



**Piedmont Imaging, LLC d/b/a Novant Health Imaging Piedmont
Comments in Opposition to
Wake Forest Baptist Imaging Kernersville
Certificate of Need Application for
One Fixed MRI Scanner in Forsyth County
November 1, 2019 Review Cycle**

INTRODUCTION

The 2019 State Medical Facilities Plan (SMFP) identified a need for one fixed MRI scanner in Forsyth County. In response to the need determination, two applicants have submitted Certificate of Need applications, Piedmont Imaging, LLC d/b/a Novant Health Imaging Piedmont (Project ID No. G-11816-19) (NHI Piedmont) and Wake Forest Baptist Imaging Kernersville (Project ID No. G-11798-19) (WFBI-Kernersville). Pursuant to N.C. Gen. Stat. §131E-185(a)(1), NHI Piedmont submits the following comments pertaining to the application filed by WFBI Kernersville to acquire one fixed MRI scanner in Forsyth County as identified in the 2019 SMFP. As discussed in the following comments, WFBI Kernersville’s application fails to meet all necessary standards and review criteria and should be disapproved. In addition, for the reasons explained in the comparative analysis section below, NHI Piedmont’s application is comparatively superior to the WFBI Kernersville application.

Criterion (1) – Consistency with State Health Plan

The WFBI Kernersville application should be found not conforming with Criterion (1) and Policy GEN-3 because it fails to demonstrate how its projected utilization incorporates the concept of maximum value for resources expended. WFBI Kernersville’s application contains unreliable MRI utilization projections, will result in an unnecessary duplication of existing services, provides unsupported financial projections, projects insufficient staffing and will not increase accessibility to the medically underserved populations. See additional discussion under Criteria (3), (4), (5), (6), (7), and (18a).

Criterion (3) – Need and Population to be Served

WFBI fails to demonstrate the need for the proposed project as required by Criterion (3) based on unreasonable and unsupported MRI utilization projections. There are several fundamental issues with the WFBI Kernersville application that render it non-conforming with Criterion (3):

- WFBI Kernersville fails to demonstrate that the development of an additional fixed MRI scanner in Kernersville is needed by the service area population in Forsyth County.
- WFBI Kernersville relies heavily on unreasonable patient-shifting from its Winston-Salem location to support the significant growth needed at the Kernersville location to reach estimated MRI volume in Year 3.
- WFBI Kernersville’s MRI utilization projections are based on a miscalculated market share percentage for CY 2019.
- WFBI Kernersville’s assertions that its market share percentages will increase by 1.0%, 0.75% and 0.5% each project year are unsupported.

WFBI Kernersville fails to demonstrate that Kernersville requires an additional fixed MRI scanner

In March 2019, WFBI Kernersville initiated mobile MRI service at its facility. As of the filing of the application, WFBI Kernersville had five months of actual MRI utilization data for the mobile MRI service, which serves as the foundation for the MRI projections. WFBI Kernersville considers the new center “well-established.” See pg. 61. A five month old center is not “well-established.” WFBI has not built up the patient base or the referral network to confidently meet its utilization projections, especially considering the presence of two fixed scanners in Kernersville, and two other mobile scanners in Kernersville that presumably will continue to serve Kernersville.

With the addition of mobile MRI service at WFBI Kernersville, Kernersville, a town of approximately 25,000 residents, currently has access to the following MRI resources, as shown in Table 1 below.

Table 1 - Existing MRI Resources in Kernersville

Provider	Facility Type	MRI Service
Novant Health Kernersville Medical Center	Hospital	Fixed
Novant Health Imaging Kernersville	Outpatient#	Fixed
OrthoCarolina	Outpatient	Mobile
Cone Health	Outpatient	Mobile
WFBI Kernersville	Outpatient	Mobile

*Kernersville Veterans Administration Hospital also operates two fixed MRI scanners for active duty and retired military personnel. #NHI Kernersville is a HOPD with a lower modified rate schedule than the hospital.

While dismissing the existing MRI resources currently located in the Kernersville area, WFBI Kernersville attempts to support its geographic location based on a need for a “freestanding” MRI on page 35:

It is important from a health planning perspective to improve local access to freestanding MRI services in Forsyth County. As the previous table shows, Kernersville is the largest town in Forsyth County that does not currently host a freestanding fixed MRI scanner. WFBI’s Kernersville facility is also central to many other medical offices, both affiliated and non-affiliated with Wake Forest Baptist Health (WFBH). As growth and development in the Kernersville area continues (described in Section Q), WFBI will be positioned to offer medical imaging services on a larger scale with the addition of the proposed fixed MRI scanner. Therefore, Kernersville is the most effective alternative for addition of a fixed MRI scanner from a geographic perspective.

While it is literally true that Kernersville does not have a freestanding fixed MRI scanner, there are already three mobile providers in Kernersville, including WFBI. These mobile sites can offer the cost advantages of a freestanding fixed site. Freestanding fixed MRI scanners are not a distinct category of scanners for which there is a specific need determination; rather, the need is for fixed MRI scanners, regardless of whether they are hospital-based or freestanding. Further, as discussed below with respect

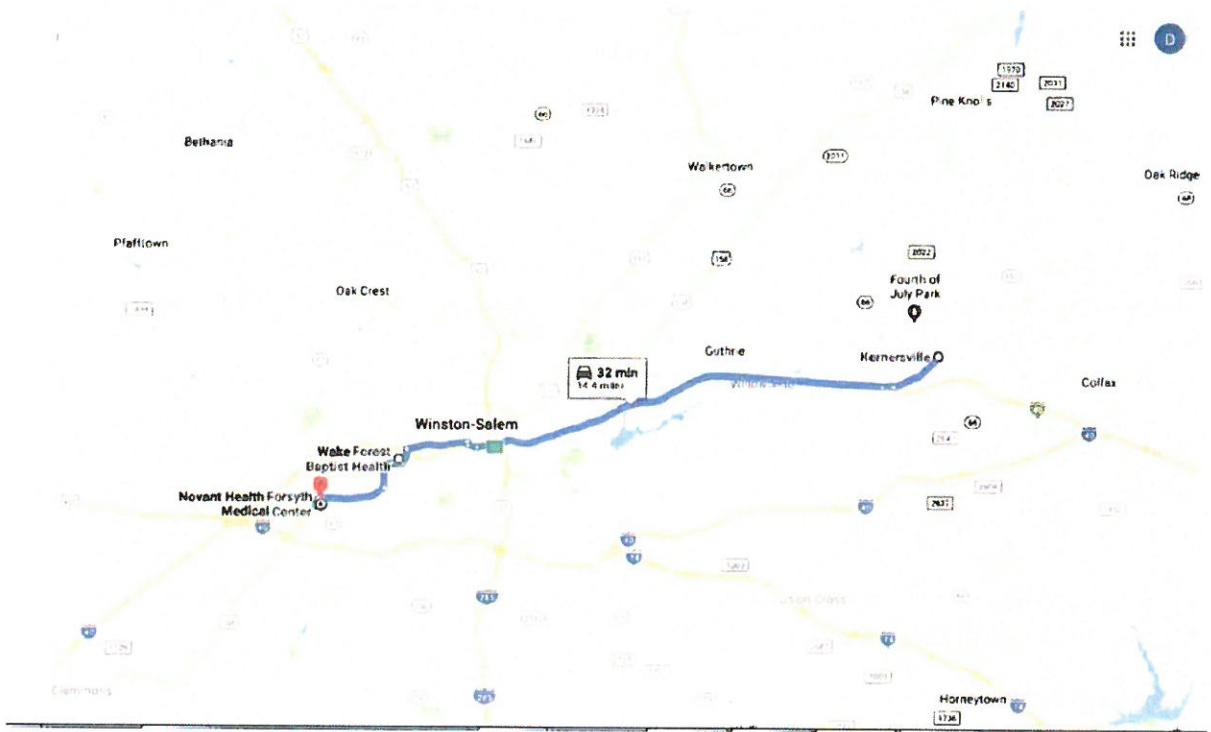
to Criterion (6), there are entire North Carolina counties with populations larger than Kernersville that do not have any MRI service. Kernersville's status as the largest town in Forsyth County without a freestanding fixed MRI scanner does not demonstrate that WFBI's project is needed. WFBI Kernersville fails to demonstrate the need for the proposed project by the service area population. The majority of the statistical data and information presented by WFBI Kernersville on pages 29-35 of the application are focused on Forsyth County, not specifically Kernersville. WFBI Kernersville fails to provide any credible documentation that Kernersville is currently underserved regarding MRI services.

On pages 36-37, WFBI Kernersville offers that traffic congestion traveling from Kernersville to Winston-Salem supports its assertions that Kernersville is the most effective location. Again, WFBI Kernersville clearly dismisses the existing MRI resources in Kernersville in an effort to bolster its unsupported argument for additional MRI services in Kernersville. WFBI suggests that there may be geographic access issues with respect to MRI services in Forsyth County because it can take over 30 minutes to travel from Kernersville to three freestanding fixed MRI scanners in Winston-Salem "and much more during times of busy traffic or inclement weather." MRIs provided at freestanding centers are always scheduled, non-emergent events so patients can plan their travel accordingly. Regarding WFBI's statement that part of Business 40 in Winston-Salem is closed, the road is expected to reopen in summer 2020. <https://www.business40nc.com/Pages/construction-timeline.aspx>. The WFBI Kernersville project does not open until 1/1/21, so Business 40 has no relevance to the proposed project's operational time frame.

From WFBI application, page 36:

Travel time is another component of geographic access. As shown on the following map, the distance from Kernersville to Novant Health Forsyth Medical Center or to Wake Forest Baptist Health ranges between 12 and 15 miles. Depending on traffic conditions, it can take over 30 minutes to travel from Kernersville to the three freestanding fixed MRI scanners in Winston-Salem, and much more during times of busy traffic or inclement weather.

Travel Time from Kernersville to Winston-Salem



This discussion by WFBI is misleading and does not accurately reflect the availability of existing MRI services, including two fixed MRI scanners and three mobile MRI host sites, located within the Kernersville community. The following map provides the locations for the existing fixed and mobile MRI resources in Kernersville.

In reality, the existing MRI resources available in Kernersville offer convenient access to both hospital-based services, for more complex and/or emergent cases, and outpatient settings, for routine visits. On page 24, WFBI Kernersville offers the following points to support its proposed location.

WFBI's proposed Kernersville fixed scanner will:

- increase patient access to MRI services for the growing population of Forsyth County and surrounding communities, including access for the medically underserved,
- help to address the growing demand for MRI services at WFBI, including at its expanding Kernersville imaging center, and by decompressing the busy Winston-Salem MRI scanner,
- improve access to value-based fixed MRI services in Forsyth County, and
- maintain a high standard of quality care, including by acquiring a 3T scanner.

WFBI Kernersville's primary focus will be serving commercially-insured patients as this payor category will represent nearly 80% of its patients. See WFBI application, page 92. Service to Medicare patients at 11.4% and Medicaid patients at 6.65% for a total of 18.05% hardly represents increased accessibility for the medically underserved populations. Overall, WFBI Kernersville fails to provide any substantive discussion that supports its proposed location.

WFBI relies heavily on unreasonable patient-shifting for MRI volume at the proposed location

WFBI-Kernersville failed to demonstrate that its projected utilization is based on reasonable assumptions. Opening in March 2019, WFBI-Kernersville has little historical operating experience to utilize in the development of its MRI utilization projections. Without sufficient historical experience to base its projections, WFBI-Kernersville must pull MRI patients from its sister facility in Winston-Salem for its estimated MRI volume. WFBI-Kernersville's projections rely heavily on unreasonable "patient-shifting" from WFBI-Winston-Salem.

WFBI Kernersville application, page 119:

For these three zip codes, WFBI assumes a 70% patient shift for PY1, 80% for PY2, and 85% for PY3. It is reasonable to anticipate a shift in this utilization pattern based on several factors, including but not limited to:

- full-time availability of Kernersville fixed MRI scanner,
- more timely access to fixed MRI services,
- reduced travel burden for patients seeking MRI services,
- convenient outpatient location, and
- proximity to referring Wake Health physicians located in Kernersville and southeast Forsyth County

The table below portrays the projected shift of unweighted MRI procedures from the Winston-Salem scanner to the Kernersville scanner for these three zip codes during the initial three project years.

Projected WFBI Unweighted MRI Procedures Shifting from Winston-Salem to Kernersville

Shift to WFBI K	2021	2022	2023
27284 zip code	246	293	324
27107 zip code	243	289	320
27265 zip code	83	99	109

It is evident that the proposed patient-shift from WFBI Winston-Salem to WFBI Kernersville is a critical component of the MRI projections. The projected patient-shift accounts for 572 procedures in Project Year 1, 681 procedures in Project Year 2, and 753 procedures in Project Year 3. However, WFBI Kernersville fails to provide any historical documentation or statistical data related to the number of procedures/patients from these zip codes that are currently being served at WFBI Winston-Salem. Without historical data regarding these zip codes from WFBI Winston-Salem, it is not possible confirm the validity of these numbers. Further, WFBI Kernersville provides no rationale for the patient shift percentages of 70% in PY 1, 80% in PY 2 and 85% in PY 3.

WFBI Kernersville's current patient total of 772 is projected to increase to 3,197 patients in Project Year 1 (CY 2021). This is an increase of 314% from 2019 to 2021, and represents an additional 2,425 patients. WFBI Kernersville fails to provide any data regarding the current number of patients originating from the zip codes that will be shifted from the Winston-Salem location (zip codes 27284, 27107, and 27265). Without historical data for WFBI Winston-Salem, it is impossible to determine the validity of those patient numbers.

WFBI Kernersville's market share percentage is not based on reasonable assumptions

Another key component of WFBI Kernersville's MRI projections centers around its estimated market share percentage for MRI services in Forsyth County in CY 2019. The calculations from pages 113-114 of the WFBI Kernersville application incorrectly calculate the facility's market share in CY 2019.

WFBI Kernersville application, page 114:

**Forsyth County
Projected MRI Procedures, CY2019 - CY2023**

	2018	2019	2020	2021	2022	2023
Forsyth Co. procedures	70,220	72,072	72,796	73,516	74,233	74,949

WFBI calculated the above projected Forsyth County MRI procedures for 2019 through 2023 by multiplying the annual projected Forsyth County population by the average Forsyth County MRI use rate of 189.0 for the past three years (from the use rates below).

As shown below, WFBI's Winston-Salem MRI market share was 8.83% in 2018, and WFBI's Kernersville MRI market share in 2019 is estimated at 2.57%.

WFBI MRI Market Share in Forsyth County

WFBI market share	2018	2019
WFBI W-S procedures	6,203	6,836
WFBI K procedures	-	1,853
Forsyth Co. procedures	70,220	72,072
W-S market share %	8.83%	9.49%
K market share %	--	2.57%

First, WFBI Kernersville estimates the county wide MRI volume for CY 2019. Next, it takes the annualized volume for the Kernersville location to determine the market share percentage. This is not accurate as the facility did not initiate mobile MRI service until March 2019 and was not in operation for entire year. Based on WFBI Kernersville's data, the facility performed 772 unweighted procedures in a five-month period. The average monthly MRI volume at WFBI Kernersville would be 154.4 procedures (772/5=154.4). Based on 10 months of service during 2019, the corrected MRI volume would be 1,544 estimated procedures not 1,853 procedures. As a result, the estimated market share for WFBI Kernersville would be lower, at 2.142%, not 2.57% as stated in the application. This error directly impacts the accuracy of the MRI projections and the application should be found non-conforming with Criterion (3).

As the following chart details, the incorrect market share percentage is the basis for the MRI utilization projections and its use creates errors in the estimated MRI volume for the facility in the interim years as well as each project year.

Projected WFBI - Kernersville MRI Market Share in Forsyth County

WFBI K market share	2019	2020	2021	2022	2023
Forsyth Co. procedures	72,072	72,796	73,516	74,233	74,949
market share %	2.57%	2.57%	3.57%	4.32%	4.82%

WFBI projects incremental market share increases of 1.0% in 2021, 0.75% in 2022, and 0.5% in 2023. This results in the following projected procedures on the proposed Kernersville fixed MRI scanner. The calculation for each year is the product of the projected Forsyth

The chart from WFBI Kernersville application page 117 details the use of the market share percentage in the MRI utilization projections. By utilizing the incorrect market share percentage, WFBI Kernersville's MRI projections as submitted are simply overstated in the interim periods and Project Years 1-3, and are therefore unreliable.

Even assuming that WFBI had not erred in calculating its market share, it offers no valid reason or assumptions for its projected market share growth. On page 115-117 of the application, WFBI surmises that newly acquired physician practices and growth in ambulatory clinic patient visits will cause WFBI-Kernersville's MRI market share to increase each project year – 3.57% in 2021, 4.32% in 2022 and 4.82% in 2023. However, the applicant fails to demonstrate the correlation between the ambulatory visits and increasing demand for MRI services at WFBI Kernersville. There is no data provided that links the number of ambulatory clinic visits that subsequently require MRI services. Likewise, the applicant's generalized statements on page 117 of the application that it owns multiple pieces of property in Kernersville, has plans to continue growth, and is evaluating the best and highest use of all of its assets in Kernersville does not support the market share assumption. The Agency cannot know from these statements exactly what the applicant's plans are and whether they would lead to growth in MRI services. The applicant fails to provide any specific discussion or data that supports the claims regarding market share growth and the impact on MRI volume at WFBI Kernersville.

The following chart details the errors in the utilization projections by WFBI Kernersville.

Table 2 -Corrected MRI Market Share and Estimated Volumes

WFBI - Kernersville	2019	2020¹	2021	2022	2023
Forsyth Co. procedures	72,072	72,796	73,516	74,233	74,949
Market Share % from Application	2.57%	2.57%	3.57%	4.32%	4.82%
Market Share Corrected#	2.142%	2.142%	3.142%	3.892%	4.392%
Corrected Unweighted MRI Volume	1,544	1,559	2,310	2,889	3,292
Patient Shift Volume from WFBI W-S	---	---	572	681	754
Total Corrected Unweighted MRI Volume	1,544	1,559	2,882	3,570	4,046
Unweighted MRI Volume – Pro Formas	1,853	1,853	3,197	3,888	4,366

Market share increased by 1.0% in PY 1, 0.75% in PY 2 and 0.5% in PY 3 based on the applicant's statements. However, it does not appear that the applicant has offered any reasonable assumption for its proposed market share growth in its application.

Overall, WFBI Kernersville's MRI projections contain substantial errors that directly impact the projected MRI volume and should be considered unreliable. Those errors, include but are not limited to, the following:

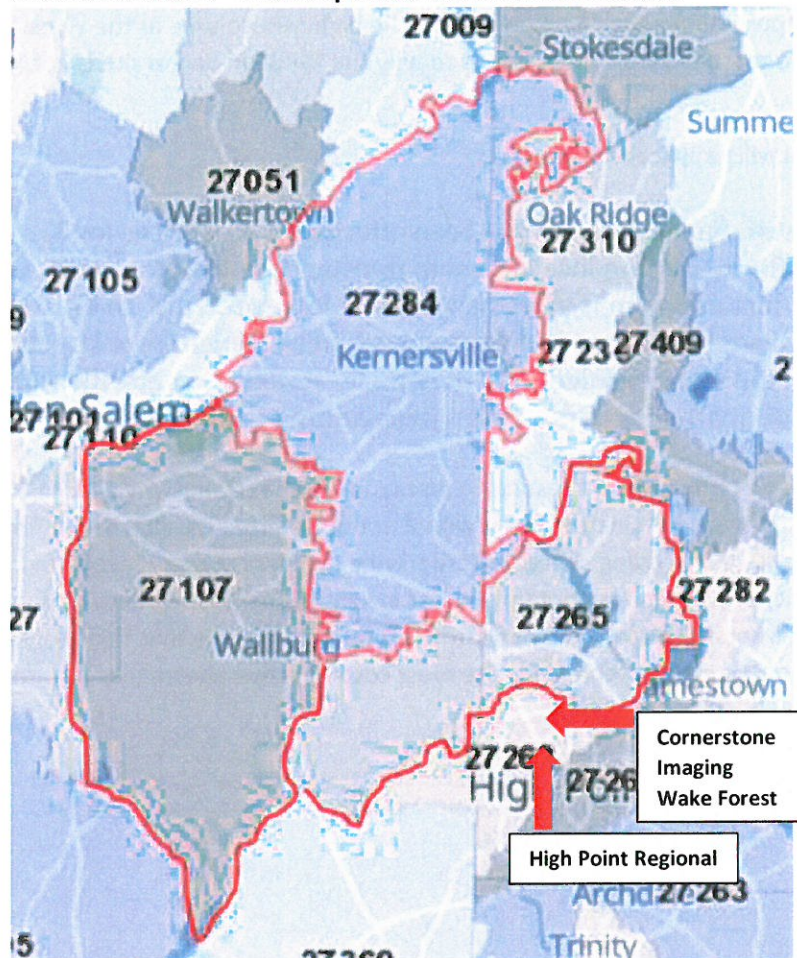
- The estimated market share percentage each year is incorrect.
- WFBI Kernersville's CY 2019 MRI data is overstated.
- The projected MRI volume for CY 2020-2023 is overstated based on the incorrect market share percentages that were utilized.
- There is no basis for the growth in the projected market share percentages for PY 1-3 of 1.0%, 0.75% and 0.5%.
- There is no documentation provided for the number of current patients that utilize WFBI Winston-Salem from the three-zip code area that will be required to shift to the proposed site.

¹ WFBI Kernersville indicates its CY 2020 volume would be 1853 procedures. However, using the applicant's methodology, the CY 2020 volume should be 1,871 using the 2.57% market share percentage. This is another calculation error by the applicant.

Wake Forest's Acquisition of Cornerstone and High Point Regional

WFBI Kernersville touts Wake Forest's acquisition of Cornerstone Health and High Point Regional Hospital, both located in Guilford County, in its application. Both Cornerstone and High Point Regional are located in the 27262 zip code area which is contiguous to WFBI Kernersville's three zip code area as shown on the map below. It should be noted that WFBI Kernersville will serve a significant percentage of patients from Guilford County (13.5% in PY 1 – currently the percentage is 14.9%). While the physician component is heavily relied upon in the application, there is no discussion regarding MRI services at Cornerstone or High Point Regional, or elsewhere in Guilford County that could be utilized by WFBI Kernersville's proposed patient population. Based on the 2020 SMFP data, High Point Regional has two fixed MRI scanners and performed only 7,948 weighted scans or 3,974 weighted scans per scanner. Cornerstone did not appear to report its MRI data in either the 2019 SMFP or Draft 2020 SMFP. In the 2018 SMFP, Cornerstone reported 3,231 weighted MRI scans (2015-16 data), which is well below the 4,805 weighted scan benchmark for the service area. In the 2017 SMFP, Cornerstone reported 5,146 weighted MRI procedures, which indicates a trend of decreasing MRI volume at the site.

WFBI Kernersville – Three Zip Code Areas for Patient Shift



WFBI Kernersville failed to demonstrate the need for the proposed project by the service area population. The applicant has failed to provide MRI utilization projections based on reasonable and supported assumptions. The WFBI Kernersville application should be found non-conforming with Criterion (3).

Criterion (4) – Alternatives

WFBI Kernersville fails to demonstrate that its proposed project is the most cost-effective alternative for the development of one fixed MRI scanner in Forsyth County. As discussed under Criterion (3), WFBI Kernersville only recently initiated mobile MRI service at its facility in Kernersville. While WFBI Kernersville's application attempts to portray the Kernersville area as underserved that is clearly not the case. WFBI Kernersville has failed to demonstrate that a relatively new imaging center, located in the midst of two fixed MRI scanners and 2 additional mobile MRI host sites at Cone Health and OrthoCarolina in Kernersville, represents the most effective alternative for the development of the proposed project at a capital cost of \$2.8 million. As discussed under Criterion (6), WFBI Kernersville's proposed project results in an unnecessary duplication of existing services. Based on the applicant's statements, the WFBI facility in Winston-Salem performed 7,395 weighted scans from August 2018-July 2019. See WFBI application page 48. Considering the high MRI volume at the Winston-Salem site, the applicant offers no reasonable explanations as to why the Winston-Salem site is not an effective alternative.

From WFBI Kernersville application, page 61:

WFBI's Winston-Salem location has been offering MRI services for 11 years and has been successful in offering local access to freestanding imaging services. The MRI scanner in Winston-Salem is extremely busy. However, Forsyth County needs greater geographic diversification of its healthcare services, which have largely been concentrated in Winston-Salem. As previously stated, Kernersville is the largest town in Forsyth County that does not host a freestanding fixed MRI scanner.

The applicant does not provide any reasonable discussion that explains why a facility performing well over 7,000 weighted scans in Winston-Salem would not be an effective alternative for the project compared to a brand-new imaging center in Kernersville with less than 800 weighted procedures. The geographic diversity argument does not hold water in light of the existing fixed and mobile MRI resources in the Kernersville area. The applicant fails to demonstrate that the alternative proposed for the development of the project represents the most cost-effective alternative.

Criterion (5) – Financial Feasibility

As discussed under Criterion (3), WFBI Kernersville’s MRI utilization projections and assumptions are both unreliable and unsupported. This calls into question the reasonableness of the financial projections as they are based on the MRI utilization projections.

In Form F.2 Revenues and Net Income, it appears that WFBI has inaccurately reported its interim year (1/1/2019-12/31/2019). The applicant states that mobile MRI service did not commence until March 2019. From March 2019-July 2019, WFBI Kernersville performed 772 unweighted MRI procedures. See WFBI application pages 112-113. The most accurate way to account for CY 2019 would be to annualize the year based on 10 months of service, not 12 months of service. Therefore, the estimated procedure total for CY 2019 should be 1,544 ($772/5 \text{ months} = 154.4 \text{ procedures} \times 10 \text{ months of service} = 1,544$ procedures for CY 2019). Instead, WFBI Kernersville annualized the data using 12 months ($154.4 \times 12 = 1,853$). This also calls into question the accuracy of the operating expenses for CY 2019 reported on Form F.3 Operating Costs.

In Form F.3 Operating Costs, the mobile MRI rental expense from CY 2019 to CY 2020 inexplicably increases from \$210,000 to \$312,000. There is no explanation provided in the financial assumptions related to this increase.

WFBI application page 113:

WFBI held the CY2019 total constant for CY2020 because access to the mobile MRI scanner will remain limited to the three days per week that it is currently on site in Kernersville.

It appears based on the applicant’s statement that mobile MRI service will not increase from CY 2019 to CY 2020. There is no explanation provided regarding the difference in the mobile MRI rental expense if the service is to remain same in CY 2020 as it was in CY 2019.

As discussed below, under Criterion 7, WFBI Kernersville did not project sufficient staffing which in turn understates the staffing expenses associated with the proposed project.

WFBI Kernersville has failed to demonstrate that its financial projections are based on supported and reasonable assumptions and should be found non-conforming with Criterion (5).

Criterion (6) – Unnecessary Duplication of Existing Services

As discussed under Criterion (3), WFBI Kernersville fails to explain why its proposed project will not result in an unnecessary duplication of existing services. Considering the population size of Kernersville with approximately 25,000 residents and the existing resources - two fixed MRI sites and three mobile MRI sites currently available, the approval of another fixed MRI scanner in this geographic area is not warranted. As noted in the Novant application, both Novant fixed MRI scanners located in Kernersville have capacity at this time to serve Kernersville residents. In addition to the MRI resources in Kernersville itself, Kernersville has excellent access to MRI services in Winston-Salem, High Point and Greensboro.

While Novant Health recognized the growth potential of Kernersville long ago, it appears that the existing fixed and mobile MRI resources located in Kernersville are more than sufficient to meet the needs of eastern Forsyth County. To put this in perspective, Yadkin County, which borders western Forsyth County has a total population of 38,729² and does not have access within the county to either fixed or mobile MRI services. Another example is Stokes County in HSA II. There are 46,600 residents in Stokes County with no access to fixed or mobile MRI services within their home county. The approval of additional fixed MRI scanners for the Kernersville market would result in unnecessary duplication of existing services and does not represent the most effective alternative for the development of the 2019 need determination for Forsyth County.

Criterion (7) – Staffing

WFBI Kernersville's proposed staffing for the facility appears to be inadequate to support the projected hours of operation. The proposed hours of operation are Monday-Friday 7am – 6pm and Saturday 8am-6pm, for a total of 65 hours per week. See WFBI application page 24. In Year 1, WFBI projects it will have 1.5 MRI tech and 0.5 MRI tech assistant. In Years 2 and 3, the MRI tech assistant will increase to 0.75 FTE and 1.00 FTE. Based on the current staffing for WFBI Kernersville, the applicant has coverage for roughly 60 hours per week of service which is inconsistent with the proposed hours of operation.

As indicated on WFBI application page 62, the facility intends to use the proposed MRI scanner to complex MRI procedures. The inadequate staffing that is proposed raises questions about quality and patient safety.

² Population data from NC OBSM for July 2019 for counties mentioned.

WFBI’s proposal to obtain a 3 Tesla (3T) fixed scanner in Kernersville will be of great benefit to the local community, offering several advantages, including:

- higher resolution which produces more detailed images, which are beneficial when diagnosing pathological conditions involving the brain, spine, and musculoskeletal system.
- lower risk of distorted images, thus eliminating the need for repeated scans. The resolution and clarity enable radiologists to identify smaller lesions and anatomical structures that cannot be seen with less powerful machines.
- more sophisticated imaging procedures with more accurate diagnosis.
- shorter examination times due to the efficiency of the 3T magnet, which maximizes patient comfort without compromising quality.

Further, the front office and support staff appear to be non-existent. See the chart below:

WFBI Staff Position	# of FTES
Administrator	0.1
Business Office Supervisor	0.1
Other – Sales Liaison	0.1
Other – Business Office Specialist	1.0
Other – Clinical manager	0.1
Source: Form H – WFBI Kernersville Application	

The lack of clinical and support staffing is a quality issue considering the projected number of MRI scans to be performed at the facility (4,366 unweighted procedures in Year 3). WFBI Kernersville fails to demonstrate the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided. WFBI Kernersville should be found non-conforming with Criterion (7).

Criterion (13) - Access by the Medically Underserved

WFBI Kernersville’s proposed project does not 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 Medicare and Medicaid patients. WFBI Kernersville’s proposed project will primarily focus on service to commercial insurance patients, which accounts for nearly 80% of its patients. See application, page 92. MRI Service to Medicare patients at 11.4% and Medicaid patients at 6.65% for a total of 18.05 % hardly represents increased accessibility for the medically underserved populations. WFBI Kernersville’s relatively limited access for medically underserved residents stands in direct contrast to its statements on pages 34 and 35 about the cost advantages of freestanding MRI scanners.

Criterion (18a) – Positive Impact on Competition

WFBI Kernersville’s application will not enhance competition in the service area nor will it have a positive impact on cost-effectiveness, quality and access. WFBI Kernersville states repeatedly that it will be the first “freestanding” fixed MRI scanner in Kernersville. This statement is misleading. The residents of Kernersville have more than adequate access to both fixed and mobile MRI services within the community. Further, WFBI Kernersville will primarily focus on serving commercially-insured patients (79.79%) and does not adequately explain how its proposed project will improve access for the residents of Forsyth County, particularly the medically underserved populations.

WFBI Kernersville proposes to develop a fixed MRI scanner in a location that is saturated with existing resources considering the size of the population of Kernersville. The development of additional MRI resources in Kernersville will not represent the most effective alternative for the 2019 MRI need determination for Forsyth County at this time.

Comparative Analysis

Pursuant to N.C. Gen. Stat. § 131E-183(a)(1) and the 2019 SMFP, there is a need for one fixed MRI scanner in Forsyth County. There are two applicants in this review but only one applicant can be approved. As outlined in these comments, WFBI Kernersville’s application contains substantial flaws that render its application non-conforming with Criteria (1), (3), (4), (5), (6), (7), (13) and (18a). The WFBI Kernersville application should be denied.

Since the WFBI application is not approvable standing alone, it cannot be comparatively superior to NHI Piedmont’s application. Nevertheless, for the sake of completeness, NHI Piedmont has provided a comparative analysis based on common factors utilized by the Agency in MRI reviews.

Geographic Accessibility

NHI Piedmont and WFBI propose to locate in different areas of the Forsyth County service area.

Applicant	Proposed Location
NHI Piedmont	Winston-Salem
WFBI Kernersville	Kernersville

WFBI Kernersville’s geographic accessibility discussion centers around its claim that Kernersville does not have a “freestanding” fixed MRI scanner. WFBI Kernersville glosses over the fact that Kernersville has two existing fixed MRI scanners, one at Novant Health Kernersville Medical Center and one at Novant Health Imaging Kernersville (outpatient imaging). There is currently a total of three mobile MRI host sites at OrthoCarolina, Cone Health and WFBI Kernersville. For a community of 25,000 residents, the residents of Kernersville have exceptional access to MRI services both in Kernersville itself, and in surrounding areas such as Winston-Salem, High Point and Greensboro. As discussed in these comments, there are counties in North Carolina with greater population numbers that do not have one fixed MRI scanner.

The MRI volumes in Forsyth County clearly point in the direction of Winston-Salem as the geographic with the greatest need. The majority of MRI scanners operating in Winston-Salem are operating at high levels of capacity. NHI Piedmont has performed 12,610 weighted MRI procedures in the last year or 6,305 weighted scans per scanner. As noted in the NHI Piedmont application, Winston-Salem represents the best geographic location for the new MRI scanner for many reasons, including the overall size of Winston-Salem at 243,445 residents in 2018 compared to just over 25,000 residents for Kernersville according to data from the NC OBSM municipal estimates.

The demographic information³ for Forsyth County further supports Novant and NHI Piedmont’s determination that the proposed fixed MRI scanner should be located in Winston-Salem in order to improve accessibility for the medically underserved and indigent populations in the proposed service area. The demographic data indicates:

³ Demographic information from the www.census.gov is contained in Exhibit C of the NHI Piedmont application.

- Over 65% of the total population of Forsyth County lives in Winston-Salem;
- Of those Forsyth County residents over the age of 65 years, more than 60% reside in Winston-Salem;
- Winston-Salem has the highest percentage of residents with NO health insurance coverage at 13.4%;
- Winston-Salem has the greatest number of residents living below the poverty level at 23.3%, which is significantly higher than the Forsyth County average of 18.7%;
- Winston-Salem has the most racially diverse population with over 54% of residents belonging to non-white racial and ethnic groups;
- Winston-Salem has a high percentage of female residents in both total population and 65+ population segment than Forsyth County's percentages; and

With respect to geographic accessibility, NHI Piedmont is the most effective alternative with a Winston-Salem location.

Access by Underserved Groups

The following table provides the payor source data for each applicant.

Payor	NHI Piedmont- Year 3		WFBI – Year 3	
	Percentages	Patients	Percentages	Patients
Charity Care	0.44%	60	1.0%	44
Self Pay	3.63%	495	0.51%	22
Medicare	35.29%	4812	11.4%	498
Medicaid	5.02%	685	6.65%	290
Totals	44.38%	6,052	19.565%	854

NHI Piedmont will provide a substantial amount of service to the medically underserved populations. The primary focus of WFBI Kernersville's facility will be the provision of service to commercial insurance patients as noted in its projected payor source. Commercial insurance patients will account for 79.79% of the services provided at WFBI Kernersville. See WFBI application, page 92. NHI Piedmont is the most effective alternative regarding the provision of service to the medically underserved populations in Forsyth County.

Projected Average Gross Revenue per MRI Procedures

The projected average gross revenue per MRI procedure is a comparative factor used by the Agency but it has its limitations. The average gross revenue per MRI procedure for each facility is directly linked to the types of MRI scans performed by the facility as each individual MRI CPT code has a different monetary value. If a facility is performing more complex MRI studies, the facility's average gross revenue per procedure could be higher as result. Further, third-party payors such as Medicare, Medicaid and commercial insurers have negotiated rates that are lower than the charge schedule for each facility.

Comparison of Average Gross Revenue per Procedure for NHI Piedmont and WFBI Kernersville

Applicant	Gross Revenue	# of Unweighted Procedures	Average Gross Revenue Per Procedure
NHI Piedmont Project Year 3 (FY	\$28,425,521	13,636	\$2,085
WFBI Kernersville Project Year 3 (CY 2023)	\$8,130,100	4,366	\$1,862

Source: Form C and Form F.2 from each application.

NHI Piedmont’s average gross revenue per procedure is based on three decades of MRI service to Forsyth County. As stated in the WFBI Kernersville application, the facility has been in operation less than a full year and is unable to perform many types of MRI scans on its mobile MRI unit. See WFBI Kernersville application, page 23. While WFBI Kernersville’s estimated average gross revenue per procedure is lower than NHI Piedmont’s, there are several issues and inaccuracies in the MRI utilization methodology that render the projections from WFBI Kernersville as unreliable. With regard to projected average gross revenue per MRI procedure, NHI Piedmont is the most effective alternative.

Projected Average Net Revenue per MRI Procedures

The following table presents the projected average net revenue per MRI procedures for the third year of operation for NHI Piedmont and WFBI Kernersville based on the information provided in Form C and Form F.2 of each application.

Comparison of Average Net Revenue per Procedure for NHI Piedmont and WFBI Kernersville

Applicant	Net Revenue	# of Unweighted MRI Procedures	Average Net Revenue Per MRI Procedure
NHI Piedmont Project Year 3 (FY	\$6,404,414	13,636	\$470
WFBI Kernersville Project Year 3 (CY 2023)	\$2,44,830	4,366	\$560

Source: Form C and Form F.2 from each application.

NHI Piedmont’s average net revenue per procedure is lower than WFBI Kernersville. With regard to projected average net revenue per MRI procedure, NHI Piedmont is the most effective alternative.

Projected Average Operating Expense per MRI Procedures

The following table presents the projected average operating expense per MRI procedures for the third year of operation for NHI Piedmont and WFBI Kernersville based on the information provided in Form C and Form F.3 of each application.

Comparison of Average Operating Expense per Procedure for NHI Piedmont and WFBI Kernersville

Applicant	Operating Expenses	# of Unweighted MRI Procedures	Average Operating Expense Per MRI Procedure
NHI Piedmont Project Year 3 (FY7/1/23-6/30/24)	\$2,929,972	13,636	\$215
WFBI Kernersville Project Year 3 (CY 2023)	\$1,602,493	4,366	\$367

Source: Form C and Form F.3 from each application.

NHI Piedmont’s average operating expense per MRI procedure is significantly less than WFBI Kernersville. With regard to projected average operating expense per MRI procedure, NHI Piedmont is the most effective alternative.

Conclusion

WFBI Kernersville’s application fails to demonstrate conformity with Criteria (1), (3), (4), (5), (6), (7), (13) and (18a) and should be denied. NHI Piedmont’s application meets all applicable review criteria and standards for MRI services. Based on the comparative analysis, NHI Piedmont application is the superior applicant based on the following factors:

- NHI Piedmont is the most effective alternative regarding geographic accessibility.
- NHI Piedmont is the most effective alternative regarding average net revenue per procedure.
- NHI Piedmont is the most effective alternative regarding average operating expense per procedure.
- NHI Piedmont is the most effective alternative regarding the provision of service to the medically underserved populations, including Charity Care/Self Pay, Medicare and Medicaid patients.

Both applicants agree that MRI scanners in Winston-Salem are over capacity and are in need of relief. Unlike WFBI Kernersville, NHI Piedmont has clearly demonstrated the need the service area population has for its proposed project in Winston-Salem. NHI Piedmont will provide patients with a state of the art 3T MRI scanner for exceptional quality scans, increase accessibility for the medically underserved populations and promote a highly integrated healthcare delivery system that will specialize in neurosciences. Thus, the application submitted by NHI Piedmont should be approved.