

# Wake Forest Baptist Imaging

December 2, 2019

Celia Inman, 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 on Forsyth County Fixed MRI Scanner CON Applications

Dear Ms. Inman:

Enclosed please find the Wake Forest Baptist Imaging written comments regarding the competing CON application for one fixed MRI scanner for Forsyth County, to meet the need identified in the *2019 State Medical Facilities Plan*. We appreciate your consideration of these public comments during your review of the two applications.

If you have any questions, please contact me at 919.247.1227. I look forward to seeing you at the public hearing.

Sincerely,

*Susan Hawkins*

Susan Hawkins  
Senior Director of Operations

**COMMENTS ABOUT COMPETING CERTIFICATE OF NEED APPLICATIONS  
FORSYTH COUNTY FIXED MRI SCANNER NEED DETERMINATION**

**Submitted by Wake Forest Baptist Imaging  
December 2, 2019**

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Two applicants submitted Certificate of Need (CON) applications in response to the need identified in the *2019 State Medical Facilities Plan (SMFP)* for one fixed MRI scanner in Forsyth County. These include:

G-11798-19 Wake Forest Baptist Imaging, LLC d/b/a Wake Forest Baptist Imaging - Kernersville

G-11816-19 Piedmont Imaging, LLC d/b/a Novant Health Imaging Piedmont (hereinafter referred to as Novant)

In accordance with N.C.G.S. §131E-185(a.1)(1), WFBI submits these written comments which address the representations in the competing application, and a discussion about whether the material in the application complies with the Certificate of Need review criteria. These comments also address the issue of which of the competing proposals represents the most effective alternative for development of an additional fixed MRI scanner in Forsyth County. These comments submitted by Wake Forest Baptist Imaging, LLC are not intended to include any additional information that would represent an amendment to its application.

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 applicant that would bring the greatest overall benefit to the community. The table on the following page summarizes 11 metrics that the Agency should use for comparing the two applications in this Forsyth County MRI batch review.

## Forsyth County Fixed MRI Scanner Application Comparative Analysis

	<b>Wake Forest Baptist Imaging</b>	<b>Novant Health Imaging Piedmont</b>
Conformity with Review Criteria & Rules	<b>Yes</b>	No
Ownership of Fixed MRI Scanners in County	<b>Most Effective</b>	Least Effective
Increases Geographic Accessibility	<b>Most Effective</b>	Least Effective
Service to Residents of the Service Area	<b>Most Effective</b>	Least Effective
Date of Offering of Services	<b>More Effective</b>	Less Effective
Projected Charity Care	<b>More Effective</b>	Less Effective
Projected Medicare	Less Effective	<b>More Effective</b>
Projected Medicaid	<b>More Effective</b>	Less Effective
Projected Average Gross Revenue per Scan	<b>More Effective</b>	Less Effective
Projected Average Net Revenue per Scan	Effective	Effective
Projected Average Operating Expense per Scan	Effective	Not approvable

As the table portrays objectively, the WFBI application is the most effective alternative. In other words, the Agency will enable the greatest benefit to local residents by approving the WFBI application. Specifically:

- **Conformity with Review Criteria.** The WFBI application is conforming to all CON review criteria. In contrast, Novant fails to conform to multiple review criteria and the administrative rules and its application is not approvable.
- **Ownership of Fixed MRI Scanners in County.** According to the 2019 SMFP, 16 fixed MRI scanners currently operate in Forsyth County, and as stated in its application, Novant is approved for one additional fixed MRI scanner which it is in the process of installing at NHFMC. Novant thus currently controls 10 of the 17 existing and approved fixed MRI scanners in Forsyth County. Control of 59% of the fixed MRI scanner inventory represents a dominant position in the marketplace, and the Agency should seek to create greater market balance with this fixed MRI review. By contrast, WFBI currently operates one fixed MRI scanner, which represents just 6% of the inventory. Competition in the marketplace will be enhanced with approval of WFBI for a second fixed scanner, and approval of Novant for an 11<sup>th</sup> fixed scanner in the county will not have a positive effect on competition in Forsyth County.
- **Increase Geographic Accessibility.** Novant proposes to locate the additional fixed MRI scanner in Winston-Salem. As described in the WFBI CON application on page 35, there are already 13 fixed MRI scanners located in Winston-Salem, with yet another currently under development at NHFMC. Novant, moreover, proposes to place a fixed scanner in a Winston-Salem facility that already operates two fixed scanners. As described in the Novant application, Winston-Salem is home to 65% of the Forsyth County population, and Novant's proposal would establish a 14<sup>th</sup> fixed scanner in Winston-Salem, which would be 78% (14/18) of the county fixed MRI scanner inventory. There is no enhanced geographic benefit achieved by the Novant proposal. In sharp contrast, WFBI proposes to develop a fixed MRI scanner in Kernersville, and specifically in a facility that does not currently host a fixed MRI scanner. Therefore, the WFBI proposal provides the greatest benefit to Forsyth County residents from the perspective of improved geographic access.
- **Service to Residents of the Service Area.** The 2019 SMFP MRI need determination is for Forsyth County; therefore, access for Forsyth County residents is paramount. WFBI projects the highest Forsyth County patient origin percentage of the competing applications, as shown in the following table. Thus, WFBI's proposal is the most effective alternative from an access perspective.

**Projected Forsyth County Patient Origin, PY3**

WFBI	Novant
63.6%	45.8%

Source: CON applications, Section C.3.

- Date of Offering of Services.** The 2019 SMFP determined a need right now for one additional fixed MRI scanner in growing Forsyth County; therefore, the timeliness of the proposals is an important comparative consideration. As shown on the table below, WFBI projects to develop its project six months earlier than Novant. Thus, the WFBI application is the most effective alternative in terms of offering timely access to fixed MRI services for local residents.

**Projected Operational Date**

WFBI	Novant
1/1/2021	7/1/2021

Source: CON Applications, Section P.

- Access for the Medically Underserved.** WFBI projects reasonable Medicare and Medicaid access, based on historical experience, as shown in the table below. WFBI projects a higher Medicaid payor mix than Novant. Generally, Medicaid recipients are considered more underserved than Medicare recipients, and therefore WFBI is the more effective alternative as to access for the medically underserved.

**Projected Medicare & Medicaid Payor Mix**

Payor Mix Year 3	WFBI	Novant
Medicare	11.4%	35.3%
Medicaid	6.7%	5.0%

Source: CON Applications, Section L.3.

WFBI also projects a greater percentage of charity care and self-pay write offs as a percentage of gross revenues, as shown in the table below.

**Projected Charity Care/Self-Pay Access**

Year 3	WFBI	Novant
Charity Care \$	\$115,222	\$125,072
Charity Care %	1.42%	0.44%

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

- **Projected Average Revenue per Scan.** WFBI proposes reasonable charges for its fixed MRI scanner in Kernersville, including projecting the lowest gross revenue per scan of the competing applicants, and a comparable net revenue per scan. The Novant application is a less effective alternative.

**Projected Average Revenue/Scan**

Average Revenue Year 3	WFBI	Novant
Gross Revenue	\$1,773	\$2,076
Net Revenue	\$470	\$462

Source: CON Applications, Section Q, Form F.2. Excludes professional fees.

- **Projected Average Operating Cost per Scan.** WFBI projects a compelling and market-competitive operating expense of \$277/scan (excluding professional fees) for the proposed Kernersville fixed scanner. This represents a modest operating expense/scan in the third project year, even though as a new location it is still in the “ramp-up” phase of offering services. The WFBI operating expense/scan will become even more competitive beyond the initial three project years. The Novant application projects \$202 (excluding professional fees) for its average expense per scan in PY3, but it is not based on reasonable utilization projections. The discussion regarding need and projected utilization found in Criterion (3) is incorporated herein by reference. Therefore, the application submitted by WFBI is the most effective alternative with regard to projected average expense per MRI scan.

## Specific comments regarding the Piedmont Imaging, LLC d/b/a Novant Health Imaging Piedmont application

**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 does not adequately demonstrate the need for the proposed project based on reasonable utilization projections. Therefore, Novant fails to adequately demonstrate how the proposed project will maximize healthcare value for resources expended in meeting the need identified in the 2019 SMFP. The discussion regarding analysis of need, including projected utilization, found in Criterion (3) is incorporated herein by reference. Therefore, Novant is not consistent with Policy GEN-3. The Novant 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.”*

Novant’s projections for MRI procedures are unreasonable and unrealistic. On page 54 of its CON application, Novant includes a table showing the projected Year 3 volumes for its MRI scanners at all sites in Forsyth County. The table shows a system total projection of 53,477 MRI scans, which for 11 fixed scanners represents an average weighted total of 4,862/fixed MRI scanner. This projection just barely meets the required performance standard of 4,805 weighted MRI procedures per fixed scanner.

Novant describes its methodology and assumptions for the utilization projections in Section Q. There are several errors and unreasonable assumptions which result in an inaccurate and unreasonable projection. Specifically:

- The 4-year CAGR for NHIP is 1.34% and not the 2.4% that Novant uses in its interim year calculations. Novant exacerbates the problem by using an even more aggressive and inaccurate utilization projection of 3.93% during the three project years.
- The 4-year CAGR for NHFMC is 3.69% and not the 3.85% that Novant uses in its calculations.
- Novant uses an overly aggressive growth rate for the interim years for NHCMC, given that the facility has offered MRI services for four years and can no longer be considered to be in a “ramp up” phase.
- The 4-year CAGR for NHKMC is 5.29% and not the 5.37% that Novant uses in its calculations.

- The 4-year CAGR for NHIK is 3.54% and not the 3.6% that Novant uses in its calculations.
- The 4-year CAGR for NHIM is 2.38% and not the 2.68% that Novant uses in its calculations.

The tables below portray Novant’s reported historical MRI procedures, as well as the projected unweighted procedures for each Novant facility based on more accurate and reasonable growth rate assumptions.

**Novant – Historical Unweighted Fixed MRI Procedures, All Sites**

Facility	FY15	FY16	FY17	FY18	FY19	4-Yr CAGR	Appropriate Growth Factor	Growth Factor Used by Novant
NHIP	10,985	11,220	11,501	11,314	11,584	1.34%	1.34%	2.4%/3.93%
NHFMC	10,104	11,275	11,129	10,939	11,682	3.69%	3.69%	3.85%
NHCMC	-	627	994	1,240	1,493	33.54%	7.50%	16.1%/11.8%/7.5%
NHKMC	1,152	1,178	1,255	1,400	1,416	5.29%	5.29%	5.37%
NHIK	1,714	1,774	1,948	2,200	2,253	7.07%	3.54%	3.60%
NHIM	7,788	7,584	8,568	7,994	8,557	2.38%	2.38%	2.68%

Source: Novant CON application, Section Q.

**Novant – Projected Unweighted Fixed MRI Procedures, All Sites**

Facility	FY20	FY21	FY22	FY23	FY24	CAGR
NHIP	11,739	11,896	12,055	12,216	12,379	1.34%
NHFMC	12,114	12,561	13,025	13,506	14,005	3.69%
NHCMC	1,605	1,725	1,855	1,994	2,143	7.50%
NHKMC	1,491	1,570	1,653	1,741	1,833	5.29%
NHIK	2,333	2,415	2,501	2,589	2,681	3.54%
NHIM	8,761	8,970	9,183	9,402	9,626	2.38%



When the Novant projections are corrected for these errors, the resulting PY3 fixed MRI utilization total is 51,958. For 11 fixed scanners, the resulting average weighted total is 4,723/fixed MRI scanner, as shown in the following table. This projection does not meet the required performance standard of 4,805 weighted MRI procedures per fixed scanner.

**Novant – Projected Weighted Fixed MRI Procedures, All Sites**

Facility	FY20	FY21	FY22	FY23	FY24	Contrast Weighting Factor*
NHIP	12,781	12,952	13,125	13,300	13,478	1.0888
NHFMC IP	11,554	11,981	12,424	12,883	13,359	1.1336
NHFMC OP	5,479	5,681	5,891	6,109	6,335	1.1336
NHCMC IP	74	79	85	92	99	1.0948
NHCMC OP	1,704	1,832	1,970	2,117	2,276	1.0948
NHKMC IP	385	406	427	450	474	1.1257
NHKMC OP	1,403	1,477	1,556	1,638	1,725	1.1257
NHIK	2,605	2,697	2,793	2,892	2,994	1.1168
NHIM	10,212	10,455	10,704	10,959	11,220	1.1656
TOTAL	46,198	47,561	48,974	50,439	51,958	
Weighted proc/fixed scanner	4,620	4,756	4,452	4,585	4,723	

\*Calculated based on contrast % described by Novant in Section Q methodology.

In summary, Novant failed to demonstrate that its projected fixed MRI scanner procedure volume is based on reasonable and supported assumptions. Therefore, the Novant 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 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. An application that cannot be approved cannot be the most effective alternative. Therefore, the Novant application is not conforming to Criterion (4).

**Criterion (5)** *“Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.”*

Novant’s financial projections are not based on reasonable utilization projections as discussed in the Criterion 3 comments. Consequently the financial projections are unreliable, causing the application to not conform to Criterion 5.

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

Novant fails to demonstrate that its proposal would not result in unnecessary duplication of fixed MRI service because the utilization projections are unreliable. Therefore the 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’s application fails to conform to Criterion (18a) because the proposal does not adequately demonstrate it will promote cost effective services. The applicant’s projected utilization is not based on reasonable and adequately supported assumptions. The discussions regarding analysis of need and projected utilization found in Criterion (3) are incorporated herein by reference.

## 10A NCAC 14C .2703 PERFORMANCE STANDARDS

*(b) An applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner, except for fixed MRI scanners described in Paragraphs (c) and (d) of this Rule, shall:*

*(3) demonstrate that the average annual utilization of the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area are reasonably expected to perform the following number of weighted MRI procedures, whichever is applicable, in the third year of operation following completion of the proposed project:*

*(A) 1,716 weighted MRI procedures in MRI service areas in which the SMFP shows no fixed MRI scanners are located,*

*(B) 3,775 weighted MRI procedures in MRI service areas in which the SMFP shows one fixed MRI scanner is located,*

*(C) 4,118 weighted MRI procedures in MRI service areas in which the SMFP shows two fixed MRI scanners are located,*

*(D) 4,462 weighted MRI procedures in MRI service areas in which the SMFP shows three fixed MRI scanners are located, or*

*(E) 4,805 weighted MRI procedures in MRI service areas in which the SMFP shows four or more fixed MRI scanners are located;*

The Novant application does not conform to the performance standards applicable for the review of fixed MRI scanners. Utilization projections for the proposed Novant fixed MRI scanner are not based on reasonable assumptions and methodology. The discussions regarding analysis of need and unnecessary duplication found in Criteria (3) and (6), respectively, are incorporated herein by reference.