

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 14, 2020

Findings Date: February 14, 2020

Project Analyst: Celia C. Inman

Team Leader: Gloria C. Hale

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**COMPETITIVE REVIEW**

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Project ID #: G-11798-19

Facility: Wake Forest Baptist Imaging - Kernersville

FID #: 190280

County: Forsyth

Applicant: Wake Forest Baptist Imaging, LLC

Project: Acquire 1 fixed MRI scanner pursuant to the need determination in the 2019 SMFP

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Project ID #: G-11816-19

Facility: Novant Health Imaging Piedmont

FID #: 955506

County: Forsyth

Applicant(s): Piedmont Imaging, LLC  
Novant Health, Inc.

Project: Acquire 1 fixed MRI scanner pursuant to the need determination in the 2019 SMFP for a total of no more than 3 fixed MRI scanners upon project completion

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**REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES**

N.C. Gen. Stat. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (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.

C – Both Applications

**Need Determination**

Chapter 9 of the 2019 North Carolina State Medical Facilities Plan (SMFP), pages 148-172, includes a methodology for determining the need for additional fixed MRI scanners by service area. Application of the need methodology in the 2019 SMFP identifies a need for one additional fixed MRI scanner in the Forsyth County MRI Service Area. Two applications were submitted to the Healthcare Planning and Certificate of Need Section, each proposing to acquire one fixed MRI scanner for Forsyth County.

**Policies**

There are two policies in the 2019 SMFP that could be applicable to this review, *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, both on page 31.

*Policy GEN-3* states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

*Policy GEN-4* states:

*“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

2019 Forsyth County  
Competitive MRI Review

Page 3

*In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.*

*Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."*

**Wake Forest Baptist Imaging, LLC (WFBI)**, the applicant, proposes to acquire one fixed MRI scanner to be located at Wake Forest Baptist Imaging-Kernersville (WFBI-K), an existing non-hospital-based imaging center located at 861 Old Winston Road, Kernersville, Forsyth County. WFBI-K contracts for mobile MRI services at the existing diagnostic center.

*Need Determination.*

WFBI does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2019 SMFP for Forsyth County. Thus, the application is consistent with the need determination.

*Policy GEN-3.*

Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section B.10, page 17; Section N.2, pages 98-101; Section O.1, pages 104-106; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section B.10, page 17; Section C.11, pages 42-43; Section L, pages 88-94; Section N.2, pages 102-103; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section B.10, page 17; Section K.3, pages 83-84; Section N.2, pages 97-98; Section Q Form F.2; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. Therefore, the application is consistent with *Policy GEN-3*.

*Policy GEN-4*.

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. The applicant describes how it will assure improved energy efficiency and water conservation in Section B.11, pages 18-19, and Section K-3, pages 83-84. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with *Policy GEN-4*.

**Conclusion.**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to acquire more MRI scanners than are determined to be needed in the service area.

- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* for the following reasons:
  - The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum 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.
  - The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* by including a written plan to assure improved energy efficiency and water conservation.

**Piedmont Imaging, LLC and Novant Health, Inc.**, collectively referred to as “Novant Health”, “NH”, or “the applicant”, proposes to acquire one fixed MRI scanner to be located at Novant Health Imaging Piedmont (NHI Piedmont), an existing non-hospital-based imaging center located at 185 Kimel Park Drive, Winston-Salem, Forsyth County. NHI Piedmont owns and operates two existing fixed MRI scanners in the existing diagnostic center.

*Need Determination.*

Novant Health does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2019 SMFP for Forsyth County. Thus, the application is consistent with the need determination.

*Policy GEN-3.*

Promote Safety and Quality

The applicant describes how it believes its proposal would promote safety and quality in Section B.10, pages 16-18 and 21; Section N.2, pages 93-94; Section O.1, pages 96-97; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access

The applicant describes how it believes its proposal would promote equitable access in Section B.10, pages 18-20; Section C.11, pages 46-48; Section L, pages 86-90; Section N.2, page 95; and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value

The applicant describes how it believes its proposal would maximize health care value in Section B.10, pages 20-21; Section K, pages 82-83; and in its pro forma financial statements provided in Section Q. The information provided by the applicant is reasonable and adequately supports the determination that the applicant's proposal would maximize healthcare value.

The applicant adequately demonstrates how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. Therefore, the application is consistent with *Policy GEN-3*.

*Policy GEN-4*.

The proposed capital expenditure for this project is less than \$2 million; therefore, *Policy GEN-4* is not applicable to this application.

**Conclusion.**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant does not propose to acquire more fixed MRI scanners than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-3* for the following reasons:
  - The applicant adequately demonstrates how its projected volumes incorporate the concepts of quality, equitable access and maximum 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.
  - The discussion regarding revenues and costs found in Criterion (5) is incorporated herein by reference.

**Decision**

The applications submitted by the two applicants are conforming to the need determination in the 2019 SMFP for an additional MRI scanner in Forsyth County. Both applications are conforming to the applicable policies in the 2019 SMFP. Collectively, the applicants propose a total of two fixed MRI scanners in Forsyth County. Therefore, both applications cannot be approved even though both are fully conforming to this criterion. See the Conclusion following the Comparative Analysis for the decision.

- (2) Repealed effective July 1, 1987.
- (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.

C – Both Applications

Table 9R, page 172 of the 2019 SMFP, provides the projected need determination for one additional fixed MRI scanner in Forsyth County, based on the standard methodology used to determine need for fixed MRI scanners in the 2019 SMFP, pages 151-152.

On page 149, the 2019 SMFP defines a fixed MRI scanner as “*an MRI scanner that is not a mobile MRI scanner.*” The 2019 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” Therefore, for the purpose of this review, Forsyth County is the service area. Facilities may also serve residents of counties not included in their service area.

Table 9P, page 158 of the 2019 SMFP, provides the current total number of MRI scanners in Forsyth County, as summarized in the following table.

2019 Forsyth County  
Competitive MRI Review

**Fixed and Mobile MRI Scanners in Forsyth County**

Facility	# of Fixed MRI Magnets*	Fixed Equivalent Magnets	Total MRI Scans	Total Weighted MRI Scans
North Carolina Baptist Hospital	6	6.00	21,774	29,412
Novant Health Forsyth Medical Center	2	2.00	10,830	14,954
Novant Health Forsyth Medical Center-Clemmons	1	1.00	1,162	1,300
Novant Health Forsyth Medical Center-Kernersville	1	1.00	1,470	1,769
Novant Health Forsyth Medical Center-Novant Health Imaging Kernersville	1	1.00	1,952	2,132
Novant Health Forsyth Medical Center-Novant Health Imaging Maplewood	2	2.00	8,277	9,667
Novant Health Imaging Piedmont (Piedmont Imaging LLC)	2	2.00	10,622	11,254
Wake Forest Baptist Imaging Winston-Salem	1	1.00	6,935	7,713
Cone Health MedCenter Kernersville (ARMC)	0	0.10	483	517
Novant Health Forsyth Medical Center-Mobile MRI	0	0.35	1,660	1,833
OrthoCarolina Kernersville	0	0.12	575	586
OrthoCarolina Winston-Salem	0	0.97	4,684	4,868
Piedmont Imaging LLC (Foundation Health Mobile Imaging LLC)^	0	0.14	668	0
<b>Total Forsyth County</b>	<b>16</b>	<b>17.68</b>	<b>71,092</b>	<b>86,004</b>

Totals may not sum due to rounding

\*The inventory of fixed MRI magnets shown in the 2019 SMFP does not include a Novant Health Forsyth Medical Center magnet identified in the 2017 SMFP as a grandfathered fixed MRI magnet at Novant Health Winston-Salem Health Care, which was approved to be replaced and relocated to Novant Health Forsyth Medical Center in an Exemption dated January 5, 2017. Per page 52 of its application, Novant Health is in the process of developing space for the magnet (10<sup>th</sup> fixed unit), which is projected to be operational by the end of 2019. This fixed MRI scanner was erroneously dropped from the SMFP inventory.

^Only unweighted scans were reported; weighted scans were not reported; the SMFP shows "0" for weighted scans.

**WFBI** proposes to acquire one fixed MRI scanner to be located in the existing imaging center, WFBI-K, at 861 Old Winston Road, Kernersville.

**Patient Origin**

In Section C.2, page 25, the applicant states that WFBI began offering mobile MRI services at its Kernersville location in March 2019. The applicant provides the historical patient origin for WFBI's mobile MRI service for March 1, 2019 through July 31, 2019, as summarized below.



2019 Forsyth County  
Competitive MRI Review  
Page 9

**WFBI-Kernersville  
Mobile MRI Scanner  
Patient Origin March 2019 – July 2019**

	<b>Number of Patients</b>	<b>Percent of Total</b>
Forsyth	456	59.1%
Guilford	115	14.9%
Davidson	42	5.5%
Stokes	33	4.3%
Davie	27	3.5%
Randolph	21	2.7%
Surry	21	2.7%
Rockingham	12	1.6%
Yadkin	12	1.5%
Other*	33	4.3%
<b>Total</b>	<b>772</b>	<b>100.0%</b>

\*Other includes <1% patient origin for the remaining counties in North Carolina

Totals may not sum due to rounding

For informational purposes, that applicant also provides the patient origin for the fixed MRI scanner at WFBI-Winston-Salem (WFBI-WS) on page 27 of its application, as reported on the 2019 Registration and Inventory of Medical Equipment form.

**WFBI-Winston-Salem  
Fixed MRI Scanner  
Patient Origin October 1, 2017 – September 30, 2018**

	<b>Number of Patients</b>	<b>Percent of Total</b>
Forsyth	2,903	51.7%
Davidson	368	6.6%
Stokes	348	6.2%
Guilford	305	5.4%
Davie	299	5.3%
Surry	243	4.3%
Yadkin	191	3.4%
Randolph	97	1.7%
Wilkes	86	1.5%
Rockingham	73	1.3%
Other NC Counties*	514	9.2%
Other States	193	3.4%
<b>Total</b>	<b>5,620</b>	<b>100.0%</b>

\*Other includes <1% patient origin for the remaining counties in North Carolina

Totals may not sum due to rounding

2019 Forsyth County  
Competitive MRI Review  
Page 10

In Section C.3, page 28, the applicant provides the projected patient origin for the first three full fiscal years following completion of the project, calendar year (CY) 2021 through CY2023, as summarized below.

**WFBI-Kernersville  
Fixed MRI Scanner  
Projected Patient Origin**

	1 <sup>st</sup> Full FY CY2021		2 <sup>nd</sup> Full FY CY2022		3 <sup>rd</sup> Full FY CY2023	
	Number of Patients	Percent of Total	Number of Patients	Percent of Total	Number of Patients	Percent of Total
Forsyth	2,040	63.8%	2,477	63.7%	2,779	63.6%
Guilford	433	13.5%	527	13.6%	593	13.6%
Davidson	186	5.8%	226	5.8%	253	5.8%
Stokes	113	3.5%	138	3.5%	155	3.6%
Davie	92	2.9%	112	2.9%	126	2.9%
Randolph	71	2.2%	87	2.2%	98	2.2%
Surry	71	2.2%	87	2.2%	98	2.2%
Rockingham	42	1.3%	51	1.3%	58	1.3%
Yadkin	39	1.2%	48	1.2%	54	1.2%
Other*	110	3.4%	135	3.5%	152	3.5%
<b>Total</b>	<b>3,197</b>	<b>100.0%</b>	<b>3,888</b>	<b>100.0%</b>	<b>4,366</b>	<b>100.0%</b>

\*Other includes <1% patient origin for the remaining counties in North Carolina  
Totals may not sum due to rounding

In Section C.3, pages 28-29, the applicant provides the assumptions used to project patient origin, stating that the projected patient origin is based on historical patient origin for the MRI service at WFBI-Kernersville, adjusted to reflect the applicant’s projected shift of WFBI patients from WFBI-WS to WFBI-K. The applicant states that the patients to be shifted live in three Zip codes (27284, 27107, and 27265) which are in closer proximity to the Kernersville facility. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 29-37, the applicant explains why it believes the population projected to utilize the proposed fixed MRI service needs the service at WFBI-K. The applicant discusses the need for the fixed MRI service at WFBI-K based on the following factors:

- The 2019 SMFP need determination for one additional fixed MRI scanner (pages 29-30).
- Historical Forsyth County MRI utilization (page 30).
- High MRI use rate in Forsyth County (pages 31-32).
- Growth and aging of the Forsyth County population (pages 32-34).

- Need for additional value-based fixed MRI scanner capacity (page 34).
- Geographic need for a freestanding fixed MRI scanner in Kernersville (pages 35-37).

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- The 2019 SMFP identifies the need for one additional fixed MRI scanner in Forsyth County.
- MRI capacity in Forsyth County currently consists of 13 hospital-based fixed scanners, three freestanding (non-hospital-based) scanners, and several mobile MRI sites.
- The Forsyth County growth in utilization of its fixed and mobile MRI capacity has increased at a compound annual growth rate (CAGR) of 1.29%.
- The Forsyth County MRI use rate is significantly higher than the North Carolina MRI use rate.
- Population growth, particularly among the elderly, is occurring in Forsyth County.
- MRI charges on freestanding MRI scanners are typically significantly lower than MRI charges on hospital-based scanners.
- Winston-Salem has three freestanding fixed MRI scanners, whereas, Kernersville does not have any freestanding fixed MRI scanners.
- Depending upon traffic, it can take over 30 minutes to travel from Kernersville to Winston-Salem to reach freestanding fixed MRI services.

### Projected Utilization

In Section Q, pages 111-125, the applicant describes its methodology and assumptions for projecting WFBI MRI utilization in Winston-Salem and Kernersville and for projecting total North Carolina Baptist Hospital (NCBH) MRI utilization.

### **Methodology for Projecting WFBI MRI Procedures**

**Steps 1 and 2. Project WFBI-WS MRI procedures and convert to calendar years.** On pages 111-112, the applicant provides the historical and projected utilization of fixed MRI services at WFBI-WS, converted to calendar year, as summarized in the following two tables:

2019 Forsyth County  
Competitive MRI Review

Page 12

**WFBI-WS**  
**Historical Fixed MRI Services Utilization**

	<b>FY2014</b>	<b>FY2015</b>	<b>FY2016*</b>	<b>FY2017</b>	<b>FY2018</b>	<b>FY2019**</b>	<b>4-Yr CAGR</b>
Number of Unweighted Procedures	5,277	5,547	5,716	6,935	6,203	6,767	4.12%
Number of Weighted Procedures	6,299	6,413	6,459	7,713	6,974	7,628	
Weighting Ratio	1.19	1.16	1.13	1.11	1.12	1.13	

Totals may not foot due to rounding

\*The applicant states that the procedure numbers differ from the incorrect data shown in the 2018 SMFP

\*\*Annualized based on nine months of data, through June 30, 2019

**WFBI-WS**  
**Projected Fixed MRI Services Utilization**

	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>	<b>FY2024</b>
Number of Unweighted Procedures	6,767	7,046	7,336	7,639	7,954	8,282
Number of Weighted Procedures	7,628	7,922	8,248	8,588	8,943	9,312
<b>FY Adjusted to CY*</b>	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>	
Number of Unweighted Procedures	6,836	7,118	7,412	7,718	8,036	
Number of Weighted Procedures	7,686	8,003	8,333	8,677	9,035	

\*Conversion from FY to CY calculated as follows - Current FY x .75 + subsequent FY x .25

Totals may not foot due to rounding

**Step 3. Project WFBI-K mobile MRI procedures CY2019 and CY2020.** On pages 112-113, the applicant provides the historical CY2019 annualized utilization of the mobile MRI services at WFBI-K and projects its 2020 mobile MRI utilization to remain at the 2019 level, as summarized below.

**WFBI-K Mobile MRI Utilization**

	<b>CY2019*</b>	<b>CY2020**</b>
Number of Unweighted Procedures	1,853	1,853
Number of Weighted Procedures	2,064	2,064
Weighting Ratio	1.114	

\*CY2019 utilization is annualized based on five months data

\*\*CY2020 utilization is held constant at 2019 utilization because mobile access will remain limited to three days per week

**Step 4. WFBI market share.** On pages 113-118, the applicant projects WFBI's future market share based on the WFBI-WS 2018 fixed scanner utilization and the 2019 annualized WFBI-K mobile MRI scanner utilization, as a portion of the total Forsyth County MRI utilization. The applicant calculates the projected number of MRI procedures for Forsyth County on page 114, as summarized below.

2019 Forsyth County  
Competitive MRI Review  
Page 13

**Forsyth County  
Projected MRI Procedures**

	<b>FY2018</b>	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>
Forsyth County Population		381,379	385,208	389,018	392,815	396,602
Number of MRI Procedures	70,220	72,072	72,796	73,516	74,233	74,949

Totals may not foot due to rounding

*Assumptions:*

- 2018 Forsyth County MRI procedures, as reported in the Proposed 2020 SMFP for FY2018 (October 2017-September 2018).
- 2019-2023 MRI procedures are based on the Forsyth County MRI use rate (189.0 per 1,000 population) calculated using the average Forsyth County MRI use rate per 1,000 Forsyth County population. Use rates for FY2015-FY2017 are based on Forsyth County population estimates from the North Carolina Office of State Budget and Management (NCOSBM) as of July each year and the number of procedures as reported in the SMFP for the applicable fiscal year. Thus, in the use rate table on page 114, the applicant's population data for FY2017 is based on the July 2017 estimate and the FY2017 MRI procedures are based on the 2019 SMFP, which uses utilization data from FY2017. The 189.0 per 1,000 use rate is applied to the NCOSBM Forsyth County projected population for 2019-2023.

On page 114, the applicant demonstrates that WFBI-WS's market share of Forsyth County MRI procedures was 8.83% and 9.49% in 2018 and 2019, respectively; and that WFBI-K's market share in 2019 was 2.57%. On pages 117-118, the applicant provides the projected WFBI-K MRI market share in Forsyth County, as summarized below.

**WFBI-K Market Share and  
Projected MRI Procedures**

	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>
Number of Forsyth County MRI Procedures	72,072	72,796	73,516	74,233	74,949
WFBI-K Market Share	2.57%	2.57%	3.57%	4.32%	4.82%
Projected WFBI-K MRI Unweighted Procedures	1,853	1,853	2,625	3,207	3,613

Totals may not foot due to rounding

*Assumptions:*

- 2020 MRI procedures are held constant at the 2019 utilization. (page 113)
- The applicant projects an incremental market share of 1.0% in 2021, 0.75% in 2022, and 0.5% in 2023. (page 117)
- WFBI-K will gain market share during the initial three project years, based on its reputation for quality service, growth in number of WFBH physician practices, growth in ambulatory visits at WFBH's Kernersville outpatient clinics and letters of physician support. (pages 115-117)

**Step 5. WFBI MRI Procedure Shift.** On pages 118-120, the applicant provides assumptions and projects a shift of procedures from WFBI-WS to WFBI-K during the initial three project years, as summarized below.

**Shift From WFBI-WS to WFBI-K**

Zip Code	CY2021	CY2022	CY2023
27284	246	293	324
27107	243	289	320
27265	83	99	109
Total	572	681	753

In Section C, page 26, the applicant provides a map showing the location of the WFBI-WS and WFBI-K facilities and the proximity of the Zip codes for the patients expected to seek MRI services at WFBI-K instead of WFBI-WS.

**Step 6. Total projected WFBI-K MRI procedures.** On page 120, the applicant projects the total WFBI-K MRI procedures, as summarized below.

**WFBI-K Projected MRI Procedures**

	CY2019	CY2020	CY2021	CY2022	CY2023
Unweighted MRI Procedures (Step 4, page 118)	1,853	1,853	2,625	3,207	3,613
Shift from WFBI-WS			572	681	753
Total Unweighted Procedures	1,853	1,853	3,197	3,888	4,366
Weighting Ratio (Step 3, page 113)	1.114	1.114	1.114	1.114	1.114
Weighted Procedures	2,064	2,064	3,562	4,331	4,864

Totals may not foot due to rounding

**Step 7. Total projected WFBI-WS MRI procedures after shift.** On page 121, the applicant shows the total projected WFBI-WS MRI procedures after the shift of MRI procedures to WFBI-K, as summarized below.

**WFBI-WS Projected MRI Procedures**

	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>
Unweighted MRI Procedures (Step 2, page 112)	6,836	7,118	7,412	7,718	8,036
Shift from WFBI-WS (Step 5, page 120)			-572	-681	-753
Total Unweighted Procedures	6,836	7,118	6,840	7,037	7,283
WFBI-WS Weighting Ratio *	1.124	1.124	1.124	1.124	1.124
Weighted Procedures	7,686	8,003	7,690	7,912	8,188

Totals may not foot due to rounding

\*On page 21, the applicant states use of WFBI-WS's 2019 weighted procedure ratio of 1.124; however, WFBI's 2019 weighted ratio was 1.127, while its 2018 weighted ratio was 1.124.

**Step 8. Total combined WFBI MRI procedures.** On pages 121-122, the applicant shows the total projected WFBI MRI procedures and market share, as summarized in the two tables below.

**WFBI Total Projected MRI Procedures  
Combined WFBI-WS and WFBI-K Weighted Procedures**

	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>
Weighted WFBI-WS MRI Procedures	7,686	8,003	7,690	7,912	8,188
Weighted WFBI-K MRI Procedures	2,064	2,064	3,562	4,331	4,864
Total Weighted WFBI Procedures	9,750	10,067	11,252	12,243	13,052
Average Weighted Procedures Per Fixed MRI Scanner (2)			5,626	6,122	6,526

Totals may not foot due to rounding

On page 122, the applicant states that WFBI currently has a market share of approximately 12.06% of the 2019 Forsyth County MRI procedures and provides the following increases in projected market share based on WFBI's historical experience, an established referral base, and documented provider support for the proposed fixed scanner.

**WFBI Market Share of Forsyth County Unweighted MRI Procedures**

	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>
Forsyth County Total Procedures	72,072	72,796	73,516	74,233	74,949
WFBI-WS Procedures	6,836	7,118	6,840	7,037	7,283
WFBI-K Procedures	1,853	1,853	3,197	3,888	4,366
WFBI-WS Market Share	9.48%	9.78%	9.30%	9.48%	9.72%
WFBI-K Market Share	2.57%	2.55%	4.35%	5.24%	5.83%
Total WFBI Market Share	12.06%	12.32%	13.65%	14.72%	15.54%

Totals may not foot due to rounding

In summary, Section Q Form C, shows the following projected MRI utilization for the proposed WFBI-K fixed MRI scanner.

**WFBI-K Total Historical and Projected Fixed MRI Procedures**

	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>
Number of Fixed MRI Scanners	1	1	1	1	1
Total Unweighted MRI Procedures	1,853	1,853	3,197	3,888	4,366
Total Weighted MRI Procedures	2,064	2,064	3,562	4,331	4,864
Average Weighted Procedures Per Fixed MRI Scanner (1)	2,064	2,064	3,562	4,331	4,864

Totals may not foot due to rounding

Projected utilization for WFBI is reasonable and adequately supported for the following reasons:

- The applicant bases future utilization on historical utilization, projected forward at a reasonable annual growth rate, supported by a growing and aging population and the expectation of WFBI physician growth in the area.
- Forsyth County fiscal year MRI procedures is used as a proxy for estimating WFBI's calendar year market share of total MRI procedures.
- The expected shift of MRI procedures from WFBI-WS to WFBI-K is reasonable and supported by the relative relationship of the patients' residences, distances to Winston-Salem and Kernersville, and their referring physicians.
- Market share is reasonable based on historical experience, an established referral base, provider support, a projected shift in procedures, and the addition of a fixed MRI scanner.



**Methodology for Projecting NCBH MRI Procedures**

NCBH is part of Wake Forest Baptist Health, which is a member of WFBI. NCBH owns and operates six clinical fixed MRI scanners at the hospital. In Section Q, pages 123-125, the applicant discusses NCBH and its provision of MRI services, providing the following statistics for the last five years.

**NCBH  
Historical Fixed MRI Utilization**

	<b>FY2014</b>	<b>FY2015</b>	<b>FY2016</b>	<b>FY2017</b>	<b>FY2018</b>	<b>FY2019*</b>	<b>4-Yr CAGR 2014-2018</b>
Number of Unweighted Procedures	22,355	23,652	22,979	21,774	22,536	23,373	0.20%
Number of Weighted Procedures	29,835	32,344	31,396	29,412	30,567	31,935	
Weighting Ratio	1.33	1.37	1.37	1.35	1.36	1.37	
Average Weighted Procedures / Scanner	4,973	5,391	5,233	4,902	5,095	5,323	

Source: FY2014-FY2018 Procedures - applicable annual SMFPs

\*FY2019 Procedures - annualized based on 11 months of applicant's data, October 2018 through August 2019

Totals may not foot due to rounding

On page 124, the applicant projects future NCBH fiscal year MRI utilization and converts it to calendar year, as summarized below.

**NCBH  
Projected Fixed MRI Utilization**

	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>	<b>FY2024</b>
Number of Unweighted Procedures	23,420	23,467	23,515	23,562	23,610
Number of Weighted Procedures	31,766	31,830	31,895	31,959	32,023
Weighting Ratio	1.36	1.36	1.36	1.36	1.36
Average Weighted Procedures / Scanner	5,294	5,305	5,316	5,326	5,337
	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>	
Number of Unweighted Procedures	23,432	23,479	23,527	23,574	
Number of Weighted Procedures	31,782	31,846	31,911	31,975	
Weighting Ratio	1.36	1.36	1.36	1.36	
Average Weighted Procedures / Scanner	5,297	5,308	5,318	5,329	

Totals may not foot due to rounding

*Assumptions:*

- NCBH calculates a 0.20% CAGR from 2014 to 2018 for MRI procedures and applies the 0.20% CAGR to project future MRI procedures.
- NCBH applies its historical weighting factor of 1.36 and applies that factor for future MRI procedures.

- To convert NCBH FY utilization to CY utilization, WFBI multiplies 0.75 x the prior federal fiscal year volume and added 0.25 times the following federal fiscal year's volume.

Projected utilization for NCBH is reasonable and adequately supported for the following reasons:

- The applicant bases future fiscal year MRI utilization on historical utilization, projected forward at the four-year CAGR of 0.20%.
- The applicant converts the fiscal year utilization to calendar year utilization, using the appropriate percentage of the applicable fiscal years.
- The applicant states that NCBH service delivery will not be affected by the proposed WFBI-K fixed MRI scanner, as NCBH patients will continue to be served by the hospital's existing scanners.
- The applicant adequately demonstrates that its existing, approved, and proposed fixed MRI scanners are reasonably expected to perform more than 4,805 weighted MRI procedures in Forsyth County in the third year of operation following the completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3).

### Access

In Section C.11, pages 42-43, the applicant states:

*“WFBI is fully committed to the health and well-being of all patients. WFBI has historically provided care and services to medically underserved populations. . . .*

*Further, WFBI does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay, or any other factor that would classify a patient as underserved.”*

The applicant provides its non-discrimination and billing policies in Exhibit C.11.

In Section L.1, page 90, the applicant provides WFBI-K's payor mix for CY2019 for the facility and for the mobile MRI service (beginning in March 2019), as summarized below.

**WFBI-K  
CY2019 Payor Mix**

<b>Payor Source</b>	<b>Entire Facility</b>	<b>Mobile MRI Service</b>
Self-Pay/Charity Care	0.83%	0.51%
Medicare*	6.51%	11.44%
Medicaid*	4.94%	6.65%
Insurance*	87.27%	79.79%
Other (Workers Comp)	0.45%	1.61%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

\*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

**Novant Health** proposes to acquire one fixed MRI scanner, for a total of three fixed MRI scanners, to be located in the existing imaging center, NHI Piedmont, at 185 Kimel Park Drive, Winston-Salem.

### **Patient Origin**

In Section C.2, page 28, the applicant provides its current patient origin for MRI services at NHI Piedmont, summarized as follows:

**NHI Piedmont  
MRI Scanner Patient Origin  
July 1, 2018-June 30, 2019**

	<b>Number of Patients</b>	<b>Percent of Total</b>
Forsyth	5,305	45.80%
Davidson	1,085	9.37%
Surry	1,054	9.10%
Stokes	945	8.15%
Yadkin	781	6.74%
Davie	717	6.19%
Wilkes	378	3.26%
Guilford	369	3.19%
Iredell	95	0.82%
Rowan	83	0.72%
Other NC Counties	487	4.20%
Other States	285	2.46%
<b>Total</b>	<b>11,584</b>	<b>100.00%</b>

Other NC counties includes the 40 counties listed on page 28

Other States includes 14 states as listed on page 28

Totals may not sum due to rounding

In Section C.3, page 29, the applicant provides the projected patient origin for the first three full fiscal years following completion of the project.

**NHI Piedmont  
Fixed MRI Scanner  
Projected Patient Origin**

	1 <sup>st</sup> Full FY July 1, 2021-June 30, 2022		2 <sup>nd</sup> Full FY July 1, 2022-June 30, 2023		3 <sup>rd</sup> Full FY July 1, 2023-June 30, 2024	
	Number of Patients	Percent of Total	Number of Patients	Percent of Total	Number of Patients	Percent of Total
Forsyth	5,782	45.80%	6,009	45.80%	6,245	45.80%
Davidson	1,183	9.37%	1,229	9.37%	1,278	9.37%
Surry	1,149	9.10%	1,194	9.10%	1,241	9.10%
Stokes	1,029	8.15%	1,069	8.15%	1,111	8.15%
Yadkin	851	6.74%	884	6.74%	919	6.74%
Davie	781	6.19%	812	6.19%	844	6.19%
Wilkes	412	3.26%	428	3.26%	445	3.26%
Guilford	403	3.19%	419	3.19%	435	3.19%
Iredell	104	0.82%	108	0.82%	112	0.82%
Rowan	91	0.72%	94	0.72%	98	0.72%
Other NC Counties	529	4.20%	551	4.20%	573	4.20%
Other States	310	2.46%	323	2.46%	335	2.46%
<b>Total</b>	<b>12,524 [12,624]*</b>	<b>100.00%</b>	<b>13,120</b>	<b>100.00%</b>	<b>13,636</b>	<b>100.00%</b>

\*Based on the fact that the percentages for the first FY are the same as those calculated by the Project Analyst using the correct total of 12,624 patients, the applicant's entry of 12,524 was a typographical error.  
Totals may not sum due to rounding

In Section C.3, page 30, the applicant provides the assumptions and methodology used to project its patient origin, stating that it expects projected patient origin to remain consistent with historical patient origin. Thus, Other NC Counties and Other States would be consistent with those provided for the historical patient origin on page 28. The applicant's assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 31-42, the applicant explains why it believes the population projected to utilize the proposed MRI scanner needs the additional fixed MRI scanner at NHI Piedmont, providing the following factors:

- The 2019 SMFP need determination for one additional fixed MRI scanner (page 31).
- Historical MRI utilization at Novant Health sites (pages 31-32).
- Growth in the Novant Health medical staff (pages 32-33).
- Referring physician growth at NHI Piedmont (pages 33-37).
- Migration towards outpatient settings to lower costs (page 37).
- High demand for MRI services at NHI Piedmont (page 38).
- Challenges facing NHI Piedmont (pages 38-39).

- Community outreach (pages 39-40).
- Population growth and aging in NHI Piedmont's service area (pages 40-41).

The information discussed in the pages referenced above is reasonable and adequately supported for the following reasons:

- The 2019 SMFP identifies the need for one additional fixed MRI scanner in Forsyth County.
- MRI utilization at the Novant Health MRI acute care and outpatient imaging sites has experienced overall growth from FY2015 to FY2019.
- Novant Health's medical staff has experienced growth in the number of physicians, the number of specialty providers, and the number of physician assistants and nurse practitioners.
- NHI Piedmont has seen its number of referring physicians rise each year and expects that its numbers will continue to grow in the foreseeable future.
- The applicant provides utilization figures for NHI Piedmont showing that it performs more than 11,000 unweighted scans annually.
- The applicant states that the need for additional MRI capacity is crucial and mobile capacity is not a viable solution because of limited access, challenging parking, and the annual expense.
- The applicant states that NHI Piedmont provided over \$483,000 in uncompensated care for its imaging patients last year and that it has strong working relationships with other local charitable organizations.
- Forsyth County population is growing and aging, causing NHI Piedmont to anticipate an ongoing increase in MRI utilization.

### Projected Utilization

In Section Q – Projected Utilization and Assumptions, pages 1-24, the applicant describes its methodology and assumptions for projecting NHI Piedmont MRI utilization and for projecting MRI utilization at the other Novant Health fixed MRI sites in Forsyth County.

### **Methodology for Projecting NHI Piedmont MRI Procedures**

**Step 1. Document historical performance.** In Section Q, pages 2-4 of 24, the applicant provides the historical utilization of the Novant Health system fixed MRI scanners in Forsyth County, providing an average annual growth rate (AAGR), as summarized below.

**Novant Health Fixed MRI Sites  
Historical Fixed MRI Services Utilization**

	FY2015	FY2016	FY2017	FY2018	FY2019	AAGR
Acute Care Sites	11,256	13,080	13,378	13,579	14,591	
Percent Change		16.20%	2.28%	1.50%	7.45%	6.88%
NH Imaging- Outpatient Sites	20,487	20,578	22,017	21,508	22,394	
Percent Change		0.44%	6.99%	-2.31%	4.12%	2.31%
Total All Sites	31,743	33,658	35,395	35,087	36,985	
Percent Change		6.03%	5.16%	-0.87%	5.41%	3.93%

Totals may not sum due to rounding

As the table above shows, the overall average annual growth for Novant Health’s MRI volume at all fixed sites in Forsyth County was 3.93%, which includes the acute care sites with the higher AAGR of 6.88%. Outpatient imaging sites grew at an AAGR of only 2.31%.

**Step 2. Establish project year start date.** In Section Q, page 4 of 24, the applicant determines that the project will begin on July 1, 2021. The first full year of operation following project completion will be July 1, 2021-June 30, 2022.

**Step 3. Determine appropriate growth rates for projected utilization.** In Section Q, pages 4-7 of 24, the applicant discusses utilization. The applicant provides NHI Piedmont’s historical utilization, as summarized below.

**NHI Piedmont  
Unweighted MRI Volume**

	FY2015	FY2016	FY2017	FY2018	FY2019
NHI Piedmont MRI Volume	10,985	11,220	11,501	11,314	11,584
Percent Change		2.14%	2.50%	-1.63%	2.40%

On page 6 of 24, the applicant provides the projected utilization of fixed MRI services at NHI Piedmont, as summarized below.

**NHI Piedmont  
Unweighted MRI Volume**

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Unweighted MRI Volume	11,584	11,862	12,147	12,624	13,120	13,636
Percent Change	2.40%	2.40%	2.40%	3.93%	3.93%	3.93%

*Assumptions:*

- The applicant uses 2.40% to project MRI volume during the interim periods.
- The applicant uses 3.93% to project MRI volume in the first three project years.

In Section Q, page 4 of 24, the applicant states:

*“In order to be conservative, NHI piedmont utilized a growth rate of 2.40% to project unweighted MRI volume during the interim period.”*

The growth rate of 2.40% is a one-year growth rate for FY2019, following a year of decreased volume in FY2018, and is one component of a four-year compound annual growth rate (CAGR) of only 1.34%. A growth rate of 2.4% is not more conservative than the historical CAGR of 1.34%; however, based on the volume provided above for the two scanners consistently being above the required performance standard of 4,805 weighted MRI scans per fixed MRI scanner and its extended operating hours, there could be lack of capacity and some pent-up demand. In addition, the applicant states that NHI Piedmont will experience ongoing demand based on the growth of the referring physician base, the availability of new 3T technology, population growth and aging, and the shift of patients from acute care settings to outpatient settings. Therefore, though the 2.40% growth rate is not conservative, the Agency does not find it to be unreasonable.

In Section Q, page 6 of 24, the applicant states that it will use the Novant Health total system’s overall growth rate of 3.93% to project growth at NHI Piedmont in the first three full operating years of the project. The applicant states:

*“This percentage is reasonable considering NHI Piedmont’s historical growth with the scanners operating at maximum capacity, the ongoing growth in the number of referring physicians, the projected population growth, and the overwhelming physician support of the proposed project.”*

However, at no time in the past has NHI Piedmont’s growth rate been over 2.50% and the average annual growth rate for all Novant Health’s outpatient MRI sites has averaged only 2.31% for the last four years as shown in the table in Step 1 above and in the applicant’s table on page 2 of 24. Thus, the growth rate of 3.93% for the first three project years may not be reasonable.

The Agency calculated the projected NHI Piedmont unweighted MRI volume using 2.40%, which is equivalent to the growth rate for FY2019, for the first three project years.



**NHI Piedmont**  
**Unweighted MRI Volume as Calculated by The Agency using 2.40%**

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Unweighted MRI Volume	11,584	11,862	12,147	12,439	12,927	13,435
Percent Change	2.40%	2.40%	2.40%	2.40%	2.40%	2.40%

As can be seen in the following comparison of the applicant’s table and the Agency’s table, the projected FY2024 volume is reduced by 201 unweighted procedures using 2.40% for the growth rate.

**NHI Piedmont**  
**Unweighted MRI Volume Difference**

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Unweighted MRI Volume per Applicant	11,584	11,862	12,147	12,624	13,120	13,636
Unweighted MRI Volume per Agency	11,584	11,862	12,147	12,439	12,927	13,435
Difference in the Total Unweighted MRI Volume	0	0	0	185	193	201

As the applicant’s methodology proceeds, the Agency will determine whether or not using the growth rate of 3.93% during the first three operating years of the project made a significant difference in the projected MRI volume, thus making its projections potentially unreasonable.

**Step 4. Determine weighted MRI volume.** In Section Q, pages 7-8 of 24, the applicant provides the historical contrast percentages, as summarized below.

**NHI Piedmont Historical Contrast Percentages**

	FY2017	FY2018	FY2019
Scans with Contrast	2,767	2,741	2,566
Scans without Contrast	8,734	8,573	9,018
Total Scans	11,501	11,314	11,584
Percent Contrast	24.1%	24.2%	22.2%
Three Year Average Contrast Percentage			23.5%

Source: NHI Piedmont internal data

The applicant provides NHI Piedmont’s projected MRI weighted volume in Section Q, pages 7-8 of 24, as summarized below.

2019 Forsyth County  
Competitive MRI Review  
Page 26

**NHI Piedmont  
Weighted MRI Volume**

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Unweighted MRI Volume	11,584	11,862	12,147	12,624	13,120	13,636
Without Contrast 77.8%	9,012	9,229	9,450	9,821	10,207	10,609
With Contrast 22.2%	2,572	2,633	2,697	2,803	2,913	3,027
With Contrast Weighted at 1.4	3,601	3,686	3,776	3,924	4,078	4,238
<b>Total Weighted MRI Volume*</b>	<b>12,613</b>	<b>12,915</b>	<b>13,226</b>	<b>13,745</b>	<b>14,285</b>	<b>14,847</b>

\*Total of scans without contrast and weighted scans with contrast, weighted at 1.4 per SMFP MRI methodology

As the applicant's calculations in the table above show, the applicant projects 14,847 weighted MRI scans in FY2024. This is 4,949 ( $14,847 / 3 = 4,949$ ) scans per scanner, which is more than the performance standard requirement of 4,805 scans per scanner.

*Assumptions:*

- The applicant uses the FY2019 procedure contrast percentage of 22.2% for projections in order to be conservative. The applicant states its belief that the availability of a full-time 3T MRI scanner will provide the facility with additional capacity to complete more complex scans in a more efficient manner; therefore, it believes the contrast percentage will increase.
- The applicant applies the additional 0.4 contrast weight to the 22.2% of the scans that the applicant projects will be with contrast.

The following table shows the projected NHI Piedmont weighted MRI volume using a 2.40% growth rate for the first three project years, as calculated by the Agency.

**NHI Piedmont  
Weighted MRI Volume as Calculated by The Agency**

	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024
Unweighted MRI Volume	11,584	11,862	12,147	12,439	12,927	13,435
Without Contrast 77.8%	9,012	9,229	9,450	9,678	10,057	10,452
With Contrast 22.2%	2,572	2,633	2,697	2,761	2,870	2,983
With Contrast Weighted at 1.4	3,601	3,686	3,776	3,866	4,018	4,176
<b>Total Weighted MRI Volume*</b>	<b>12,613</b>	<b>12,915</b>	<b>13,226</b>	<b>13,544</b>	<b>14,075</b>	<b>14,628</b>

\*Total of scans without contrast and weighted scans with contrast, weighted at 1.4 per SMFP MRI methodology

2019 Forsyth County  
Competitive MRI Review  
Page 27

The Agency’s calculations in the table above show 14,628 projected weighted MRI scans in FY2024, only 201 procedures less than the applicant projected in the previous table. This is 4,876 (14,628 / 3 = 4,876) scans per scanner, which is more than the performance standard requirement of 4,805 scans per scanner and only 73 scans per scanner less than projected by the applicant. Therefore, use of the 3.93% growth rate did not result in a significant difference from the use of the 2.40% historical growth rate, as both rates projected utilization above the required performance standard. Thus, the Agency does not find the applicant’s projections to be unreasonable.

**Step 4. Determine MRI volume for other Novant Health fixed MRI sites.** In Section Q, pages 8-23, the applicant projects the MRI volume for Novant Health Forsyth Medical Center (NHFMC), pages 9-10, Novant Health Clemmons Medical Center (NHCMC), pages 11-15, Novant Health Kernersville Medical Center (NHKMC), pages 16-18, Novant Health Imaging-Kernersville (NHIK), pages 19-20, and Novant Health Imaging-Maplewood (NHIM), pages 21-23. On page 24 of 24, the applicant provides a table of the MRI projections for FY2024 for the five sites listed above. The following table summarizes the applicant’s table with the addition of the applicant’s previous projections for NHI Piedmont, showing the system’s projected MRI utilization in Forsyth County for the third year of operation following project completion.

**Projected MRI Procedures – All Novant Health Fixed Sites  
Third Full Operating Year (FY2024)**

	NHFMC	NHCMC	NHKMC	NHIK	NHIM	NHI Piedmont	Totals
Number of Fixed MRIs	3	1	1	1	2	3	11
Inpatient Scans	8,481	72	302				
Outpatient Scans	5,630	2,334	1,537				
With contrast	4,713	570	579	785	4,044	3,027	
Without contrast	9,398	1,836	1,260	1,903	5,723	10,609	
Unweighted Total	14,111	2,406	1,839	2,688	9,767	13,636	
Inpatient Weight (0.4)	3,392	29	121				
With Contrast Weight (0.4)	1,885	228	232	314	1,618	1,211	
Weighted Total	19,389	2,663	2,191	3,002	11,385	14,847	53,477
Weighted Scans per MRI Scanner	6,463	2,663	2,191	3,002	5,692	4,949	
NH Total SA MRI Weighted Scans	53,477						
NH Total SA Fixed Scanners	11						
Average Weighted Scans/Scanner	4,862						

Totals may not sum due to rounding

*Assumptions:*

- NHFMC - use historical average growth rate of 3.85%; maintain current percentages of inpatient/outpatient and contrast/no contrast for projections; use the 2019 SMFP weighting factors for inpatient and contrast MRI scans

- NHCMC – use historical FY2019 growth rate reduced by 4.3% each year through the interim years to 7.5% growth rate for the project years (NHCMC’s average historical growth rate was 34.5%); maintain current percentages of inpatient/outpatient and contrast/no contrast for projections; use the 2019 SMFP weighting factors for inpatient and contrast MRI scans
- NHKMC - use historical average growth rate of 5.37%; maintain current percentages of inpatient/outpatient and contrast/no contrast for projections; use the 2019 SMFP weighting factors for inpatient and contrast MRI scans
- NHIK – use one half its historical average growth rate of 7.2%, or 3.6%; maintain current percentages of contrast/no contrast for projections; use the 2019 SMFP weighting factor for contrast MRI scans
- NHIM - use historical average growth rate of 2.68%; maintain current percentages of contrast/no contrast for projections; use the 2019 SMFP weighting factor for contrast MRI scans

Projected utilization is reasonable and adequately supported for the following reasons:

- The applicant adequately demonstrates that its existing fixed MRI scanners in Forsyth County performed above the average of 3,328 weighted MRI procedures in the most recent 12-month period for which it had data, as required in 10A NCAC 14C .2703(b)(1).
- The applicant bases future MRI volume on historical volumes at each facility, projected forward at a reasonable growth rate based on the individual facility’s experience.
- The applicant applies each facility’s current percentages of inpatient/outpatient and contrast/no contrast for projections.
- The applicant uses the 2019 SMFP weighting factors for inpatient and contrast MRI scans.
- The applicant adequately demonstrates that its existing, approved, and proposed fixed MRI scanners are reasonably expected to perform more than 4,805 weighted MRI procedures in Forsyth County in the third year of operation following the completion of the proposed project, as required in 10A NCAC 14C .2703(b)(3).

### Access

In Section C.11, pages 46-48, the applicant states:

*“NHI Piedmont will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay, including the medically indigent, the uninsured, and the under insured.”*

The applicant provides Novant Health’s non-discrimination and billing policies in Exhibit B-10.

In Section L.1, page 87, the applicant provides NHI Piedmont's payor mix for FY2019 (July 1, 2018 – June 30, 2019), for the facility and for the MRI service, as summarized below.

**NHI Piedmont  
FY2019 Payor Mix**

<b>Payor Source</b>	<b>Entire Facility</b>	<b>MRI Service</b>
Self-Pay	3.75%	3.63%
Charity Care	0.38%	0.44%
Medicare*	37.95%	35.29%
Medicaid*	3.95%	5.02%
Insurance*	49.50%	49.21%
Workers Compensation	3.87%	5.79%
TRICARE	0.60%	0.62%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

\*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on the review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently

served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA – Both Applications

Neither applicant proposes to reduce or eliminate a service, nor relocate a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

C – Both Applications

**WFBI** proposes to acquire one fixed MRI scanner to be located in the existing imaging center, WFBI-K, at 861 Old Winston Road, Kernersville.

In Section E.2, pages 60-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- 1) Maintain the Status Quo – the applicant determined that this was not an effective alternative because the 2019 SMFP identifies the need for an additional fixed MRI in Forsyth County. The applicant states that operating the mobile MRI is expensive, results in equipment downtime, is relatively inefficient, necessitates patients going outside the building to the mobile unit, has limited days on site, and does not provide adequate capacity. Therefore, the applicant determines that maintaining the status quo is not an effective alternative.
- 2) Develop the Freestanding MRI in Another Location – the applicant states that this alternative is not the most effective or least costly alternative because of several limitations: Forsyth County needs greater geographic diversification of its healthcare services, which have largely been in Winston-Salem; Kernersville is central to many medical offices; and the WFBI-K diagnostic center is well established and provides all the needed ancillary and support services for a fixed MRI scanner.
- 3) Develop a Hospital-Based MRI Scanner – the applicant states that hospital-based MRI services are essential to the good health of a community. However, as a member of WFBI, WFBH supports the development of the proposed fixed MRI scanner at WFBI-K in order to address the greater need for additional freestanding MRI capacity in the Kernersville area of Forsyth County and to improve geographic

access to lower cost MRI services. Thus, the applicant determines that developing a hospital-based MRI scanner is a less effective alternative.

- 4) Acquire a 1.5T MRI Scanner – the applicant states that it believes that the higher resolution of the 3T scanner will produce more detailed images, reduce distorted images, and produce more accurate diagnoses and shorter exam times. The applicant further states that the price of a 3T scanner has decreased, making it more cost efficient. Therefore, the applicant determines that acquiring a 1.5T MRI scanner is a less effective alternative.

On pages 62-63, the applicant states that the project, as proposed, is a more effective alternative because developing a fixed 3T MRI scanner at WFBI-K will redirect MR patients to the new geographically appealing Kernersville diagnostic center location. WFBI will be able to decompress the highly utilized WFBI-WS MRI service while simultaneously providing convenient, high quality and cost-effective services in a convenient location that is easily accessible to Business 40/US Highway 421, Interstate 40, and NC 66.

The applicant adequately demonstrates that the alternative proposed in this application is the more effective alternative to meet the applicant's identified need for the following reasons:

- Maintaining the status quo is not an effective option because the existing mobile MRI is expensive, experiences equipment downtime, is relatively inefficient, necessitates patients going outside the building to the mobile unit, has limited days on site, and does not provide adequate capacity.
- Developing the MRI elsewhere would not provide the needed access to MRI services at the diagnostic center in Kernersville.
- Developing the MRI as hospital-based would not improve geographic access to lower cost MRI services in a freestanding setting.
- Developing a 1.5T scanner would provide less efficient MRI services than a 3.0T scanner.

## **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Novant Health** proposes to acquire one fixed MRI scanner to be located in the existing imaging center, NHI Piedmont, at 185 Kimel Park Drive, Winston-Salem.

In Section E.2, pages 63-65, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in its application to meet the need. The alternatives considered were:

- 1) Use Mobile MRI Service – the applicant states that this alternative is not an effective alternative because of several limitations: mobile service is not conducive to patients using additional medical equipment, claustrophobic or obese patients; inclement weather is a problem; and ongoing mobile MRI services would be more costly than the proposed fixed MRI.
- 2) Refer patients to Other Facilities – the applicant states that it would not be feasible to refer patients to either Kernersville or Clemmons for imaging services, considering the high volumes of MRI procedures on the Novant Health scanners in Winston-Salem and its referring physician preferences. This alternative does not address the ongoing demand for additional fixed MRI capacity at NHI Piedmont and does not meet the needs of referring physicians and their patients to receive MRI services in the Winston-Salem area. Therefore, this is not an effective alternative.

On pages 64-65, the applicant states that the project as proposed is a more effective alternative because developing the 3T fixed MRI scanner at NHI Piedmont would result in expanded MRI capacity, provide enhanced imaging capabilities, offer imaging services to medically indigent or underinsured, exceed the expectations of the referring physicians for excellence in imaging and patient care, reduce unnecessary operating expenses related to the mobile MRI services, and provide accessible MRI services for all patients, including obese, claustrophobic, and those with medical devices like pain pumps.

The applicant adequately demonstrates that the alternative proposed in this application is the more effective alternative to meet the applicant's identified need for the additional scanner for the following reasons:

- Mobile MRI service is not as patient friendly or cost effective.
- Referring patients to Kernersville or Clemmons from Winston-Salem does not address ongoing demand at NHI Piedmont and referring physicians in the Winston-Salem area.



**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

C – Both Applications

**WFBI** proposes to acquire one fixed MRI scanner to be located in the existing imaging center, WFBI-K, in leased space at 861 Old Winston Road, Kernersville.

**Capital and Working Capital Costs**

In Section Q Form F.1a Capital Costs, the applicant projects the total capital cost of the project as shown in the table below:

**WFBI-K**  
**Fixed MRI Scanner Capital Cost**

Construction/Renovation Contract	\$600,000
Architect and Engineering Fees	\$57,900
Medical Equipment	\$1,665,779
Furniture	\$5,000
Consultant Fees	\$52,000
Financing and Interest Costs	\$32,500
Other*	\$35,000
<b>Total Capital Cost</b>	<b>\$2,448,179</b>

\*Other includes information technology and contingency costs

In Section F.3, pages 66-67, the applicant projects there will be no start-up or initial operating expenses for the project because it currently staffs and operates the facility's existing mobile MRI service.

**Availability of Funds**

In Section F.2, page 65, the applicant states that the capital cost will be funded with loans and accumulated reserves of WFBI, as summarized below.

**Sources of Capital Cost Financing**

GE Healthcare Finance Agreement	\$2,265,779
Accumulated Reserves or OE	\$182,400
<b>Total Financing</b>	<b>\$2,448,179</b>

The applicant provides a financing agreement with GE Healthcare in the amount of \$2,265,779 for the proposed scanner in Exhibit F.2. Exhibit F.2 contains a letter dated October 15, 2019 from WFBI, LLC's Chief Manager documenting the commitment and availability of accumulated reserves up to \$250,000 for capital costs for the proposed project. Exhibit F.2 also contains WFBI's Balance Sheet, as of September 30, 2019, showing cash of \$778,349, total assets of \$5,501,483, and net equity of \$1,941,231.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project in Section Q Form F.2. The applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

**Projected Revenue and Expenses for WFBI MRI Services**

	CY2021	CY2022	CY2023
Total MRI Procedures	3,197	3,888	4,366
Total Gross Revenue (Charges)	\$5,953,176	\$7,239,958	\$8,130,100
Deductions from Gross Revenue*	\$4,162,976	\$5,062,805	\$5,685,270
Total Net Revenue	\$1,790,200	\$2,177,152	\$2,444,830
Average Net Revenue/Procedure	\$560	\$560	\$560
Total Operating Expenses	\$1,296,997	\$1,499,354	\$1,602,493
Operating Expense/Procedure	\$406	\$386	\$367
<b>Net Income (Loss)</b>	<b>\$493,203</b>	<b>\$677,799</b>	<b>\$842,337</b>

Totals may not sum due to rounding

\*Includes Charity Care and Bad Debt as follows:

	CY2021	CY2022	CY2023
Charity Care	\$59,532	\$72,400	\$81,301
Bad Debt	\$133,946	\$162,899	\$182,927
Self-pay Write Off	\$24,839	\$30,207	\$33,921

As shown in the table above, the applicant projects a positive net income in all three initial operating years following completion of the proposed project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

**Novant Health** proposes to acquire one fixed MRI scanner, for a total of three fixed MRI scanners, to be located in the existing imaging center, NHI Piedmont, at 185 Kimel Park Drive, Winston-Salem.

**Capital and Working Capital Costs**

In Section Q Form F.1a, page 106, the applicant projects the capital cost of the project as summarized in the table below:

**NHI Piedmont  
Fixed MRI Scanner Capital Cost**

	<b>NHI Piedmont</b>	<b>Novant Health</b>	<b>Total</b>
Construction Contract	\$0	\$375,000	\$375,000
Architect/Engineering Fees	\$0	\$35,000	\$35,000
Medical Equipment	\$0	\$1,545,650	\$1,545,650
Non-Medical Equipment and Furniture	\$0	\$2,500	\$2,500
Consultant Fees	\$0	\$30,000	\$30,000
Other- Contingency	\$0	\$10,000	\$10,000
<b>Total Capital Cost</b>	<b>\$0</b>	<b>\$1,998,150</b>	<b>\$1,998,150</b>

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 68, the applicant projects that no start-up expenses or initial operating expenses for the project because the proposed project is not a new service.

**Availability of Funds**

In Section F.2, page 66, the applicant states that the project will be funded with owner's equity/accumulated reserves of Novant Health, Inc. Exhibit F-2.1 contains a letter, dated October 8, 2019, from the Senior VP Operational Finance for Novant Health, Inc. stating that Novant Health will fund the capital costs of the proposed project from accumulated reserves. In addition, the letter states the availability of \$228,653,000 in cash and cash equivalents, and \$3,072,165,000 in total assets available for capital expenditures. Exhibit F.2 contains the audited financial statements for Novant Health, Inc. and Affiliates, as of December 31, 2018, which shows \$4,038,900,000 in net assets (total assets less total liabilities). The applicant adequately demonstrates that sufficient funds will be available for the capital needs of the project.

**Financial Feasibility**

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F-2, page 108, the applicant projects that MRI revenues will exceed operating expenses in each of the first three full fiscal years of the project, as summarized in the table below:

**Projected Revenue and Expenses for NHI Piedmont MRI Services**

	<b>FY2022</b>	<b>FY2023</b>	<b>FY2024</b>
Total MRI Procedures	12,624	13,120	13,636
Total Gross Revenue (Charges)	\$26,315,912	\$27,349,871	\$28,425,521
Deductions from Gross Revenue*	\$20,386,804	\$21,187,806	\$22,021,107
Total Net Revenue	\$5,929,108	\$6,162,064	\$6,404,414
Average Net Revenue/Procedure	\$470	\$470	\$470
Total Operating Expenses	\$2,701,602	\$2,855,611	\$2,926,044
Operating Expense/Procedure	\$214	\$218	\$215
<b>Net Income (Loss)</b>	<b>\$3,227,506</b>	<b>\$3,306,453</b>	<b>\$3,478,370</b>

Totals may not sum due to rounding

\*Includes Charity Care and Bad Debt as follows:

	<b>FY2022</b>	<b>FY2023</b>	<b>FY2024</b>
Charity Care	\$115,790	\$120,339	\$125,072
Bad Debt	\$411,454	\$427,621	\$444,439

As shown in the table above, the applicant projects a positive net income in all three initial operating years following completion of the proposed project. Furthermore, the applicant would have a positive net income in each year with a projected utilization calculated using the lower growth rate of 2.40% as calculated by the Agency in the discussion of projected utilization in Criterion (3). The applicant also projects a positive net income in each project year for the entire facility on page 107. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

#### C – Both Applicants

Table 9R, page 172 of the 2019 SMFP, provides the projected need determination for one additional fixed MRI scanner in Forsyth County, based on the standard methodology used to determine need for fixed MRI scanners in the 2019 SMFP, pages 151-152.

On page 149, the 2019 SMFP defines a fixed MRI scanner as “*an MRI scanner that is not a mobile MRI scanner.*” The 2019 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.*” Therefore, for the purpose of this review, Forsyth County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

Table 9P, page 158 of the 2019 SMFP, provides the current total number of MRI scanners in Forsyth County, as summarized in the following table.

2019 Forsyth County  
Competitive MRI Review  
Page 39

**Fixed and Mobile MRI Scanners in Forsyth County**

Facility	# of Fixed MRI Magnets*	Fixed Equivalent Magnets	Total MRI Scans	Total Weighted MRI Scans
North Carolina Baptist Hospital	6	6.00	21,774	29,412
Novant Health Forsyth Medical Center	2	2.00	10,830	14,954
Novant Health Forsyth Medical Center-Clemmons	1	1.00	1,162	1,300
Novant Health Forsyth Medical Center-Kernersville	1	1.00	1,470	1,769
Novant Health Forsyth Medical Center-Novant Health Imaging Kernersville	1	1.00	1,952	2,132
Novant Health Forsyth Medical Center-Novant Health Imaging Maplewood	2	2.00	8,277	9,667
Novant Health Imaging Piedmont (Piedmont Imaging LLC)	2	2.00	10,622	11,254
Wake Forest Baptist Imaging Winston-Salem	1	1.00	6,935	7,713
Cone Health MedCenter Kernersville (ARMC)	0	0.10	483	517
Novant Health Forsyth Medical Center-Mobile MRI	0	0.35	1,660	1,833
OrthoCarolina Kernersville	0	0.12	575	586
OrthoCarolina Winston-Salem	0	0.97	4,684	4,868
Piedmont Imaging LLC (Foundation Health Mobile Imaging LLC)^	0	0.14	668	0
<b>Total Forsyth County</b>	<b>16</b>	<b>17.68</b>	<b>71,092</b>	<b>86,004</b>

Totals may not sum due to rounding

\*The inventory of fixed MRI magnets shown in the 2019 SMFP does not include a Novant Health Forsyth Medical Center magnet identified in the 2017 SMFP as a grandfathered fixed MRI magnet at Novant Health Winston-Salem Health Care, which was approved to be replaced and relocated to Novant Health Forsyth Medical Center in an Exemption dated January 5, 2017. Per page 52 of its application, Novant Health is in the process of developing space for the magnet (10<sup>th</sup> fixed unit), which is projected to be operational by the end of 2019. This fixed MRI scanner was erroneously dropped from the SMFP inventory.

^Only unweighted scans were reported; weighted scans were not reported; the SMFP shows "0" for weighted scans.

**WFBI** proposes to acquire one fixed MRI scanner to be located in the existing imaging center, WFBI-K, at 861 Old Winston Road, Kernersville.

The applicant does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2019 SMFP for Forsyth County. In Section G, pages 72-74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved MRI services in Forsyth County. The applicant states:

*“As evidenced by the need determination in the 2019 SMFP, the State considers the existing fixed MRI scanners inadequate to meet the need in the MRI service*

*area, and has determined a need for one additional fixed MRI scanner in Forsyth County.*

*WFBI's MRI service is needed by referring providers to aid them in diagnosing and treating their patients' illnesses or conditions."*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for one additional fixed MRI scanner in Forsyth County and the applicant proposes to develop one fixed MRI scanner in Forsyth County.
- The applicant adequately demonstrates that the proposed MRI is needed in addition to the existing or approved MRIs in Forsyth County.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Novant Health** proposes to acquire one fixed MRI scanner, for a total of three fixed MRI scanners, to be located in the existing imaging center, NHI Piedmont, at 185 Kimel Park Drive, Winston-Salem.

The applicant does not propose to acquire and operate more fixed MRI scanners than are determined to be needed in the 2019 SMFP for Forsyth County. In Section G.3, page 73, the applicant explains why it believes its proposal would not result in an unnecessary duplication of existing or approved services in the service area. The applicant states:

*"NHI Piedmont proposes to acquire a third fixed MRI scanner at its outpatient center to address the high demand at the facility. The existing two MRI units performed 12,610 weighted procedures in the last year which indicates a need for 2.6 MRI scanners ( $12,610 / 4,805 = 2.62$ ). Existing providers, even those within the Novant Health system, are unable to meet the demand for additional fixed MRI capacity at NHI Piedmont. . . . The ability to improve accessibility at NHPMC [NHI Piedmont] for its patients will not result in an unnecessary duplication of MRI services in the service area."*



The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- There is a need determination in the 2019 SMFP for one additional fixed MRI scanner in Forsyth County and the applicant proposes to develop one fixed MRI scanner in Forsyth County.
- The applicant adequately demonstrates that the proposed MRI is needed in addition to the existing or approved MRIs in Forsyth County.

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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.

### C – Both Applications

**WFBI.** In Section Q Form H, the applicant provides the current and projected full-time equivalent (FTE) positions for the proposed MRI services as summarized in the following table:

2019 Forsyth County  
Competitive MRI Review  
Page 42

Position	Current FTE Positions	Projected FTE Positions		
	9/01/19	CY2021	CY2022	CY2023
Administrator	0.10	0.10	0.10	0.10
Business Office Supervisor	0.10	0.10	0.10	0.10
MRI Tech	0.75	1.50	1.50	1.50
MRI Tech Assistant	0.00	0.50	0.75	1.00
Sales Liaison	0.20	0.10	0.10	0.10
Business Office Specialist	1.00	1.00	1.00	1.00
Clinical Manager	0.10	0.10	0.10	0.10
<b>TOTAL</b>	<b>2.25</b>	<b>3.40</b>	<b>3.65</b>	<b>3.90</b>

Source: Section Q, Form H, of the application.

The assumptions and methodology used to project staffing are provided in Section H.1, page 75, and Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 75-76, the applicant identifies the medical director for MRI services and describes the methods used to recruit or fill new positions. On pages 76-77, it describes its existing training and education programs. Exhibit H.1 contains a letter from John Holbert, M.D., indicating his intent to continue to serve as Medical Director for the proposed service. The applicant provides physician support letters in Exhibit I.2.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Novant Health.** In Section Q Form H, page 111, the applicant provides current and projected FTE positions for the proposed services as summarized in the following table:

2019 Forsyth County  
Competitive MRI Review  
Page 43

Position	Current FTE Positions	Projected FTE Positions		
	As of June 30, 2019	1 <sup>st</sup> Full FY	2 <sup>nd</sup> Full FY	3 <sup>rd</sup> Full FY
Radiology Techs	16.50	17.50	17.50	17.50
Aides/Orderlies	5.89	6.89	6.89	6.89
Clerical Staff	7.40	7.40	7.40	7.40
Administrator	1.00	1.00	1.00	1.00
<b>TOTAL</b>	<b>31 [30.79]</b>	<b>33 [32.79]</b>	<b>33 [32.79]</b>	<b>33 [32.79]</b>

Source: Section Q, Form H of the application.

The Form H Staffing provided in Section Q, page 111, appears to be for the entire facility, based on the total salary cost in Form H being the same amount as the Salaries line in the Form F.3 Operating Costs for the entire facility on page 109. Form F.3 Operating Costs for the MRI component, page 110, states that the figures provided for Salaries are from Form H Staffing; however, the Agency was unable to find a Form H Staffing for the MRI component. On page 113, the applicant provides the volume of procedures by imaging component and total for the facility. MR procedures in the third project year are 25% of the total imaging procedures at the facility (13,636 / 53,894 = 25.3%). The salary cost shown on Form F.3 Operating Costs for the MR component, page 110, shows \$545,879 for Salaries, which represents 25% of the total salary cost for the facility, as shown in Form H and on Form F.3, page 109, for the entire facility (\$2,148,744 / \$545,879 = 25.4%). Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, page 110, which is found in Section Q. In Section H, pages 74-76, the applicant describes the methods used to recruit new positions and its existing training and continuing education programs. The applicant provides physician support letters in Exhibit C-4.3.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

**Conclusion**

The Agency reviewed the

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary

and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

#### C – Both Applications

**WFBI.** In Section I.1, page 78, the applicant provides a listing of necessary ancillary and support services provided for its MRI services, including scheduling, accounting/billing, medical records, human resources/payroll, staff education, infection control, quality and performance improvement, information technology, equipment maintenance and housekeeping/linens. The applicant further discusses how the ancillary and support services will continue to be made available.

In Section I.2, pages 78-79, the applicant discusses its working relationships with the referring physician community in Forsyth County and surrounding counties and the broader healthcare provider community. Exhibit I.2 contains copies of support letters from referring physicians representing a variety of specialties.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

#### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Novant Health.** In Section I.1, page 78, the applicant states that all necessary ancillary and support services for the additional MRI are already in place at NHI Piedmont and will continue to be provided upon completion of the proposed project. Exhibit I.1 contains a letter from the center manager at NHI Piedmont confirming the availability of all necessary ancillary and support services for the proposed project.

In Section I.2, page 78, the applicant states that NHI Piedmont is an existing healthcare facility and part of the Novant Health system, which has established relationships with other local healthcare and social service providers. The applicant provides supporting documentation in Exhibit C-4.2 from area clinics and Exhibit C-4.3 from area physicians.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing healthcare system.

**Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA – Both Applications

Neither applicant projects to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, neither applicant projects to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA – Both Applications

Neither applicant is an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (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.

#### C – Both Applications

**WFBI.** In Section K.1, page 83, the applicant states that the project involves constructing 1,179 square feet of new space at the existing diagnostic facility. A documentation letter from the facility landlord, authorizing the addition, is included in Exhibit K.4. Line drawings and the cost estimate/scope of proposed work are provided in Exhibits K.1 and K.3, respectively.

In Section, K.3(a), page 83, the applicant explains how the cost, design and means of construction represent the most reasonable alternative for the proposed services.

In Section K.3(b), page 84, the applicant adequately explains why the proposal will not unduly increase the cost to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 84, the applicant identifies any applicable energy saving features that will be associated with the proposed project.

On pages 85-86, the applicant provides site information regarding the current facility. Supporting documentation is provided in Exhibits K.1, K.3 and K.4.

#### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Novant Health.** In Section K, page 82, the applicant states that the project involves renovating approximately 900 square feet of existing space at NHI Piedmont. Line drawings are provided in Exhibit K.2.

On page 82, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 83, the applicant adequately explains why the proposal will not unduly increase the cost to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

On page 83, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 84-85, the applicant provides site information regarding the current facility.

### **Conclusion**

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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;

### C – Both Applications

**WFBI.** In Section L.1(b), page 90, the applicant provides the historical payor mix during CY2019 for WFBI-K, as shown in the table below:

**WFBI-Kernersville  
CY2019 Payor Mix**

<b>Payor Category</b>	<b>Entire Facility</b>	<b>Mobile MRI Service**</b>
Self-Pay	0.83%	0.51%
Medicare*	6.51%	11.44%
Medicaid*	4.94%	6.65%
Insurance*	87.27%	79.79%
Other (Workers Comp)	0.45%	1.61%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Source: Table L.1(b) on page 90

\*Including any managed care plans

\*\*Since March 2019 opening

In Section L.1(a), page 89, the applicant states that WFBI-K only began offering MRI services in March 2019; therefore, for informational purposes, the applicant also provides the following payor mix for its WFBI-WS location for 2019 on page 90.

**WFBI-Winston-Salem  
CY2019 Payor Mix**

<b>Payor Category</b>	<b>Entire Facility</b>	<b>Fixed MRI Service</b>
Self-Pay	0.59%	0.28%
Medicare*	10.57%	14.77%
Medicaid*	3.05%	5.26%
Insurance*	83.17%	78.77%
Other (Workers Comp)	2.61%	0.92%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Source: Table L.1(b) on page 90

\*Including any managed care plans

In Section L.1(a), page 89, the applicant provides a comparison of the demographic of its WFBI-WS fixed MRI services to the demographics of the Forsyth County service area for CY2018, as summarized below.



2019 Forsyth County  
Competitive MRI Review  
Page 49

	Percentage of Total Patients Served by WFBI-WS during CY2018	Percentage of the Population of the Service Area: Forsyth County
Female	78.0%	52.5%
Male	22.0%	47.5%
Unknown	0.0%	0.0%
64 and Younger	63.0%	84.4%
65 and Older	37.0%	15.6%
American Indian	*	0.8%
Asian	*	2.5%
Black or African-American	*	27.4%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	56.2%
Other Race	*	13.0%
Declined / Unavailable	*	0.0%

\*WFBI does not track racial and ethnic minority data on patients  
Sources: WFBI and United States Census Bureau

**Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

**Novant Health.** In Section L.1, page 87, the applicant provides the historical payor mix during FY2019 for the existing NHI Piedmont facility, as shown in the table below:

2019 Forsyth County  
Competitive MRI Review  
Page 50

**NHI Piedmont  
July 1, 2018-June 30, 2019**

<b>Payor Category</b>	<b>Entire Facility</b>	<b>MRI Services</b>
Self-Pay	3.75%	3.63%
Charity Care	0.38%	0.44%
Medicare*	37.95%	35.29%
Medicaid*	3.95%	5.02%
Insurance*	49.50%	49.21%
Workers Compensation	3.87%	5.79%
TRICARE	0.60%	0.62%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

\*Including any managed care plans

In Section L.1, page 86, the applicant provides the following comparison:

	<b>Percentage of Total Patients Served by NHI Piedmont during Last Full FY</b>	<b>Percentage of the Population of the Service Area: Forsyth County</b>
Female	72.0%	52.6%
Male	28.0%	47.4%
Unknown	*	*
64 and Younger	65.0%	84.0%
65 and Older	35.0%	16.0%
American Indian	*	0.9%
Asian	*	2.6%
Black or African-American	*	27.5%
Native Hawaiian or Pacific Islander	*	0.1%
White Alone <sup>^</sup>	*	66.7%
Other Race	4.0%	13.0%
Declined / Unavailable	96.0%	*

Source: <https://www.census.gov/quickfacts/fact/table/US/PST045218>

\*Not specified

<sup>^</sup>The source table at census.gov shows 66.7% for “White alone” and 56.5% for “White alone, not Hispanic or Latino”

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the applicant adequately documents 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. Therefore, the application is conforming to this criterion.

- (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 – Both Applications

**WFBI.** Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, pages 90-91, the applicant states that it has no obligations for uncompensated care or community service, or access by minorities and handicapped persons. The applicant states that WFBI does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. Exhibit C.11 contains WFBI's policies related to non-discrimination, accessibility, patient rights and uninsured discounts.

In Section L, page 91, the applicant states that during the last five years no civil rights equal access complaints have been filed against WFBI or any of its affiliated facilities located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Novant Health.** Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 87, the applicant states that it has had no obligations to provide uncompensated care in any specified amount, community service, or access by minorities and handicapped persons.

In Section L, page 87, the applicant states that during the last five years no civil rights access complaints have been filed against NHI Piedmont or any Novant Health facility located in North Carolina.

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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

C – Both Applications

**WFBI.** In Section L.3, page 92, the applicant projects the following payor mix for the proposed services during the third full year of operation following completion of the project, as summarized in the table below:

**WFBI-Kernersville  
CY2023 Payor Mix**

<b>Payor Category</b>	<b>Entire Facility</b>	<b>Fixed MRI Service</b>
Self-Pay	0.83%	0.51%
Medicare*	6.51%	11.44%
Medicaid*	4.94%	6.65%
Insurance*	87.27%	79.79%
Other (Workers Comp)	0.45%	1.61%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

Source: Table L.3(a) on page 92

\*Including any managed care plans

As shown in the table above, during the third full year of operation following completion of the project, the applicant projects that less than 1% of total MRI services will be provided to self-pay patients, 11.44% to Medicare patients and 6.65% to Medicaid patients.

On page 92, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on historical payor mix and the applicant states it assumes it will remain the same as historical payor mix.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Novant Health.** In Section L.3, page 88, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as summarized in the table below:

**NHI Piedmont  
July 1, 2023-June 30, 2024**

<b>Payor Category</b>	<b>Entire Facility</b>	<b>MRI Services</b>
Self-Pay	3.75%	3.63%
Charity Care	0.38%	0.44%
Medicare*	37.95%	35.29%
Medicaid*	3.95%	5.02%
Insurance*	49.50%	49.21%
Workers Compensation	3.87%	5.79%
TRICARE	0.60%	0.62%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 3.63% of MRI services will be provided to self-pay patients, 35.29% to Medicare patients and 5.02% to Medicaid patients.

On page 88, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project, stating that it is based upon historical payor mix. The projected payor mix is reasonable and adequately supported because it is based on historical payor mix for its MRI services and the applicant does not expect payor mix for its MRI services to change.

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,

- remarks made at the public hearing, and
- responses to comments.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (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.

#### C – Both Applications

**WFBI.** In Section L.5, page 94, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

**Novant Health.** In Section L.5, page 90, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the application is conforming to this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

#### C – Both Applications

**WFBI.** In Section M.1, page 95, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

**Novant Health.** In Section M.1, page 91, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M-1.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.

- (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.

#### C – Both Applications

Table 9R, page 172 of the 2019 SMFP, provides the projected need determination for one additional fixed MRI scanner in Forsyth County, based on the standard methodology used to determine need for fixed MRI scanners in the 2019 SMFP, pages 151-152.

2019 Forsyth County  
Competitive MRI Review  
Page 56

On page 149, the 2019 SMFP defines a fixed MRI scanner as “an MRI scanner that is not a mobile MRI scanner.” The 2019 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.” Therefore, for the purpose of this review, Forsyth County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

Table 9P, page 158 of the 2019 SMFP, provides the current total number of MRI scanners in Forsyth County, as summarized in the following table.

**Fixed and Mobile MRI Scanners in Forsyth County**

Facility	# of Fixed MRI Magnets*	Fixed Equivalent Magnets	Total MRI Scans	Total Weighted MRI Scans
North Carolina Baptist Hospital	6	6.00	21,774	29,412
Novant Health Forsyth Medical Center	2	2.00	10,830	14,954
Novant Health Forsyth Medical Center-Clemmons	1	1.00	1,162	1,300
Novant Health Forsyth Medical Center-Kernersville	1	1.00	1,470	1,769
Novant Health Forsyth Medical Center-Novant Health Imaging Kernersville	1	1.00	1,952	2,132
Novant Health Forsyth Medical Center-Novant Health Imaging Maplewood	2	2.00	8,277	9,667
Novant Health Imaging Piedmont (Piedmont Imaging LLC)	2	2.00	10,622	11,254
Wake Forest Baptist Imaging Winston-Salem	1	1.00	6,935	7,713
Cone Health MedCenter Kernersville (ARMC)	0	0.10	483	517
Novant Health Forsyth Medical Center-Mobile MRI	0	0.35	1,660	1,833
OrthoCarolina Kernersville	0	0.12	575	586
OrthoCarolina Winston-Salem	0	0.97	4,684	4,868
Piedmont Imaging LLC (Foundation Health Mobile Imaging LLC)^	0	0.14	668	0
<b>Total Forsyth County</b>	<b>16</b>	<b>17.68</b>	<b>71,092</b>	<b>86,004</b>

Totals may not sum due to rounding

\*The inventory of fixed MRI magnets shown in the 2019 SMFP does not include a Novant Health Forsyth Medical Center magnet identified in the 2017 SMFP as a grandfathered fixed MRI magnet at Novant Health Winston-Salem Health Care, which was approved to be replaced and relocated to Novant Health Forsyth Medical Center in an Exemption dated January 5, 2017. Per page 52 of its application, Novant Health is in the process of developing space for the magnet (10<sup>th</sup> fixed unit), which is projected to be operational by the end of 2019. This fixed MRI scanner was erroneously dropped from the SMFP inventory.

^Only unweighted scans were reported; weighted scans were not reported; the SMFP shows “0” for weighted scans.



**WFBI** proposes to acquire one fixed MRI scanner to be located in the existing imaging center, WFBI-K, at 861 Old Winston Road, Kernersville.

In Section N, pages 97-103, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed service. The applicant states:

*“With this proposed project to acquire a fixed MRI scanner, WFBI is proposing to enhance the medical diagnostic imaging services it currently offers at its convenient Kernersville location, in order to improve patient access to quality, cost-effective diagnostic care. With acquisition of a fixed MRI scanner, WFBI will continue to have a positive effect on competition in the service area. The proposed fixed MRI scanner will promote cost effective, high quality medical diagnostic imaging services that will be even more accessible by local residents, as described in Section N.2 below.*

...

*The outpatient diagnostic imaging services in Kernersville contribute to cost-effective patient care because the services have a charge structure different from hospital-based diagnostic services, typically less costly.*

...

*WFBI will continue to maintain the highest standards and quality of care, consistent with the standards that it has sustained throughout its years of providing patient care in Forsyth County.*

...

*The proposed project will enable improved access to freestanding MRI diagnostic services for medically underserved groups.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, K, N and Q of the application and any exhibits).
- Quality services will be provided (see Sections B, N and O of the application and any exhibits).

- Access will be provided to underserved groups (see Sections B, L and N of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

**Novant Health** proposes to acquire one fixed MRI scanner, for a total of three fixed MRI scanners, to be located in the existing imaging center, NHI Piedmont, at 185 Kimel Park Drive, Winston-Salem.

In Section N, pages 93-95, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost effectiveness, quality and access to MRI services in Forsyth County. The applicant states:

*“The additional MRI capacity at NHI Piedmont will provide the facility with improved accessibility for patients in need of imaging services.*

...

*The approval of the proposed project will create access to enhanced 3T MR imaging in a low-cost setting.*

...

*NHI Piedmont is committed to providing exceptional quality of care for service area residents.*

...

*NHI Piedmont will continue to provide services to all persons, regardless of race, sex, age, religion, creed, disability, national origin or ability to pay.”*

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections B, F, K, N and Q of the application and any exhibits).
- Quality services will be provided (see Sections B, N and O of the application and any exhibits).
- Access will be provided to underserved groups (see Sections B, L and N of the application and any exhibits).

### **Conclusion**

The Agency reviewed the:

- application,
- exhibits to the application,
- written comments,
- remarks made at the public hearing,
- responses to comments, and
- information publicly available during the review and used by the Agency.

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C – Both Applications

**WFBI.** In Section A.6, page 12, the applicant identifies Outpatient Imaging Affiliates, LLC (OIA) as its management company. In Section Q Form A, the applicant provides a list of five diagnostic centers owned by WFBI and/or managed by OIA or a related entity in North Carolina. In Section O.3, page 108, the applicant identifies Wake Forest Baptist Medical Center (WFBMC) as a member of WFBI and lists the hospital facilities that WFBMC operates in North Carolina: North Carolina Baptist Hospital, Lexington Medical Center, Davie Medical Center, and Wilkes Regional Medical Center.

In Section O.3, pages 107-108, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care resulting in a finding of immediate jeopardy or noncompliance with any Medicare Conditions of Participation at any facilities owned, operated, or managed in

North Carolina by WFBI, OIA, WFBMC, or related entities, other than the February 2018 pathology issue at NCBH, which has since been brought back into compliance with Medicare Conditions of Participation.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all four of the related facilities are currently in compliance with all Medicare Conditions of Participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Novant Health.** In Section A, page 13, and Section Q Form A, page 101, the applicant identifies the Novant Health related diagnostic imaging facilities across North Carolina. The applicant identifies a total of 23 of this type of facility located in North Carolina. In addition to the Novant Health diagnostic centers across the state, Novant Health also owns, operates, or manages 13 hospitals in North Carolina.

In Section O, page 98, the applicant states that, during the 18 months immediately preceding the submittal of the application, Novant Health and NHI Piedmont have provided quality care for its patients, implying in response to the specific questions on page 98, that no incidents resulting in a finding of immediate jeopardy occurred in any of these facilities and that each facility is in full compliance.

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, all of the facilities are in compliance with all Medicare Conditions of Participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 13 hospitals and 23 imaging centers, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C – Both Applications

The Criteria and Standards for Magnetic Resonance Imaging Scanner, promulgated in 10A NCAC 14C.2700, are applicable to both applications in this review and are discussed below.

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

**10A NCAC 14C .2703 PERFORMANCE STANDARDS**

(a) *An applicant proposing to acquire a mobile magnetic resonance imaging (MRI) scanner shall:*

- (1) *demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the mobile MRI region in which the proposed equipment will be located, except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; with the exception that in the event an existing mobile MRI scanner has been in operation less than 12 months at the time the application is filed, the applicant shall demonstrate that this mobile MRI scanner performed an average of at least 277 weighted MRI procedures per month for the period in which it has been in operation;*
- (2) *demonstrate annual utilization in the third year of operation is reasonably projected to be at least 3328 weighted MRI procedures on each of the existing, approved and proposed mobile MRI scanners owned by the applicant or a related entity to be operated in the mobile MRI region in which the proposed equipment will be located [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.]; and*
- (3) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants proposes to acquire a mobile MRI scanner. Therefore, this rule is not applicable to this review.

(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:*

*(1) demonstrate that the existing fixed MRI scanners which the applicant or a related entity owns a controlling interest in and located in the proposed MRI service area performed an average of 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data;*

- C- **WFBI.** In Section C, page 48, the applicant states that WFBI owns one fixed MRI scanner in Forsyth County at WFBI-Winston-Salem, where it performed 6,974 weighted procedures in FY2018. During the most recent 12-month period (August 2018 through July 2019), WFBI-WS performed 7,395 weighted MRI procedures on its one scanner. This exceeds the requirement of an average of 3,328 weighted MRI procedures in this performance standard.

A related entity, NCBH owns and operates six fixed MRI scanners in Forsyth County. During the most recent 12-month period (September 2018 through August 2019), NCBH performed 31,935 weighted MRI procedures, an average of 5,323 weighted procedures per scanner ( $31,935 / 6 = 5,323$ ). This exceeds the requirement of an average of 3,328 weighted MRI procedures per scanner in this performance standard.

The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

- C- **Novant Health.** In Section C, page 52, the applicant states that Novant Health's nine existing fixed MRI scanners in Forsyth County performed an average of 4,943 weighted MRI procedures from July 1, 2018 through June 30, 2019. However, Novant Health owns one additional fixed MRI scanner that was approved to be relocated from Novant Health Winston-Salem Health Care to NHFMC. Therefore, the average weighted MRI procedures per scanner is 4,449. This exceeds the requirement of an average of 3,328 weighted MRI procedures in this performance standard.

The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

*(2) demonstrate that each existing mobile MRI scanner which the applicant or a related entity owns a controlling interest in and operates in the proposed MRI service area except temporary MRI scanners, performed 3,328 weighted MRI procedures in the most recent 12 month period for which the applicant has data [Note: This is not the average number of weighted MRI procedures performed on all of the applicant's mobile MRI scanners.];*

-NA- **WFBI.** The applicant states that neither WFBI nor any related entities have ownership in a mobile MRI scanner that operates in Forsyth County. Therefore, this Rule is not applicable to this applicant.

-NA- **Novant Health.** In Section C, page 53, the applicant states:

*“As of the filing date of this application, neither Novant Health, nor any of its related entities, owns a controlling interest in and operates any mobile MRI units in Forsyth County.”*

Therefore, this Rule is not applicable to this applicant.

*(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 located 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 2019 SMFP shows that there are more than four (4) fixed MRI scanners located in the fixed MRI service area of Forsyth County. Therefore, each applicant must demonstrate that the average annual utilization for the existing, approved and proposed fixed MRI scanners which the applicant or a related entity owns and locates in Forsyth County will be at least 4,805 weighted MRI procedures in the third operating year.

-C- **WFBI.** In Section C, pages 49-50, the applicant states:

*“As described in Section Q, WFBI projects to perform 13,052 weighted MRI procedures on its existing [WFBI-WS] and proposed [WFBI-K] fixed MRI scanners in Forsyth County during the third year of the proposed project (CY2023), or an average of 6,526 weighted procedures per scanner. [page 121]*

*As described in Section Q, NCBH projects to perform 31,975 weighted MRI procedures on its MRI scanners in Forsyth County during the third year of the proposed WFBI project (CY2023), or an average of 5,329 weighted procedures per scanner.” [page 124]*

The applicant’s projected average, annual weighted MRI procedures for all of its existing, approved and proposed fixed MRI scanners exceeds the 4,805 average annual procedures required in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

- C- **Novant Health.** In Section C.12, page 53, the applicant states that the average annual weighted MRI procedures that all Novant Health existing, approved, and proposed fixed MRI scanners are projected to perform in the third year of operation of the proposed project is 4,862. The applicant provides the calculations in a table on page 54.

The applicant’s projected weighted MRI procedures exceeds the 4,805 average annual procedures required in this performance standard. The discussion regarding projected utilization in Criterion (3) is incorporated herein by reference.

*(4) if the proposed MRI scanner will be located at a different site from any of the existing or approved MRI scanners owned by the applicant or a related entity, demonstrate that the annual utilization of the proposed fixed MRI scanner is 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;*



- C- **WFBI.** In Section C, page 50, the applicant refers to Section Q, page 120, where it projects performing 4,864 weighted MRI procedures during CY2023, the third year of operation following completion of the project. The discussion on projected utilization in Criterion (3) is incorporated herein by reference.
  
- NA- **Novant Health.** In Section C, page 55, the applicant states that the proposed scanner will be located at NHI Piedmont's existing outpatient imaging center, where it currently operates two fixed MRI scanners.
  - (5) *demonstrate that annual utilization of each existing, approved and proposed mobile MRI scanner which the applicant or a related entity owns a controlling interest in and locates in the proposed MRI service area is reasonably expected to perform 3,328 weighted MRI procedures in the third year of operation following completion of the proposed project [Note: This is not the average number of weighted MRI procedures to be performed on all of the applicant's mobile MRI scanners.]; and*
  
- NA- **WFBI.** The applicant states that neither WFBI nor any related entities have ownership in a mobile MRI scanner that operates in Forsyth County. Therefore, this Rule is not applicable to this applicant.
  
- NA- **Novant Health.** The applicant states that neither Novant Health nor any related entities have controlling interest in a mobile MRI scanner that operates in Forsyth County. Therefore, this Rule is not applicable to this applicant.
  - (6) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*
  
- C- **WFBI.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q, pages 111-125.
  
- C- **Novant Health.** The applicant's assumptions and data supporting the methodology used for each projection required by this Rule are described in Section Q – Projected Utilization and Assumptions, pages 1-24.
  
- (c) *An applicant proposing to acquire a fixed dedicated breast magnetic resonance imaging (MRI) scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 1,664 weighted MRI procedures which is .80 times 1 procedure per hour times 40 hours per week times 52 weeks per year; and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants proposes the acquisition of a dedicated fixed breast MRI scanner. Therefore, this Rule is not applicable to this review.

(d) *An applicant proposing to acquire a fixed extremity MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for an adjustment to the need determination shall:*

- (1) *demonstrate annual utilization of the proposed MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(f)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants proposes the acquisition of a fixed extremity MRI scanner. Therefore, this Rule is not applicable to this review.

(e) *An applicant proposing to acquire a fixed multi-position MRI scanner for which the need determination in the State Medical Facilities Plan was based on an approved petition for a demonstration project shall:*

- (1) *demonstrate annual utilization of the proposed multi-position MRI scanner in the third year of operation is reasonably projected to be at least 80 percent of the capacity defined by the applicant in response to 10A NCAC 14C .2702(g)(7); and*
- (2) *document the assumptions and provide data supporting the methodology used for each projection required in this Rule.*

-NA- Neither of the applicants proposes the acquisition of a fixed multi-position MRI scanner. Therefore, this Rule is not applicable to this review.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2019 SMFP, no more than one additional fixed MRI scanner may be approved in this review for Forsyth County. Because the two applications in this review collectively propose to acquire two additional fixed MRI scanners for Forsyth County, only one of the applications can be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable review criteria, the Agency conducted a comparative analysis of the proposals to decide which proposal should be approved. For the reasons set forth below and in the rest of the findings, the application submitted by Wake Forest Baptist Imaging, LLC is approved, and the application submitted by Piedmont Imaging, LLC and Novant Health, Inc. is denied.

Below is a brief description of each project included in this review.

- **Project ID #G-11798-19, Wake Forest Baptist Imaging, LLC (WFBI)**, proposes to acquire one fixed MRI scanner to be located at Wake Forest Baptist Imaging-Kernersville, in an existing imaging center in leased medical office space at 861 Old Winston Road, Kernersville, Forsyth County. The applicant proposes to perform 4,864 total weighted MRI procedures on the proposed fixed MRI scanner from January 1, 2023–December 31, 2023, the third full year of operation following completion of the project.
- **Project ID #G-11816-19, Piedmont Imaging, LLC and Novant Health, Inc. (Novant Health)**, proposes to acquire one fixed MRI scanner to be located at Novant Health Imaging Piedmont, for a total of three fixed MRI scanners at the existing imaging center located at 185 Kimel Park Drive, Winston-Salem, Forsyth County. The applicant proposes to perform 14,847 total weighted MRI procedures (4,949 weighted procedures per fixed MRI scanner) at NHI Piedmont from July 1, 2023-June 30, 2024, the third full year of operation following completion of the project.

### **Conformity with Statutory and Regulatory Review Criteria**

Both applications are conforming with all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, the applications are equally effective alternatives.

### **Scope of Services**

Both applicants propose to acquire and operate a 3T fixed MRI scanner in a freestanding outpatient setting, which would imply that both applicants will be capable of providing the same types of MRI services to the same types of patients. Therefore, regarding this comparative factor, the applications are equally effective alternatives.

**Historical Utilization**

The following table illustrates historical utilization of each applicant as provided in the 2020 SMFP representing FY2018 reported utilization.

**Fixed MRI Scanners in Forsyth County  
2020 SMFP Based on FY2018 Data**

Facility	# of Fixed MRI Scanners*	Weighted Procedures	Weighted MRI Procedures per Scanner
North Carolina Baptist Hospital	6	30,567	5,095
Wake Forest Baptist Imaging Winston-Salem	1	6,974	6,974
Total WFBI	7	37,541	5,363
Novant Health Forsyth Medical Center	2 [3]	14,686	7,343 [4,895]
Novant Health Forsyth Medical Center-Clemmons	1	1,612	1,612
Novant Health Forsyth Medical Center-Kernersville	1	1,876	1,876
Novant Health Forsyth Medical Center-Novant Health Imaging Kernersville	1	2,086	2,086
Novant Health Forsyth Medical Center-Novant Health Imaging Maplewood	2	9,182	4,591
Novant Health Imaging Piedmont (Piedmont Imaging LLC)	2	11,164	5,582
Total Novant Health	9 [10]	40,606	4,512 [4,061]

Source: 2020 SMFP, page 426

\*The inventory of fixed MRI magnets shown in the 2018, 2019 and 2020 SMFPs does not include a Novant Health Forsyth Medical Center fixed MRI magnet identified in the 2017 SMFP as a grandfathered fixed MRI magnet at Novant Health Winston-Salem Health Care, which was approved to be replaced and relocated to Novant Health Forsyth Medical Center in an Exemption Letter dated January 5, 2017. Per page 52 of its application, Novant Health is in the process of developing space for the magnet (10<sup>th</sup> fixed unit), which is projected to be operational by the end of 2019. This fixed MRI scanner was inadvertently dropped from the SMFP inventory.

The following table illustrates historical utilization over the most recent 12-month period for WFBI and NHI Piedmont and their related entities, as provided by each applicant, and adjusted to reflect the 10<sup>th</sup> existing Novant Health fixed MRI scanner, which was inadvertently dropped from the SMFP inventory.

2019 Forsyth County  
Competitive MRI Review  
Page 69

Applicant	# of Fixed MRI Scanners in Service Area	Weighted MRI Procedures	Weighted MRI Procedures per Scanner
WFBI*	7	39,330	5,619
NHI Piedmont*	10**	44,491	4,449

\*Most recent 12-month period of data, as reported by each applicant:

WFBI: WFBI-WS - August 2018-July 2019 and NCBH – September 2018- August 2019

Novant Health: July 2018-June 2019

\*\* The inventory of fixed MRI magnets shown in the 2018, 2019 and 2020 SMFPs does not include a Novant Health Forsyth Medical Center fixed MRI magnet identified in the 2017 SMFP as a grandfathered fixed MRI magnet at Novant Health Winston-Salem Health Care, which was approved to be replaced and relocated to Novant Health Forsyth Medical Center in an Exemption Letter dated January 5, 2017. Per page 52 of its application, Novant Health is in the process of developing space for the magnet (10<sup>th</sup> fixed unit), which is projected to be operational by the end of 2019. This fixed MRI scanner was inadvertently dropped from the SMFP inventory.

During each of the time periods provided above, both applicants exceed the performance standard related to the historical operation of their approved fixed MRI scanners in the service area; therefore, regarding this comparative factor, the applications are equally effective alternatives.

**Geographic Accessibility (Location within the Service Area)**

The 2019 SMFP identifies the need for one fixed MRI scanner in Forsyth County. The following table identifies the location of the existing and approved fixed MRI scanners in Forsyth County.

**Fixed MRI Scanners in Forsyth County  
2019 SMFP Based on FY2017 Data**

Facility	# of Fixed MRI Scanners*	Hospital-based or Freestanding	Location
North Carolina Baptist Hospital	6	Hospital-based	Winston-Salem
Novant Health Forsyth Medical Center	2 [3]	Hospital-based	Winston-Salem
Novant Health Forsyth Medical Center-Clemmons	1	Hospital-based	Clemmons
Novant Health Forsyth Medical Center-Kernersville	1	Hospital-based	Kernersville
Novant Health Forsyth Medical Center-Novant Health Imaging Kernersville	1	Hospital-based	Kernersville
Novant Health Forsyth Medical Center-Novant Health Imaging Maplewood	2	Hospital-based	Winston-Salem
Novant Health Imaging Piedmont (Piedmont Imaging LLC)	2	Freestanding	Winston-Salem
Wake Forest Baptist Imaging Winston-Salem	1	Freestanding	Winston-Salem

\*The inventory of fixed MRI magnets shown in the 2018, 2019 and 2020 SMFPs does not include a Novant Health Forsyth Medical Center fixed MRI magnet identified in the 2017 SMFP as a grandfathered fixed MRI magnet at Novant Health Winston-Salem Health Care, which was approved to be replaced and relocated to Novant Health Forsyth Medical Center in an Exemption Letter dated January 5, 2017. Per page 52 of its application, Novant Health is in the process of developing space for the magnet (10<sup>th</sup> fixed unit), which is projected to be operational by the end of 2019. This fixed MRI scanner was inadvertently dropped from the SMFP inventory.

The table in the 2019 SMFP shows there are 16 existing fixed MRI scanners located in Forsyth County. However, as discussed in the footnote above, the 2018 SMFP inadvertently dropped a fixed MRI from Novant Health's inventory and subsequent SMFPs have continued to omit it. Thus, there are 17 approved fixed MRI scanners in Forsyth County. Of the 17 fixed scanners in the county, 14 fixed MRI scanners are located in Winston-Salem (11 hospital-based and three freestanding), two hospital-based fixed scanners are located in Kernersville, and one hospital-based fixed scanner is located in Clemmons. There are no fixed MRI scanners located in other Forsyth County cities.

Winston-Salem had a 2018 estimated population of 246,328, while Kernersville's 2018 estimated population was 24,767.<sup>1</sup> Based on the 2018 population and the number of existing fixed MRI scanners in each location, Winston-Salem has one fixed MRI scanner for every 17,595 people, while Kernersville has one fixed MRI scanner for every 12,384 people. However, the only three existing freestanding fixed MRI scanners are located in Winston-Salem. Kernersville and surrounding area residents only have access to hospital-based fixed MRI services, which are typically a higher cost alternative to freestanding, non-hospital-based services.

WFBI proposes to locate one freestanding fixed MRI scanner in Kernersville, Forsyth County, for a total of two hospital-based and one freestanding fixed scanner in Kernersville.

Novant Health proposes to locate one freestanding fixed MRI scanner in Winston-Salem for a total of 11 hospital-based fixed scanners and four freestanding fixed MRI scanners in Winston-Salem.

Thus, regarding geographic distribution of fixed freestanding MRI scanners, the proposal submitted by WFBI is the more effective proposal.

### **Access by Service Area Residents**

On page 149, the 2019 SMFP defines a fixed MRI scanner as *“an MRI scanner that is not a mobile MRI scanner.”* The 2019 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1. The fixed MRI service area is a single county, except where there is no licensed acute care hospital located within the county.”* Therefore, for the purpose of this review, Forsyth County is the service area because it has multiple licensed acute care hospitals. Facilities may also serve residents of counties not included in their service area.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

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<sup>1</sup> <https://www.census.gov/quickfacts>

2019 Forsyth County  
Competitive MRI Review  
Page 71

Applicant	Forsyth County Residents Served	Forsyth County Residents per Scanner	Forsyth County Residents Served as a % of Total
WFBI	2,779	2,779	63.6%
Novant Health	6,245	2,082	45.8%

Source: Section Q Form F.2 and Section C of the respective applications  
Totals may not sum due to rounding

As shown in the table above, Novant Health projects to serve the highest total number of service area residents; however, NHI Piedmont would be operating three MRI scanners and WFBI-K would be operating only one scanner. WFBI projects to serve the highest number of Forsyth County residents per scanner and the highest percentage of service area residents during the third full fiscal year following project completion. Therefore, regarding projected service to residents of the service area, the application submitted by WFBI is a more effective alternative.

**Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per MRI procedure
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid dollars per MRI procedure

Which of the above metrics the Agency uses is determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

*Projected Charity Care*

The following table compares projected charity care in the third full fiscal year following project completion for both applicants as a percentage of gross and net revenue, and per MRI scan, as shown below.

The total number of charity care, Medicare and Medicaid patients was not provided by either applicant in this review; therefore, total charity care patients and charity care patients as a percentage of total patients cannot be compared. Total charity care, Medicare and Medicaid dollars are provided by both applicants and therefore can be compared; however, such a comparison is of little value based on the vast difference in the total number of MRI procedures projected by each applicant in the third year of operation: 4,366 MRI scans on one MRI scanner at WFBI-K and 13,636 scans on three MRI scanners at NHI-Piedmont. Thus, in this review, charity care is compared as a percentage of gross and net revenue, and per MRI procedure, as shown below.

<b>Applicant</b>	<b>Gross Revenue</b>	<b>Net Revenue</b>	<b>MRI Scans</b>	<b>Charity Care</b>	<b>Charity Care as a % of Gross Revenue</b>	<b>Charity Care as a % of Net Revenue</b>	<b>Charity Care / MRI Scan</b>
WFBI	\$8,130,100	\$2,444,830	4,366	\$81,301	1.00%	3.33%	\$18.62
NH	\$28,425,521	\$6,404,414	13,636	\$125,072	0.44%	1.95%	\$9.17

Source: Section Q Form C and Form F.2 of the respective applications

WFBI proposes to provide \$81,301 in charity care in its third year of operation. This is 1.0% of gross revenue, 3.33% of net revenue, and \$18.62 per MRI scan. WFBI also projects that it will write off \$33,921 of self-pay charges in CY2023, which results in a total charity care and self-pay write-off of \$115,222 in the third year of operation. This represents 1.42% of the applicant's proposed MRI gross revenue, 4.71% of MRI net revenue, and \$26.39 per MRI scan.

Novant Health proposes to provide \$125,072 in charity care in its third year of operation. This is 0.44% of gross revenue, 1.95% of net revenue, and \$9.17 per MRI scan.

As a percent of both gross and net revenue, WFBI proposes a higher percentage of charity care than Novant Health. WFBI also provides a higher dollar amount of charity care per MRI scan than Novant Health. Therefore, regarding access to charity care, the proposal by WFBI is a more effective alternative.

*Projected Medicare*

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for both applicants in the review using gross Medicare dollars as a percentage of gross revenue.



2019 Forsyth County  
Competitive MRI Review  
Page 73

The total number of Medicare patients was not provided by either applicant in this review; therefore, total Medicare patients and Medicare patients as a percentage of total patients cannot be compared. Novant Health did not provide information to identify the total amount of contractual adjustments to revenue allowed for Medicare; therefore, total Medicare provided, Medicare provided per MRI scan, and Medicare as a percentage of net revenues cannot be compared in this review. Thus, in this review, Medicare is compared as a percentage of gross revenue only.

<b>Applicant</b>	<b>Gross Revenue</b>	<b>Medicare</b>	<b>Medicare as a % of Gross Revenue</b>
WFBI	\$8,130,100	\$929,717	11.44%
NH	\$28,425,521	\$10,031,366	35.29%

Source: Section Q Form F.2 of the respective applications

WFBI proposes to provide \$929,717 of care to Medicare recipients in its third year of operation. This represents 11.44% of the applicant’s proposed MRI gross revenue for that year ( $\$929,717 / \$8,130,100 = 11.44\%$ ).

Novant Health proposes to provide \$10,031,366 of care to Medicare recipients in its third year of operation. This represents 35.29% of the applicant’s proposed MRI gross revenue for that year ( $\$10,031,366 / \$28,425,521 = 35.29\%$ )

As a percent of gross revenue, Novant Health proposes a higher percentage of Medicare than WFBI. Therefore, regarding access to Medicare patients, the proposal by Novant Health is a more effective alternative.

*Projected Medicaid*

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for both applicants using gross Medicaid dollars as a percentage of gross revenue.

The number of Medicaid patients was not provided by either applicant in this review; therefore, total Medicaid patients and Medicaid patients as a percentage of total patients cannot be compared. Novant Health did not provide information to identify the total amount of contractual adjustments to revenue allowed for Medicaid; therefore, total Medicaid provided, Medicaid provided per MRI scan, and Medicaid as a percentage of net revenues cannot be compared in this review. Thus, in this review, Medicaid is compared as a percentage of gross revenue only.

<b>Applicant</b>	<b>Gross Revenue</b>	<b>Medicaid</b>	<b>Medicaid as a % of Gross Revenue</b>
WFBI	\$8,130,100	\$540,761	6.65%
NH	\$28,425,521	\$1,426,961	5.02%

Source: Section Q Form F.2 of the respective applications

WFBI proposes to provide \$540,761 of care to Medicaid recipients in its third year of operation. This represents 6.65% of the applicant’s proposed MRI gross revenue for that year ( $\$540,761 / \$8,130,100 = 6.65\%$ ).

Novant Health proposes to provide \$1,426,961 of care to Medicaid recipients in its third year of operation. This represents 5.02% of the applicant’s proposed MRI gross revenue for that year ( $\$1,426,961 / \$28,425,521 = 5.02\%$ ).

As a percent of gross revenue, WFBI proposes a higher percentage of Medicaid than Novant Health. Therefore, regarding access to Medicaid patients, the proposal by WFBI is a more effective alternative.

**Competition (Access to a New or Alternative Provider in the Service Area)**

Both applicants and/or related entities provide MRI services in the service area of Forsyth County; therefore, neither applicant would qualify as a new or alternative provider in the service area. Thus, with regard to this comparative factor, the proposals are equally effective.

**Projected Average Net Revenue per MRI Procedure**

The following table compares the projected average net revenue per unweighted MRI procedure for the third year of operation following project completion for both applicants, based on the information provided in the applicants’ pro forma financial statements (Section Q). Generally regarding this factor, the application proposing the lowest average net revenue per MRI procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

<b>Applicant</b>	<b>Net Revenue</b>	<b># of Unweighted MRI Procedures</b>	<b>Average Net Revenue per MRI Procedure</b>
WFBI	\$2,444,830	4,366	\$560
NH	\$6,404,414	13,636	\$470

Source: Section Q Form C and Form F.2 of the respective applications

As shown in the table above, Novant Health proposes the lower average net revenue per unweighted MRI procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the proposal by Novant Health is a more effective alternative.

**Projected Average Total Operating Cost per MRI Procedure**

The following table compares the projected average operating expense per unweighted MRI procedure for the third year of operation following project completion for both applicants, based on the information provided in the applicants' pro forma financial statements (Section Q). Generally regarding this factor, the application proposing the lowest average operating expense per MRI procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

<b>Applicant</b>	<b>Operating Expense</b>	<b># of Unweighted MRI Procedures</b>	<b>Average Operating Expense per Procedure</b>
WFBI	\$1,602,493	4,366	\$367
NH	\$2,926,044	13,636	\$215

Source: Section Q Form C, Form F.2, and Form F.3 of the respective applications

As shown in the table above, Novant Health proposes a lower average operating expense per unweighted MRI procedure. Therefore, regarding average operating expense per MRI procedure, the proposal by Novant Health appears more effective. However, given that a portion of operating costs are fixed costs, and do not vary based on the number of procedures provided, the operating expense per procedure would normally decrease as the expense is spread over more procedures; thus, a comparison of total operating expense for 4,366 procedures performed on one MRI scanner and total operating expense for 13,636 procedures performed on three MRI scanners is not reasonable; thus, this comparative factor is inconclusive.

**SUMMARY**

The following is a summary of the comparative analysis performed on the proposed projects submitted during this review, ranking the effectiveness of the proposals.

<b>Comparative Factor</b>	<b>WFBI</b>	<b>Novant Health</b>
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective
Scope of Services	Equally Effective	Equally Effective
Historical Utilization	Equally Effective	Equally Effective
Geographic Accessibility	More Effective	Less Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Charity Care Patients	More Effective	Less Effective
Access by Medicare Patients	Less Effective	More Effective
Access by Medicaid Patients	More Effective	Less Effective
Competition (Access to New or Alternative Provider)	Equally Effective	Equally Effective
Projected Average Net Revenue per MRI procedure	Less Effective	More Effective
Projected Average Operating Expense per MRI procedure	Inconclusive	Inconclusive

As shown in the table above, the applicants are equally effective on four comparative factors. WFBI’s proposal is more effective regarding geographic accessibility, access to service area residents, access to charity care patients, and access to Medicaid patients. Novant Health’s proposal is more effective regarding access to Medicare patients and projected average net revenue per MRI procedure. The comparative factor of projected average operating expense per MRI procedure was found to be inconclusive. Thus, based on the comparative analysis, the application submitted by WFBI is the more effective alternative in this review.

**CONCLUSION**

Both of the applications are conforming to the need determination in the 2019 SMFP for one fixed MRI scanner in Forsyth County. N.C.G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed MRI scanners that can be approved by the Agency. The Agency determined that the application submitted by Wake Forest Baptist Imaging, LLC is the more effective alternative proposed in this review for one additional fixed MRI scanner for Forsyth County and is approved. The approval of any other application would result in the approval of MRI scanners in excess of the need determination in the 2019 SMFP and therefore, the application submitted by Piedmont Imaging, LLC and Novant Health, Inc. is denied.

The application submitted by Wake Forest Baptist Imaging, LLC is approved subject to the following conditions:

- 1. Wake Forest Baptist Imaging, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Wake Forest Baptist Imaging, LLC shall acquire no more than one fixed MRI scanner to be located at Wake Forest Baptist Imaging-Kernersville.**
- 3. Wake Forest Baptist Imaging, LLC. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 4. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Wake Forest Baptist Imaging, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
  - a. Payor mix for the services authorized in this certificate of need.**
  - b. Utilization of the services authorized in this certificate of need.**
  - c. Revenues and operating costs for the services authorized in this certificate of need.**
  - d. Average gross revenue per unit of service.**
  - e. Average net revenue per unit of service.**
  - f. Average operating cost per unit of service.**
- 5. Wake Forest Baptist Imaging, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**