

Source: CON Applications, Form F.1a.

Therefore, the Novant Health application is not conforming to Criterion (4).

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

Novant Health fails to demonstrate that its proposal would not result in unnecessary duplication of existing fixed MRI capacity. Although Novant Health attempts to obfuscate this in its application, Novant Health recently received approval for one additional New Hanover County fixed MRI scanner (CON Project ID# O-12124-21). As implied in its application (Section Q utilization projections), Novant Health has not yet made that approved fixed MRI scanner operational, and yet now is already seeking approval for a sixth fixed MRI scanner in New Hanover County. An application cannot be approved when it cannot demonstrate that the project will not result in unnecessary duplication of existing capacity that has not yet even gone into service. Therefore the Novant Health application is not conforming to Criterion (6).

Criteria (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."

Novant Health's application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate that it will promote cost-effective services. The discussion regarding demonstration of need, alternatives, and unnecessary duplication are found in Criteria (3), (4), and (6), and are incorporated herein by reference.

SECTION .2700 - CRITERIA AND STANDARDS FOR MAGNETIC RESONANCE IMAGING SCANNER

10A NCAC 14C .2703 PERFORMANCE STANDARDS

(a) An applicant proposing to acquire a fixed 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:

(3) 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 fixed MRI scanner service area during the 12 months before the application deadline for the review period;

The Novant Health application does not conform to the .2703(a)(3) performance standard applicable for the review of MRI scanners. Novant Health did not account for or provide utilization projections for a mobile MRI scanner which a related entity owns and operates within New Hanover County. The discussions regarding this is found in Criterion (3) and is incorporated herein by reference.

The Agency typically performs a comparative analysis when evaluating competing fixed MRI scanner applications in a need determination batch review. The purpose is to identify the application that would provide the greatest overall benefit to the service area community. The table below summarizes standard metrics that the Agency has previously used for comparing applications in a competitive fixed MRI scanner batch review.

	EmergeOrtho	Novant Health RMC
Conformity with Review		
Criteria & Administrative Rules	Yes	No
Scope of Services	Effective	Not approvable
Historical Utilization	More Effective	Not approvable
Competition (Access to New		
Provider)	Effective	Not approvable
Ownership of Fixed MRI		
Scanners in Service Area	More Effective	Not approvable
Geographic Accessibility	More Effective	Not approvable
Access by Service Area		
Residents	More Effective	Not approvable
Access by Medically		
Underserved	Effective	Not approvable
Projected Average Net		
Revenue per MRI procedure	More Effective	Not approvable
Projected Average Operating		
Expense per MRI procedure	More Effective	Not approvable

2023 New Hanover County Fixed MRI Scanner Review CON Application Comparative Analysis

As the table objectively portrays, aside from the Novant Health application not being approvable, the EmergeOrtho application is the more effective alternative, and will enable the greatest benefit to local residents. Specifically:

• <u>Conformity with Review Criteria.</u> The EmergeOrtho application is conforming to all CON review criteria. In contrast, the Novant Health application fails to conform to multiple review criteria and to the MRI administrative rules and is not approvable.

- <u>Scope of Services.</u> Both applicants propose to acquire and operate a fixed MRI scanner. Although Novant Health proposes to operate the fixed MRI scanner in a hospital setting with availability to both inpatients and outpatients, its application is not conforming to all CON review criteria, and thus is not approvable. Therefore, EmergeOrtho is the more effective alternative.
- <u>Historical Utilization</u>. Both applicants have a history of offering fixed MRI services in New Hanover County. As shown in the table below, EmergeOrtho has historically had higher utilization per fixed MRI scanner compared to Novant Health. Therefore, the EO application is the most effective alternative in terms of historical utilization of fixed MRI scanners.

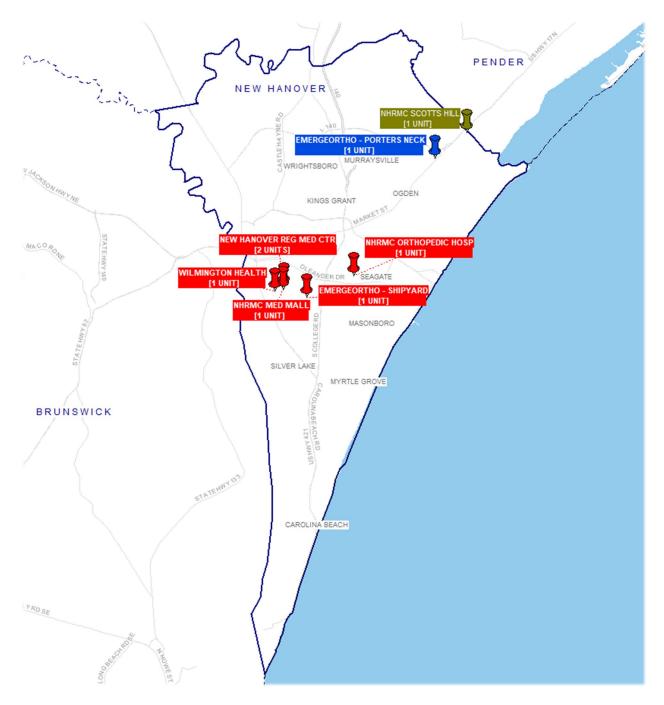
	EmergeOrtho	Novant Health
FY2022 Unweighted MRI Scans	4,510	16,570
Operational & Approved Fixed MRI Scanners	1	5
Average Unweighted Scans/Operational Scanner	4,510	4,143
Average Unweighted Scans/Total Scanner	4,510	3,314

Comparison of Fixed MRI Scanner Historical Utilization

Sources: 2023 SMFP, Table 17E-1

• <u>Competition (Access to a New Provider)</u>. Both applicants currently provide MRI services in New Hanover County, so neither applicant represent access to a new provider. However, the Novant Health application is not conforming to all CON review criteria, and thus is not approvable. Therefore, EmergeOrtho is the more effective alternative.

- Ownership of Fixed MRI Scanners in New Hanover County. According to the 2023 SMFP, currently seven fixed MRI scanners operate or are approved in New Hanover County (see page 82 of the EO application). Novant Health owns and operates or is approved for five fixed MRI scanners in New Hanover County, and thus already controls 71.4% (5/7) of the existing or approved fixed MRI scanners in New Hanover County. EmergeOrtho owns and operates one fixed MRI scanner in New Hanover County, and thus controls just 14.3% (1/7) of the existing or approved fixed MRI scanners in New Hanover County. Approval of the Novant Health application would result in even more dominant Novant Health control -- 75.0% (6/8) -- of the New Hanover County fixed MRI scanners. By contrast, EmergeOrtho does not operate a fixed MRI scanner at the Porters Neck site, but must lease access to a mobile MRI scanner owned by RAYUS Radiology. Control of 71.4% (or 75%) of the New Hanover County fixed MRI scanner inventory represents an overly dominant position in the marketplace for Novant Health. Consistent with the 2023 SMFP goal of promoting "a balance of competition and market advantage" (page 4, 2023 SMFP), the Agency should seek to improve the competitive balance within the local service area via this fixed MRI scanner review. Competition in the New Hanover County marketplace will be enhanced with approval of EO for a fixed MRI scanner, while approval of Novant Health for a 6th fixed MRI scanner will not have a positive effect on MRI competition. Clearly, the EO application is a more effective alternative as to ownership of fixed MRI scanners in New Hanover County.
- Geographic Accessibility. Novant Health proposes to install a fixed MRI scanner • at its existing New Hanover Regional Medical Center main campus, where it already offers fixed MRI services. Therefore, the Novant Health application offers no benefit at all in terms of geographic accessibility. Indeed, as quoted in Novant Health's 2021 New Hanover County fixed MRI scanner application (p.87): "adding another MRI unit at an existing location in Wilmington does not improve geographic access to MRI services." By great contrast, as stated beginning on page 47 of its application, EmergeOrtho's proposed fixed MRI scanner will improve access by creating a new geographic point of access for fixed MRI services in populous and growing New Hanover County. New Hanover County needs greater geographic diversification of its MRI services. As portrayed on the EO application map recreated below, the six existing operational New Hanover County fixed MRI scanners are located in central Wilmington (in red below). Porters Neck is in the northeastern part of New Hanover County, and as shown on the following map, although NHRMC recently received approval to develop a hospital-based fixed MRI scanner at its planned Scotts Hill Medical Center, this growing area of the county does not host any freestanding fixed MRI scanners.



New Hanover County Fixed MRI Locations

Clearly, the EO application is a more effective alternative for enhancing geographic access to fixed MRI scanners in New Hanover County.

• <u>Access by Service Area Residents.</u> The following table shows the projected patient origin percentages of the EO and Novant Health applications. EmergeOrtho projects to serve a higher percentage of residents of New Hanover County (the SMFP-designated MRI service area). Therefore, the EO application is the more effective alternative for improving access to fixed MRI services by service area residents.

EmergeOrtho	Novant Health RMC
45.9%	41.9%

Source: CON applications, Section C.3.

• <u>Access for the Medically Underserved.</u> Each applicant projects Medicare and Medicaid access, based on their historical experience. Both are effective alternatives as to access for Medicare and Medicaid patients; however, the Novant Health application fails to conform to multiple review criteria and to the MRI administrative rules and the application is not approvable.

EO projects to offer charity care for MRI patients at Porters Neck. As a not-forprofit hospital that receives exemption from paying taxes, Novant Health RMC has an obligation to provide charity care. Thus, not surprisingly, Novant Health portrays higher charity care, as summarized in the following table. However, the Novant Health application fails to conform to multiple review criteria and to the MRI administrative rules and the application is not approvable. Therefore, EmergeOrtho is the more effective alternative.

Year 3	EmergeOrtho	Novant Health RMC
Charity Care \$/MRI Procedure	\$18.02	\$207.33
Charity Care % of Gross Revenue	1.50%	4.10%
Charity Care % of Net Revenue	4.56%	16.32%

Projected Charity Care

Source: CON Applications, Section Q, Form F.2b.

• **<u>Projected Average Net Revenue per MRI Procedure.</u>** As a value-based imaging provider, EO offers market-competitive charges for MRI services in New Hanover County, projecting a lower average net revenue per unweighted MRI procedure than Novant Health. Therefore, the EO application is a more effective alternative.

	EmergeOrtho	Novant Health RMC
Average Net Revenue, Year 3	\$330	\$1,270

Source: CON Applications, Section Q, Form F.2b. To equalize the comparison, the EO total excludes professional fees.

• <u>Projected Average Operating Expense per MRI Procedure.</u> EO offers costeffective operating expenses for its MRI service in New Hanover County; its application projects a lower average operating expense per unweighted MRI procedure than Novant Health. Therefore, the EO application is a more effective alternative.

Projected Average Operating Expense/Unweighted MRI Procedure

	EmergeOrtho	Novant Health RMC
Average Operating Expense, Year 3	\$247	\$448

Source: CON Applications, Section Q, Form F.3b. To equalize the comparison, the EO total excludes professional fees.

Competitive Comparison Conclusion

As described in the above comparative analysis, EmergeOrtho ranks more favorably on the comparative metrics, and the Novant Health application is not approvable. Thus, EmergeOrtho is a more effective alternative for development of the need-determined fixed MRI scanner in New Hanover County.