

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 27, 2022

Findings Date: July 27, 2022

Project Analyst: Tanya M. Saporito

Co-Signer: Michael J. McKillip

Project ID #: G-12208-22

Facility: Novant Health Imaging Piedmont

FID #: 955506

County: Forsyth

Applicants: Novant Health, Inc.

Piedmont Imaging, LLC

Project: Replace existing, dedicated breast MRI scanner with a general use MRI scanner and relocate it to Novant Health Imaging Piedmont

REVIEW CRITERIA

G.S. 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.

NA

Novant Health, Inc. and Piedmont Imaging, LLC, herein after collectively referred to as Novant Health Imaging Piedmont (NHI Piedmont) or “the applicant”, propose to replace an existing dedicated breast MRI scanner with a general use MRI scanner and relocate it to NHI Piedmont.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2022 SMFP.
- acquire any medical equipment for which there is a need determination in the 2022 SMFP.

- offer a new institutional health service for which there are any policies in the 2022 SMFP.

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

C

Novant Health, Inc. and Piedmont Imaging, LLC, herein after collectively referred to as Novant Health Imaging Piedmont (NHI Piedmont) or “the applicant”, propose to replace an existing dedicated breast MRI scanner with a general use MRI scanner and relocate it to NHI Piedmont.

On November 27, 2006, in Project ID #G-7601-06, Novant Health Breast Clinic (“Novant”) was awarded a certificate of need (CON) pursuant to an adjusted need determination in the 2006 State Medical Facilities Plan (SMFP) for a dedicated, fixed breast MRI scanner. On December 18, 2015, Novant received Agency approval to replace that MRI scanner with an Aurora 1.5T general purpose MRI scanner with a specialized breast coil (the “Aurora”). Consistent with the Conditions of Approval for Project ID #G-7601-06, the Aurora scanner was restricted to breast scans only.

In 2006, pursuant to Project ID #G-7387-06, Novant acquired a 3T MRI scanner with bilateral breast coils for use at the Maplewood Imaging Center, an outpatient imaging center located in Winston-Salem. The applicant states that, because of the superior imaging quality of the 3T scanner. The Aurora was sparingly used and in 2017 was severely damaged in a flood, which rendered it useless. The Aurora remains unused in storage, and patients needing breast MRI scans are served at the Maplewood Imaging Center.

In 2021, the State Health Coordinating Council (SHCC) approved a petition filed by Novant to move the Aurora into the general MRI inventory in the 2022 SMFP for Forsyth County, thereby allowing it to perform general MRI scans and not exclusively breast scans. The MRI scanner at the Maplewood Imaging Center still performs breast MRIs.

In this application, the applicant proposes to replace the damaged Aurora MRI scanner with a new 3T MRI scanner, allowing it to perform all types of MRI scans, including breast scans. The applicant proposes to relocate the replacement MRI scanner to Novant Health Piedmont Imaging, less than one mile away from the Breast Clinic. At project completion, Novant Health Imaging Piedmont will operate a total of 3 general-use fixed MRI scanners, and the Novant Health Imaging Breast Clinic will no longer offer fixed MRI services.

Patient Origin

On page 341, the 2022 SMFP states:

“A fixed MRI service area is the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”.

Figure 5.1 on page 38 of the 2022 SMFP shows Forsyth County as a single acute care bed service area. Therefore, for the purpose of this review, the fixed MRI service area is Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin for MRI services for NHI Piedmont:

NHI Piedmont MRI Services				
COUNTY	HISTORICAL CALENDAR YEAR 2021		THIRD FULL FY OF OPERATION FOLLOWING PROJECT COMPLETION FY 2026 (10/01/25-09/30/26)	
	PATIENTS	% OF TOTAL	PATIENTS	% OF TOTAL
Forsyth	5,279	45.6%	5,825	45.6%
Davidson	1,147	9.9%	1,265	9.9%
Surry	1,004	8.7%	1,111	8.7%
Stokes	862	7.4%	945	7.4%
Yadkin	772	6.7%	856	6.7%
Davie	702	6.1%	779	6.1%
Guilford	440	3.8%	485	3.8%
Wilkes	336	2.9%	370	2.9%
Rowan	156	1.3%	166	1.3%
Randolph	93	0.8%	102	0.8%
Iredell	84	0.7%	89	0.7%
Rockingham	76	0.7%	89	0.7%
Other*	623	5.4%	690	5.4%
Total	11,574	100.0%	12,775	100.0%

Source: Application pages 32 and 35.

Numbers may not sum due to rounding.

*The applicant states “other” includes 37 other North Carolina counties and other states.

In Section C, page 35, the applicant provides the assumptions and methodology used to project its patient origin, which it states is based on the historical operating experience of NHI Piedmont. The applicant’s assumptions are reasonable and adequately supported because they are based on the applicant’s experience providing fixed MRI services to patients in the service area.

Analysis of Need

In Section C, pages 37-50, the applicant explains why it believes the population projected to utilize the proposed replacement MRI services needs the proposed services, summarized below:

- Demographic analysis – The applicant analyzed the population composition in three major areas in Forsyth County: Winston-Salem, Clemmons and Kernersville. The applicant states Winston-Salem comprises 65% of the total Forsyth County population, Kernersville comprises 7% and Clemmons comprises 5% of the Forsyth County population. Since the applicant proposes to locate the replacement MRI scanner in Winston-Salem, the applicant focused its analysis primarily on the population composition in that city and found that Winston-Salem has more residents who are more likely to use MRI services than other cities (pages 37-40).
- Population growth and aging in the service area – Citing data from the North Carolina Office of State Budget and Management, the applicant states that the over 65 population cohort in Forsyth County currently comprises 17.0% of the total county population and has increased by 10% since 2019. That population is projected to increase to 17.6% of the county population by 2024, the applicant’s first project year. The applicant also provides statistics from the National Cancer Institute that show the incidence of cancer in Forsyth County is higher than the statewide incidence. MRI scans are critical as a diagnostic tool for many types of cancer. The applicant also states that many patients declined healthcare during the COVID-19 Pandemic, which resulted in delayed diagnosis and treatment. The applicant states MRI utilization has increased since the COVID-19 Pandemic has lessened and will lead to a further increase in MRI utilization (pages 40-44).
- Demand for MRI services at NHI Piedmont and challenges facing the facility – The applicant states NHI Piedmont performed a weighted volume of 12,406 MRI scans from July 1, 2018 to June 30, 2019. In addition, the applicant states current MRI scanners operate 14 hours per day on Monday-Thursday, 12 hours on Friday and 8 hours on Saturday, which equates to 152 hours per week. That utilization, combined with space and logistical challenges with using a mobile MRI scanner, necessitate additional fixed MRI capacity at NHI Piedmont (pages 44-46).
- Distribution of Novant Health fixed MRI scanners – The applicant states it currently operates five fixed MRI scanners at acute care hospitals, four at hospital outpatient departments, and two at freestanding sites. Based on its historical utilization and the continued demand for fixed MRI services at a lower cost to patients, the applicant determined that relocating the proposed replacement fixed MRI scanner to NHI Piedmont, a freestanding facility, will provide needed access to those services for its patients (pages 46-50).

Projected Utilization

In Section Q, Form C.2a, the applicant provides historical and projected utilization for MRI services at NHI Piedmont for fiscal years (FY) 2021 - 2026, as illustrated in the following table:

NHI Piedmont Historical and Projected MRI Utilization

	HISTORICAL AND INTERIM			PROJECTED		
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
# Scanners	2	2	2	3	3	3
# MRI Scans	11,382	11,593	11,807	12,205	12,448	12,775

In Section Q, pages 1-17, the applicant provides the assumptions and methodology used to project utilization, summarized below:

- Step 1: Document historical performance of MRI scanners at Novant Health Piedmont system in Forsyth County – The applicant examined historical MRI utilization at all the Novant Health facilities in the service area, including the decrease resulting from the COVID-19 Pandemic, and determined that the overall growth in MRI utilization from October 1, 2019 through September 30, 2020 was 3.1%. The applicant states that MRI volume continues to increase across all Novant Health sites.
- Step 2: Establish a project year start date – The applicant consulted with its planning and development and other internal departments and determined that October 1, 2023 represents the best start date for the project.
- Step 3: Determine growth rate for future MRI utilization based on historical utilization – The applicant states the proposed 3T MRI scanner will allow referring physicians enhanced imaging capabilities in breast, neurological, orthopedic and other specialized MRI scans. Referrals for MRI scans at NHI Piedmont has continued to increase because the number of referring physicians has increased since 2018. The applicant calculated the compound annual growth rate (CAGR) for MRI utilization at NHI Piedmont from FY 2018 to FY 2021 to be 3.7%, despite the decrease during the COVID-19 Pandemic during FY 2020. The applicant projects future MRI utilization using 1.85%, one-half of the historical CAGR, stating that MRI utilization has rebounded to pre-COVID levels.
- Step 4: Project the number of breast MRI scans to be performed at NHI Piedmont – The applicant examined historical utilization at NHI Piedmont and at its Maplewood facility, since the majority of the breast MRI scans have been performed at the Maplewood facility following the damage to the Aurora MRI scanner. The applicant states the proposed 3T MRI scanner will have a breast MRI coil, allowing NHI Piedmont to provide breast MRI scans for its patients. The applicant cited statistics that show Forsyth County residents have a higher incidence rate of breast cancer than the North Carolina average, and that females in the general population and in the over 65 population of the county comprise over half the population. The applicant states it discussed the proposal with referring physicians and determined the following number of referrals:

NHI Piedmont Referring Physician Breast MRI Projections

PROJECT YEAR IN FY: 10/1 – 9/30	ESTIMATED MONTHLY REFERRALS	PROJECTED ANNUAL UNWEIGHTED BREAST MRI SCANS
1 – FY 2024	15	180
2 – FY 2025	20	240
3 – FY 2026	25	300

Source: Application Section Q, Utilization Assumptions, page 11

The applicant provides referral letters in Exhibit C.4 from physicians in the Novant Health Prevention and Wellness Clinic, a clinic that offers genetic testing and counseling for women who are at high risk for developing breast cancer. The applicant states these letters support the projected referrals to NHI Piedmont.

- **Step 5:** Determine a contrast percentage from historical MRI utilization at NHI Piedmont to project future contrast MRIs – The applicant examined historical MRI scans with contrast at NHI Piedmont from FY 2018 to FY 2021 and determined the average percentage of MRI scans with contrast was 22.5% of total MRI scans. The applicant projects future contrast MRI scans using the same 22.5% average.
- **Step 6:** Determine a contrast percentage from historical breast MRI utilization at Maplewood to project future contrast breast MRIs – The applicant examined historical breast MRI scan utilization at its Maplewood facility, where the majority of the breast MRIs in the area are performed, to determine the contrast percentage at that facility. The applicant states contrast improves the diagnostic accuracy of MRI scans, which is critical for breast imaging. The applicant determined that 99.7% of all breast MRI scans performed at its Maplewood facility from FY 2018 to FY 2021 involved contrast. The applicant states it is reasonable to assume that same percentage of breast MRI scans to be performed at NHI Piedmont. The applicant thus determined how many of its total MRIs will be breast MRIs and applied the 99.7% contrast percentage to the projected breast MRIs.
- **Step 7:** Combine the weighted totals for general MRIs and breast MRIs to determine overall weighted MRI volume for the three project years – The applicant determined that NHI Piedmont will perform 14,018 total weighted MRI scans by project year three, FY 2026. NHI Piedmont will have three fixed MRI scanners at its facility, which would be an average of 4,673 weighted MRI scans per MRI scanner [14,018 total scans / 3 fixed MRI scanners = 4,673]. The Performance Standards promulgated at 10A NCAC 14C .2703 do not apply to a review for replacement equipment; however, using those standards as a guide, the applicant’s projections would exceed the minimum threshold of 3,364 weighted MRI scans per fixed MRI scanner.

Projected utilization is reasonable and adequately supported based on the following:

- The applicant relied on its general historical MRI utilization as the starting point for projecting future utilization.

- The applicant relied on historical breast MRI utilization to determine future breast MRI scans to be performed at the NHI Piedmont facility.
- The applicant relied on demographic data to analyze the population in the service area most likely to utilize both general and breast MRI services.

Access to Medically Underserved Groups

In Section C, page 55, the applicant states:

“Any patient, regardless of income, racial and ethnic background, sex, disability, age or payor status, will have access to the imaging services at NHI Piedmont with the appropriate physician referral.”

On page 55, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table:

MEDICALLY UNDERSERVED GROUPS	% OF TOTAL PATIENTS
Low income persons	57.6%
Racial and ethnic minorities	*
Women	61.0%
Persons with disabilities	*
Persons 65 and older	69.4%
Medicare beneficiaries	34.8%
Medicaid recipients	3.6%

Source: Section C, page 55

*The applicant states it does not require patients to identify their racial background or physical disabilities.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant states that it will provide access to all underserved groups.
- The applicant provides supporting documentation of the access it provides and programs to assist the underserved in Section L.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

- (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, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

In Section D, page 60, the applicant explains why it believes the needs of the population presently utilizing the MRI services to be relocated will be adequately met following completion of the project. The applicant states the existing MRI scanner at the Breast Center has not been operational since it was damaged in a flood. In addition, on page 60, the applicant states:

“The proposed project has no impact on MHI Breast Center’s current operations as it will continue to offer diagnostic and screening mammography, breast biopsy and other services for its patients. NHI Breast Center patients in need of breast MRI scans will then have access to 3T imaging at NHI Maplewood or NHI Piedmont as a result of the proposed project.”

The applicant states NHI Piedmont currently offers a full range of imaging modalities for women, including screening and diagnostic mammography and breast imaging. Additionally, the applicant states the NHI Piedmont is less than one mile from the Breast Center, so no travel or access hardships will result from this project.

The information is reasonable and adequately supported because the applicant provides information to show the patients presently served will continue to be served following the proposed relocation of the MRI scanner less than one mile from its current location.

Conclusion

The Agency reviewed the:
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- Application
- Exhibits to the application

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

- (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.

CA

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

In Section E, pages 64-66, 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:

- Use mobile MRI service – the applicant states mobile MRI services are insufficient to meet the increasing needs of NHI Piedmont’s patient population, particularly claustrophobic and obese patients, which make up approximately 33% of the state’s population. The applicant states over 3,000 of its patients are either obese or claustrophobic, and mobile MRI service does not serve those patients or address existing capacity constraints. Thus, the applicant states this alternative is not effective to meet patient needs.
- Refer patients to other facilities for MRI services – the applicant states Novant Health operates 10 fixed MRI scanners in Forsyth County, five of which are hospital-based and five of which are at outpatient facilities. According to the applicant, each of those facilities provides MRI services to each varying patient population and to the physicians who refer patients for specialized scans (breast, brain and spine, for example). The applicant states that referring its patients to other facilities is not an effective alternative because it fails to address the ongoing demand for additional fixed MRI capacity at NHI Piedmont and its referring physicians.

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

- The applicant provides reasonable and adequately supported information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above. Therefore, the application is approved subject to the following conditions:

- 1. Novant Health, Inc. and Piedmont Imaging, LLC (hereinafter certificate holders) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holders shall acquire no more than one replacement fixed MRI scanner to be located at Novant Health Imaging Piedmont.**
- 3. Upon completion of the project, Novant Health Imaging Piedmont shall have no more than three fixed MRI scanners.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holders shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holders shall complete all sections of the Progress Report form.**
 - c. The certificate holders shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on January 2, 2023.**
- 5. The certificate holders 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.**
- 6. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holders 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.

7. The certificate holders 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.

- (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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

Capital and Working Capital Costs

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

Construction Costs	\$377,000
Medical Equipment	\$1,545,650
Miscellaneous Costs	\$120,000
Total	\$2,042,650

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- In Exhibit F.1, the applicant provides an equipment quote for the proposed MRI.
- In Exhibit K.3, the applicant provides a renovation cost estimate signed by an architect which includes a cost break down and which matches the construction cost listed on Form F.1a.

In Section F.3, page 69, the applicant states there will be no working capital costs because it is an existing facility currently offering MRI services.

Availability of Funds

In Section F, page 67, the applicant states the capital cost will be funded through the accumulated reserves of Novant Health, Inc.

Exhibit F.2 contains a letter signed by the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health Inc., which commits to funding the capital cost from

accumulated reserves of Novant Health, Inc. Exhibit F.2 also contains the most recent Novant Health, Inc. audited financial statements documenting the availability of the necessary funds.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- The applicant provides documentation of Novant Health, Inc.'s commitment to use the necessary funding toward development of the proposed project.
- The applicant documents the availability of sufficient financial resources to fund the proposed capital cost.

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.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project for both MRI services and NHI Piedmont as a whole. The following table shows the projections for the MRI services:

NHI PIEDMONT MRI SERVICES			
	FY 2024	FY 2025	FY 2026
# of Scans	12,205	12,448	12,775
Gross Revenue	\$28,443,753	\$29,010,064	\$29,772,138
Net Revenue	\$4,805,856	\$4,901,540	\$5,030,300
Average Net Revenue per MRI Scan	\$394	\$394	\$394
Operating Costs	\$2,728,614	\$2,877,298	\$2,934,213
Average Operating Costs per MRI Scan	\$224	\$231	\$230
Net Profit	\$2,077,242	\$2,024,242	\$2,096,087

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant accounts for projected operating expenses and clearly explains the revenue projections.
- Projected utilization is based on reasonable and adequately supported assumptions. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 cost is based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- (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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

On page 341, the 2022 SMFP states:

“A fixed MRI service area is the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”.

Therefore, for the purpose of this review, the fixed MRI service area is Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Forsyth County service area, summarized from Table 17E-1, page 349 of the 2022 SMFP:

FORSYTH COUNTY FIXED MRI SCANNERS			
FACILITY	# OF LINACS	TOTAL # OF PROCEDURES	AVERAGE # OF PROCEDURES/UNIT
North Carolina Baptist Hospital	6	22,214	3,702
Novant Health Forsyth Medical Center	3	10,768	3,589
Novant Health Forsyth MC-Clemmons	1	1,451	1,451
Novant Health Imaging-Kernersville	2	3,189	1,594
Novant Health-Maplewood	2	7,662	3,831
Novant Health Breast Clinic	1	0	0
Piedmont Imaging	2	9,760	4,880
Wake Forest Baptist Imaging	1	8,870	8,870
Wake Forest Baptist Imaging-Kernersville	1	0	0
Total Forsyth County MRI Scanners	19	63,914	3,364

Source: Table 17C-1, page 349, 2022 SMFP

In Section G, pages 75-76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI services in Forsyth County. The applicant states the Aurora breast MRI scanner that was approved in 2006 not only became obsolete as technological changes were not adapted by the manufacturer, but also was

irreparably damaged in a flood. The applicant states current and projected MRI volume in the service area demonstrates a need for 2.6 additional MRI scanners at NHI Piedmont [12,406 total procedures / 4,805 threshold = 2.58]. The applicant proposes to replace the Aurora with a 3T MRI scanner, providing superior imaging and breast capability. Relocating the proposed replacement scanner to NHI Piedmont rather than the Breast Clinic will also improve patient access to specialized breast scans and general MRI scans.

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

- The applicant uses its historical utilization to support the need to replace its existing MRI scanner.
- The applicant does not propose to increase the number of fixed MRI scanners in the service area .

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described 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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

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

NHI PIEDMONT STAFFING – CURRENT AND PROJECTED				
POSITION	CURRENT	PROJECTED		
	As of 1/1/21	FY 2024	FY 2025	FY 2026
Chief Technician	1.0	1.0	1.0	1.0
CT Technician	1.0	1.0	1.0	1.0
Mammography Technician	3.1	3.1	3.1	3.1
MRI Technician	3.5	4.5	4.5	4.5
Radiographer, Multimodality	1.0	1.0	1.0	1.0
Radiology Technician	4.2	4.2	4.2	4.2
Sonographer	3.5	3.5	3.5	3.5
Administrator	1.0	1.0	1.0	1.0
Patient Access Specialist	6.1	7.1	7.1	7.1
Radiology Operations Assistant	4.5	5.5	5.5	5.5
Supervisor Clerical	1.0	1.0	1.0	1.0
Total	30.0	33.0	33.0	33.0

The assumptions and methodology used to project staffing are provided in Sections H and Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3(b). In Section H, pages 77-79, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant currently has sufficient staff and has projected sufficient staff to operate the replacement fixed MRI scanner once it is operational.
- The applicant provides supporting documentation of its existing training and continuing education programs in Exhibit H.3.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

Ancillary and Support Services

In a table in Section I, page 80, the applicant identifies the necessary ancillary and support services for the proposed fixed MRI services. In Section H, page 81 the applicant explains how each ancillary and support service is and will be available. The applicant adequately demonstrates that the necessary ancillary and support services are and will be made available because it is already providing all of the necessary ancillary and support services necessary for the proposed replacement fixed MRI scanner.

Coordination

In Section I, page 82, the applicant describes its existing and proposed relationships with other local health care and MRI providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system because the applicant is already coordinating services with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

The applicant does not project 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, the applicant does not project 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

The applicant is not 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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

In Section K, page 85, the applicant states that the project involves renovating approximately 900 square feet of existing space. Line drawings are provided in Exhibit K.2.

In Section K, page 85, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal. The applicant states it worked closely with an architect and a general contractor on the project. The estimated renovation costs were reviewed by those people, who have worked on prior projects with the applicant. Exhibit K.3 provides a letter from the architect verifying construction costs and measures that will be taken to contain costs.

In Section K, page 86, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states its plan to utilize existing space results in capital cost savings.

On page 86, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 persons with disabilities, 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

In Section L, page 88 the applicant provides the historical payor mix during FY 2021 (October 1, 2020-September 30, 2021) for the its existing services at NHI Piedmont, as shown in the table below:

NHI Piedmont Historical Payor Mix, FY 2021

PAYOR CATEGORY	SERVICES AS % OF TOTAL
Self-Pay	3.65%
Charity Care	1.65%
Medicare	39.20%
Medicaid	4.20%
Insurance	46.00%
Workers Compensation	3.90%
TRICARE	1.40%
Total	100.00%

Source: Application page 88

In Section L, page 89, the applicant provides the following comparison:

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	61.0%	52.6%
Male	39.0%	47.4%
Unknown	--	--
64 and Younger	30.6%	84.0%
65 and Older	69.4%	16.0%
American Indian	*	0.9%
Asian	*	2.6%
Black or African-American	*	27.5%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	66.7%
Other Race	*	13.0%
Declined / Unavailable	--	--

*The applicant states NHI Piedmont patients are not required to identify racial background.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 90, the applicant states it has no such obligation.

In Section L, page 90, the applicant states that no patient civil rights equal access complaints have been filed against NHI Piedmont or Novant Health in the 18 months immediately preceding the application deadline.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

In Section L, page 91, the applicant projects the following payor mix for NHI Piedmont as a whole and NHI Piedmont MRI services during the third full fiscal year of operation following completion of the project, as shown in the tables below:

NHI Piedmont Projected Payor Mix, FY 2026

PAYOR CATEGORY	MRI SERVICES AS % OF TOTAL
Self-Pay	3.65%
Charity Care	1.65%
Medicare	39.20%
Medicaid	4.20%
Insurance	46.00%
Workers Compensation	3.90%
TRICARE	1.40%
Total	100.00%

Source: Application page 91

NHI Piedmont MRI Services Projected Payor Mix, FY 2026

PAYOR CATEGORY	MRI SERVICES AS % OF TOTAL
Self-Pay	1.35%
Charity Care	2.85%
Medicare	36.10%
Medicaid	4.50%
Insurance	46.50%
Workers Compensation	6.70%
TRICARE	2.00%
Total	100.00%

Source: Application page 91

As shown in the tables above, during the third full fiscal year of operation, the applicant projects that 3.65% of total services provided by NHI Piedmont will be provided to

self-pay patients, 39.2% and 4.2% of total services will be provided to Medicare and Medicaid patients, respectively.

Additionally, during the third full fiscal year of operation, the applicant projects that 1.35% of MRI services provided by NHI Piedmont will be provided to self-pay patients, 36.1% and 4.5% of total MRI services will be provided to Medicare and Medicaid patients, respectively.

On page 91, the applicant provides the assumptions 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 the applicant's historical payor mix for all of NHI Piedmont services and MRI services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

In Section L, page 92, the applicant did not respond to the question regarding the means by which a patient will have access to the MRI services. However, the applicant has been providing MRI services in the service area. This application is for a replacement MRI scanner that is damaged and unusable. Additionally, in Section C, pages 45 and 47, the applicant describes how physicians will refer patients to the new MRI scanner with advanced breast and general technology. In Exhibit C, the applicant provides support letters from physicians that indicate an intent to refer patients for both breast and general MRI scans. The applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- 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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

In Section M, page 93, 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 applicant describes the educational programs currently in place in Section M, page 93. The applicant adequately demonstrates that health professional training programs in the area have and will have access to the facility for training purposes.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

On page 341, the 2022 SMFP states:

“A fixed MRI service area is the same as an Acute Care Bed Service Area as defined in Chapter 5 and shown in Figure 5.1”.

Therefore, for the purpose of this review, the fixed MRI service area is Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following table identifies the existing and approved fixed MRI scanners located in the Forsyth County service area, summarized from Table 17E-1, page 349 of the 2022 SMFP:

FORSYTH COUNTY FIXED MRI SCANNERS			
FACILITY	# OF LINACS	TOTAL # OF PROCEDURES	AVERAGE # OF PROCEDURES/UNIT
North Carolina Baptist Hospital	6	22,214	3,702
Novant Health Forsyth Medical Center	3	10,768	3,589
Novant Health Forsyth MC-Clemmons	1	1,451	1,451
Novant Health Imaging-Kernersville	2	3,189	1,594
Novant Health-Maplewood	2	7,662	3,831
Novant Health Breast Clinic	1	0	0
Piedmont Imaging	2	9,760	4,880
Wake Forest Baptist Imaging	1	8,870	8,870
Wake Forest Baptist Imaging-Kernersville	1	0	0
Total Forsyth County MRI Scanners	19	63,914	3,364

Source: Table 17C-1, page 349, 2022 SMFP

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 94, the applicant states:

“The additional MRI capacity at NHI Piedmont will provide the facility with improved accessibility for patient in need of imaging services. The availability of a 3T MRI scanner in a convenient and affordable outpatient setting committed to providing patients with the highest clinical quality of care will set a standard in the service area for other providers to model. NHI Piedmont’s commitment to its patients and referring physicians to offer outstanding service in turn hold all providers to a higher standard of excellence.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 94, the applicant states:

“Novant Health is collaborating with payors and partners to identify payment models that match Novant Health’s value-based care delivery. Getting the right care in the right setting at the right price is the future of healthcare. ... It is Novant Health’s new approach to delivering remarkable healthcare that people can get better and stay healthy. The approval of the proposed project will create access to enhanced 3T MR imaging in a low-cost setting.”

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 95, the applicant states:

*“NHI Piedmont is committed to providing exceptional quality of care for service area residents. The American College of Radiology (ACR) provides a rigorous accreditation process that mandates each facility offer outstanding quality in order to bear its seal.
...*

In addition to maintaining its ACR accreditation status, NHI Piedmont adheres to all applicable Novant Health quality and safety policies.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 95-96, the applicant states:

“NHI Piedmont will continue to provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin or ability to pay. Based on historical data, NHI Piedmont currently provides a substantial amount of service to the medically underserved groups. For example, 72% of its patients are females and 35% are over the age of 65 years. Over 44% of its patients fall under the following categories: indigent, self-pay, Medicare and Medicaid.”

See also Sections C and L of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application

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

The applicant proposes to replace an existing dedicated breast MRI currently located at the Novant Health Imaging Breast Center with a new general use MRI scanner, and relocate the replacement MRI scanner to Novant Health Imaging Piedmont.

In Section Q Form O, the applicant identifies the diagnostic centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 32 diagnostic centers located in North Carolina.

In Section O, page 98, the applicant states that all of the facilities identified in Section A.4 have provided quality care during the 18 months immediately preceding the submittal of the application. After reviewing and considering information provided by the applicant, the Agency determines that the applicant provided 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.

G.S. 131E-183 (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.

NA

The applicant proposes to replace an existing fixed MRI scanner currently located at the Breast Clinic and relocate it to NHI Piedmont. The Criteria and Standards for Magnetic Resonance Imaging Scanners, which are promulgated in 10A NCAC 14C .2700, are not applicable to this review because they do not apply to proposals to replace existing MRI scanners.