

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: March 28, 2025

Findings Date: April 4, 2025

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: B-12567-24

Facility: Novant Health Asheville Imaging Center

FID #: 240865

County: Buncombe

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

Project: Develop a diagnostic center

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.

C

Novant Health Asheville Imaging Center, LLC and Novant Health, Inc., herein after collectively referred to as “the applicant,” propose to develop a diagnostic center unit in an upfitted medical office building in Buncombe County, by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one bone density (DXA). The diagnostic center will be an Independent Diagnostic Testing Facility (IDTF) located in Asheville and named NH Asheville Imaging Center (“NH Asheville”).

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2024 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

One policy in Chapter 4 of the 2024 SMFP is applicable to this application: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4 on page 30 of the 2024 SMFP states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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

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

The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 25, the applicant describes the project’s plan to improve energy efficiency and water conservation.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 based on the following:

- The applicant does not propose to develop any beds, services, or equipment for which there is a need determination in the 2024 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* based on the following:
 - The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to ensure improved energy efficiency and water conservation.
 - The applicant states it will develop and implement an Energy Efficiency and Sustainability Plan for the project as required by the CON Section, that will not adversely affect patient or resident health, safety, or infection control.

(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.

NC

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. The applicant proposes locating the diagnostic center in an existing building space in Buncombe County. The applicant is also proposing to serve Henderson County. Thus, the service area is Buncombe and Henderson counties. Facilities may also serve residents not included in the defined service area.

The applicant is proposing to develop a new facility in the service area. There is no historical patient origin to report. The following tables illustrate projected patient origin.

NH Asheville Imaging Center Projected Patient Origin Entire Facility						
County	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2026- 12/31/2026		01/01/2027- 12/31/2027		01/01/2028- 12/31/2028	
	CY 2026		CY 2027		CY 2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Buncombe	2,685	63.0%	5,418	63.0%	7,025	63.0%
Henderson	1,151	27.0%	2,322	27.0%	3,011	27.0%
Other	426	10.0%	860	10.0%	1,115	10.0%
Total	4,263	100.0%	8,600	100.0%	11,150	100.0%

Source: Section C, page 50

Totals may not foot due to rounding.

NH Asheville Imaging Center Projected Patient Origin By Service Component						
CT Service						
County	1st Full FY		2nd Full FY		3rd Full FY	
	CY 2026		CY 2027		CY 2028	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Buncombe	630	63.0%	1,276	63.0%	1,607	63.0%
Henderson	270	27.0%	547	27.0%	689	27.0%
Other	100	10.0%	203	10.0%	255	10.0%
Total	1,000	100.0%	2,025	100.0%	2,550	100.0%
Ultrasound						
Buncombe	1,008	63.0%	2,032	63.0%	2,741	63.0%
Henderson	432	27.0%	871	27.0%	1,175	27.0%
Other	160	10.0%	323	10.0%	435	10.0%
Total	1,600	100.0%	3,225	100.0%	4,350	100.0%
Mammography						
Buncombe	788	63.0%	1,591	63.0%	2,016	63.0%
Henderson	338	27.0%	682	27.0%	864	27.0%
Other	125	10.0%	253	10.0%	320	10.0%
Total	1,250	100.0%	2,525	100.0%	3,200	100.0%
DXA Scan						
Buncombe	260	63.0%	520	63.0%	682	63.0%
Henderson	111	27.0%	223	27.0%	284	27.0%
Other	41	10.0%	83	10.0%	105	10.0%
Total	413	100.0%	825	100.0%	1,050	100.0%

Source: Section C, pages 49-50

Totals may not foot due to rounding.

In Section C, pages 48 and 50, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant's patient origin percentages are based on the applicant's experience operating IDTFs.
- The applicant reasonably projects patient origin based on the assumption that the level of services offered will benefit patients from in and outside the service area.
- The proposed project will serve as a lower cost and convenient alternative to hospital-based imaging services.

Analysis of Need

In Section C, page 51-58, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

The applicant states that the need for proposed services is based on several factors. The proposal includes the development of an IDTF-based diagnostic center to include CT, ultrasound, mammography, and DXA services. The applicant states that the proposed diagnostic center will offer high-quality diagnostics services at a lower price than imaging services offered at a hospital or a hospital outpatient department (HOPD). The applicant states that CT, ultrasound, mammography, and DXA services can provide patient-centered care, a streamlined diagnostic process, and safety and convenience for vulnerable populations. Additionally, the proposed diagnostic center will add capacity and expand access to diagnostic services while meeting the growing demand as the service area continues to grow and age.

The information is reasonable and adequately supported based on the following:

- The applicant cites data from North Carolina Office of State Budget Management (NCOSBM) to illustrate the projected growth and aging of the population in the service area which demonstrates the need to maintain capacity and expand access for diagnostic imaging.
- The applicant adequately demonstrates how the proposed diagnostic center will serve as a cost-effective and convenient alternative to hospital-based imaging services for service area residents.

Projected Utilization

In Section Q, Form C.2a, the applicant provides projected utilization, as illustrated in the following tables.

NH Asheville Imaging Center Projected Utilization			
	1st Full FY	2nd Full FY	3rd Full FY
	FY 2026	FY 2027	FY 2028
<i>CT Scanner</i>			
# of Unit	1	1	1
# of Scans	1,000	2,025	2,550
# of HECT Units	1,703	3,449	4,343
<i>DXA Scan</i>			
# of Units	1	1	1
# of Procedures	413	825	1,050
<i>Mammography</i>			
# of Units	3	3	3
# of Procedures	1,250	2,525	3,200
<i>Ultrasound</i>			
# of Units	2	2	2
# of Procedures	1,600	3,225	4,350

In Section Q, *Utilization Methodology and Assumptions*, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

To project the number of imaging procedures to be performed at NH Asheville, the applicant begins its methodology by identifying the number imaging procedures performed annually in the service area. The applicant considers “*Key Demographic Variables*” such as age and sex distribution among procedures. For example, gender or age-specific procedures such as mammograms performed on women over 40 or DXA scans perform on older individuals.

The applicant estimates the imaging utilization rates for each modality based on unidentified statistical data of procedures performed in North Carolina. This includes demographic utilization and population data. The applicant applies the data to determine the projected utilization of outpatient procedures (by modality) per 1,000 members of the population.

CT scans

According to the data, approximately 1.5 million CT scans were performed in North Carolina and 80 percent were outpatient.

$$(Total\ CT\ Scans\ \times\ Outpatient\ \%) / (Total\ NC\ Population / 1,000) \\
 (1,500,000\ \times\ 80\%) / (10,842,949 / 1,000) = 110.7\ CT\ scans\ per\ 1,000$$

Mammograms

Approximately 700,000 mammograms were performed in North Carolina. According to data from the U.S. Preventive Services Task Force, 60 percent of females aged 40 and older received a mammogram annually and almost 100 percent were performed on females aged 18 and older.

$(\text{Total Mammograms} \times \% \text{ of Females Over } 18+) / (\text{Total NC Female } 18+ / 1,000)$
 $(700,000 \times 100\%) / (4,473,390 / 1,000) = 156.5 \text{ mammograms per } 1,000$

DXA Scans

Approximately 200,000 DXA scans were performed in North Carolina. According to the data, 70 percent were performed on females aged 50 and over and 30 percent on males aged 50 and over.

$(\text{Total DXA Scans} \times \% \text{ of Females } 50+) / (\text{Total NC Females } 50+ / 1,000)$
 $(200,000 \times 70\%) / (2,153,935 / 1,000) = 65.0 \text{ DXA Scans per } 1,000$

$(\text{Total DXA Scans} \times \% \text{ of Males } 50+) / (\text{Total NC Males } 50+ / 1,000)$
 $(200,000 \times 30\%) / (1,832,281 / 1,000) = 32.7 \text{ DXA Scans per } 1,000$

Ultrasound

Approximately 1,200,000 outpatient ultrasounds were performed in North Carolina. According to the data, 90 percent were performed on females aged 18 and over and 10 percent on males aged 50 and over.

$(\text{Total Ultrasounds} \times \% \text{ of Females } 18+) / (\text{Total NC Females } 18+ / 1,000)$
 $(1,200,000 \times 90\%) / (4,473,390 / 1,000) = 241.1 \text{ Ultrasounds per } 1,000$

$(\text{Total Ultrasounds} \times \% \text{ of Males } 18+) / (\text{Total NC Males } 18+ / 1,000)$
 $(1,200,000 \times 10\%) / (4,098,077 / 1,000) = 29.3 \text{ Ultrasounds per } 1,000$

Using the utilization rates, including the demographic data illustrated above, and the total projected service area population, the applicant calculates the projected imaging modality market. The Project Analyst is unable to determine how the applicant arrived at the calculations for DXA and Ultrasound, which would subsequently affect the calculations for modality market and volume.

CT scans (for service area total population):

$(\text{Total Service Area Population} / 1,000) \times \text{CT Scan Rate per } 1,000$

2026: $(409,609 / 1,000) \times 110.7 = 45,332 \text{ CT scans } [45,344]$

2027: $(413,956 / 1,000) \times 110.7 = 45,813 \text{ CT scans } [45,828]$

2028: $(418,307 / 1,000) \times 110.7 = 46,294 \text{ CT scans } [46,307]$

Mammograms (for service area female 18+ population):

$(\text{Service Area Female } 18+ \text{ Population} / 1,000) \times \text{Mammogram Rate per } 1,000$

2026: $(179,126 / 1,000) \times 156.5 = 28,030 \text{ Mammograms } [28,033]$

2027: $(181,358 / 1,000) \times 156.5 = 28,379 \text{ Mammograms } [28,383]$

2028: $(183,567 / 1,000) \times 156.5 = 28,725 \text{ Mammograms } [28,728]$

DXA Scans (for service area female and male 50+ population):

(Service Area Female 50+ Population x DXA Rate per 1,000) +
 (Service Area Female 50+ Population x DXA Rate per 1,000)

2026: $(99,090 / 65.0) + (83,832 \times 32.7) = 9,186$ DXA Scans
 2027: $(100,635 / 65.0) + (85,224 \times 32.7) = 9,332$ DXA Scans
 2028: $(102,165 / 65.0) + (86,569 \times 32.7) = 9,475$ DXA Scans

Ultrasounds:

(Service Area Female 18+ Population x Ultrasound Rate per 1,000) +
 (Service Area Female 18+ Population x Ultrasound Rate per 1,000)

2026: $(179,126 / 241.4) + (163,118 \times 29.3) = 48,022$ Ultrasounds
 2027: $(181,358 / 241.4) + (165,243 \times 29.3) = 48,623$ Ultrasounds
 2028: $(183,567 / 241.4) + (167,333 \times 29.3) = 49,218$ Ultrasounds

The applicant projects to capture a market share of the imaging procedures by modality. The applicant’s projections are based on Novant Health’s experience providing health services in the service area and in western, North Carolina. The applicant estimates that NH Asheville will capture 10 percent of mammograms, 10 percent DXA scans, eight percent of ultrasound procedures and five percent of CT scans by the third project year. The applicant states that projected volumes are reasonable and conservative considering Novant Health’s experience with imaging centers during startup and development, and the expansion of the physician network.

Projected Tiered, Service Area Imaging Modality Market Percentage			
	2026	2027	2028
CT	2.0%	4.0%	5.0%
Ultrasound	3.0%	6.0%	8.0%
Mammography	4.0%	8.0%	10.0%
DXA Scan	4.0%	8.0%	10.0%

The applicant applies the projected percentages by modality, illustrated above, to the projected imaging modality market calculations.

Projected Service Area Imaging Modality Market			
	2026	2027	2028
CT	45,332	45,813	46,294
Ultrasound	48,022	48,623	49,218
Mammography	28,030	28,379	28,725
DXA Scan	9,186	9,332	9,475

Projected Service Area Imaging Modality Volumes			
	2026	2027	2028
CT	900	1,823	2,295
Ultrasound	1,440	2,903	3,915
Mammography	1,125	2,273	2,880
DXA Scan	372	743	945

Calculation: Projected Tiered Service Area Imaging Modality Market Percentages x Projected Service Area Imaging Modality Market

The applicant assumes that 90 percent of volume will originate from the service area and 10 percent will originate from surrounding counties. The following table illustrates the total projected imaging modality volumes originating from surrounding counties, based on the percentage assumptions.

Projected Imaging Modality Volumes from In-migration			
	2026	2027	2028
CT	100	203	255
Ultrasound	160	323	435
Mammography	125	253	320
DXA Scan	41	83	105

Calculation: 10% of Total Projected Imaging Modality Volumes

The following table illustrates the volumes that originated from the service area combined with the volumes originated from surrounding counties.

Total Projected Imaging Modality Volumes			
	2026	2027	2028
CT	1,000	2,025	2,550
Ultrasound	1,600	3,225	4,350
Mammography	1,250	2,525	3,200
DXA Scan	413	825	1,050

Calculation: Projected Service Area Imaging Modality Market volumes + Projected Imaging Modality Volumes from Immigration.

The applicant states that projections are reasonable and conservative. To validate its projections, the applicant identifies FY 2023 outpatient imaging modality volumes for service area hospitals, except for CT scans because they are not differentiated between inpatient and outpatient. The applicant states that the actual imaging modality market in the service area could be significantly higher than projected, considering the other imaging modality providers in the services that do not report volumes and are not included in the FY 2023 data for service area hospitals.

Reported Imaging Modality Volumes				
	Mission Hospital	UNC Pardee	AdventHealth Hendersonville	Total
CT	86,254	21,972	23,997	132,223
Ultrasound	20,901	7,996	4,211	33,108
Mammography	48,123	21,064	5,693	74,880
DXA Scan	1,311	3,987	288	5,586

Source: 2024 Hospital License Renewal Application (FY 2023 data)

Projected utilization is not reasonable and adequately supported based on the following:

- To project use rates in the service area and subsequent market share, the applicant relied on statewide statistical data related to modality use rates. However, the applicant relied on data that does not include the timeframe of data and in some instances does not include the source of the data. The project Analyst is unable to determine if the information is reliable and sufficient to support the applicant's projections. Therefore, the applicant's service area use rates and subsequent market share projections are not adequately supported.
- The applicant projects that market share percentages by modality will be no more than 10 percent. This is based on Novant Health's presence as a provider in Western North Carolina. This includes Novant Health's affiliates in the service area such as Open MRI and imaging of Asheville, GoHealth Urgent Care, Novant Health Surgical Partners-Biltmore, and the potential recruitment of physician practices. Assumptions regarding market share based on the potential expansion of services and access can be reasonable. However, the applicant does not provide any historical utilization or market share data of existing providers in the service area to support the applicant's projected market share. Therefore, projected utilization is not reasonable or adequately supported.
- Based on the applicant's assumptions and methodology, the Project Analyst attempted to verify the applicant's final projections. The Project Analyst arrived at different calculations for CT scans and Mammograms. (See Project Analyst's calculations in brackets.) The difference was not that significant since it could be the result of rounding. However, as previously stated, the Project Analyst is unable to determine how the applicant arrived at the calculations for DXA and Ultrasound, which would subsequently affect the calculations for modality market share and volume. The steps taken by the applicant to arrive at those calculations were not clearly explained. The Project Analyst was unable to verify the applicant's final projections. Therefore, projected utilization is not reasonable or adequately supported.

Access to Medically Underserved Groups

In Section C, page 64, the applicant states:

"NH Asheville Imaging Center will not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. NH Asheville Imaging Center will participate in both the Medicaid and Medicare programs.

Furthermore, Novant Health does not exclude from participation, deny benefits to, or otherwise discriminate against patients, students, or visitors on the basis of race; color; religion; national origin; culture; language; physical or mental disability; age; sex, including pregnancy, childbirth or related medical conditions; marital status; sexual orientation; gender identity or expression; socioeconomic status; source of payment; or any other protected status in admission to, participation in, or receipt of the services and benefits of any of its programs and activities, whether carried out by Novant Health directly or through a contractor or other entity with whom Novant Health arranges to carry out its programs and activities.

Novant Health facilities and programs do not discriminate against the listed persons, or other medically underserved persons, regardless of their ability to pay.”

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	14.0%
Racial and ethnic minorities	17.5%
Women	82.2%
Persons with Disabilities	NH Asheville Imaging center will not track this metric.
Persons 65 and Older	43.6%
Medicare beneficiaries	43.6%
Medicaid recipients	14.0%

Source: Section C, page 65

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, which is consistent with all Novant Health facilities.
- In Exhibit C.6, the applicant provides supporting documentation of its non-discrimination policies and financial aid programs to assist the underserved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is not 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.

NA

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

NC

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

In Section E, pages 74-76, 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:

Maintain the Status Quo-The applicant states that maintaining the status quo is unreasonable because the purpose of the proposal is to provide high quality, diagnostic imaging and serve as a lower cost alternative to hospital-based imaging services. Additionally, the proposal will increase access to diagnostic imaging services in the service area.

Not Provide Other Diagnostic Imaging Modalities (Diagnostic Center)-The applicant states that not providing the diagnostic imaging modalities is not an effective alternative because these modalities are considered more efficient based on their accuracy, cost-savings, and accessibility. Additionally, the applicant states that diagnostic centers can serve as a critical resource for community health while providing person-centered diagnostic imaging services.

The applicant explains why it chose the selected alternative over other alternatives. However, the applicant did not demonstrate that there is an unmet need for a diagnostic center. Furthermore, the application is not conforming to all other applicable statutory and regulatory review criteria, and thus, is not approvable.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

- (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.

NC

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

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/Renovation Contract(s)	\$2,811,429
Architecture/Engineering Fees	\$281,143
Medical Equipment	\$3,772,687
Non-Medical Equipment	\$258,225
Furniture	\$63,052
Consultant Fees	\$60,000
Other: 15% Contingency	\$1,086,980
Total	\$8,333,516

In Exhibit F.1., the applicant provides the assumptions used to project the capital cost. Assumptions that are based on the vendor's cost estimates to develop the diagnostic center. Cost estimates include cost for construction, architecture, engineering, and equipment.

In Section F, pages 79-80, the applicant projects that start-up costs will be \$195,463 and initial operating expenses will be \$1,216,083 for a total working capital of \$ 1,411,546. On page 80, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicant assumes a 24-month period when operating expenses exceed net income.
- The applicant estimates the start-up costs based on initial operating expenses such as salaries, rent, utilities, and supplies.

Availability of Funds

In Exhibit F.2., the applicant provides a letter dated October 8, 2024, from the senior vice-president of Novant Health, Inc., stating its commitment to fund the capital and working capital cost of the proposed project using accumulated reserves.

Exhibit F.2. includes a copy of the financial statements for Novant Health, Inc. for the year ended December 31, 2023, documenting sufficient reserve to fund the capital and working capital needs of the project. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the information provided in Section F and Exhibits F.1. and F.2. of the application.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the third full fiscal year completion of the project, as shown in the table below.

NH Asheville Imaging Center	1st Full FY FY2026	2nd Full FY FY2027	3rd Full FY FY2028
Total Procedures (all service components)	4,966	10,024	12,943
Total Gross Revenue	\$2,913,540	\$6,060,560	\$8,088,447
Total Net Revenue	\$951,440	\$1,979,077	\$2,641,818
Average Net Revenue per Procedure	\$192	\$197	\$204
Total Operating Expenses (Costs)	\$1,877,058	\$2,269,542	\$2,516,261
Average Operating Expense per Procedure	\$378	\$226	\$194
Net Income	(\$925,618)	(\$290,465)	\$125,557

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. However, the applicant does not adequately demonstrate that the financial feasibility of the proposal is reasonable and adequately supported because projected utilization is not based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference. Therefore, projected revenues and operating expenses, which are based in part on projected utilization, are also questionable.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion because the applicant does not adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

NC

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. The applicant proposes locating the diagnostic center in an existing building space in Buncombe County. The applicant is also proposing to serve Henderson County. Thus, the service area is Buncombe and Henderson counties. Facilities may also serve residents not included in the defined service area.

Diagnostics centers are not regulated by the Division of Health Service Regulation. In Section G, page 87, the applicant provides a list of facilities in Buncombe County that currently provide imaging services similar to the services proposed.

County	Facility
Buncombe	Emerge-Ortho-Blue Ridge Division
Buncombe	Mission Imaging Services
Buncombe	Mission Hospital
Buncombe	Open MRI Asheville
Buncombe	Providence Imaging Services
Buncombe	AdventHealth Hendersonville
Buncombe	Providence Imaging Services
Buncombe	UNC Pardee Hospital

In Section G, pages 88-89, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved imaging services in Buncombe and Henderson counties. The applicant states:

“Developing an IDTF/diagnostic center in the Buncombe and Henderson counties service area, that includes CT scans, mammography, ultrasound, and DXA scans presents an opportunity for Novant Health to enhance healthcare access in the region. NH Asheville Imaging Center will not only complement existing healthcare services but also address gaps in service availability, accessibility, and patient experience.”

However, the applicant does not adequately demonstrate 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 did not adequately demonstrate the need it has for the proposed imaging services because its projected utilization is not based on reasonable and adequately supported assumptions. The discussion regarding analysis of need including projected utilization found in Criteria (3) is incorporated herein by reference.
- Because the applicant did not demonstrate the need for the diagnostic center, it cannot demonstrate that it is needed in addition to existing and approved diagnostic centers in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not 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 develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

In Section Q, Form H, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE		
	1 st Full FY FY2026	2 nd Full FY FY2027	3 rd Full FY FY2028
CT Scanner			
Technologist	1.0	1.0	1.0
DXA Scan			
Technologist	0.3	0.4	0.5
Mammography			
Technologist	1.0	1.5	2.0
Ultrasound			
Technologist	1.0	1.5	2.0
Administrative/Support			
Manager	1.0	1.0	1.0
Office Support	2.0	2.0	2.0
Imaging Support	2.0	2.0	2.0
Total	8.3	9.4	10.5

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 92-94, 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 will utilize Novant Health’s existing regional and corporate human resource and employee education departments to recruit appropriate staff.
- The applicant will leverage Novant Health facilities’ relationships with nursing schools and health professional programs in local community colleges to recruit potential employees.
- The applicant provides support documentation in Exhibit H.3, Novant Health’s job descriptions with competencies requirements.
- Staff are encouraged to participate in continuing education programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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.

C

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

Ancillary and Support Services

In Section I, page 96, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 97-98, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant is an existing provider of MRI services in the service area with existing ancillary and support services that will be extended to the proposed diagnostic center.
- In Exhibit I.1, the applicant provides a letter from the senior vice-president of Novant Health, Inc., attesting to the availability of ancillary and support services for the proposed diagnostic center.

Coordination

In Section I, page 98, the applicant describes its efforts to develop relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on existing relationships with local healthcare social services providers in the service area Open MRI Asheville, an existing facility in Buncombe County. The applicant states that these relationships will be extended to the proposed facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

In Section K, page 101, the applicant states that the project involves renovating 6,500 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 103, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed diagnostic based on the applicant's representations and supporting documentation.

On page 102, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the architecture's cost estimate to upfit the existing space.

On page 102, 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 based on the following:

- The applicant states that the upfits to the building are needed to develop the project based on the expertise of the architect. The applicant provides supporting documentation in Exhibit F.1
- The applicant states that the project will be developed to meet all requirements for energy efficiency and consumption.

On page 102, 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
- Written comments
- Responses to comments

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;

NA

The applicant is proposing to develop a new diagnostic center in the service area. There is not historical payor mix to report. Therefore, Criterion (13a) is not applicable to this review.

- (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 107, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 107, the applicant states that NH Asheville is not an existing facility and has no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina in the 18 months immediately preceding the application deadline.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 108, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

NH Asheville Imaging Center Projected Payor Mix Entire Facility 3rd Full FY, 01/01/2026-12/31/2026*	
Payor Category	% of Total
Charity Care	5.5%
Self-Pay	33.7%
Insurance *	43.6%
Medicare*	14.1%
Medicaid*	3.2%
Other (Gov't)	5.5%
Total	100.0%

On page 108, the applicant identified the third full fiscal year as CY 2026. However, in Section Q, the applicant identifies the third full fiscal year as FY 2028, 10/1/2027-9/30/2028.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 33.7% of total services will be provided to self-pay patients, 5.5% to charity care patients, 14.1% to Medicare patients and 3.2% to Medicaid patients.

In Section Q, *Form F.2 Revenue Assumptions*, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported. Projected payor mix is based on the historical payor mix for Novant Health patients residing in the service area who have received outpatient diagnostic imaging services from a Novant Health facility. The applicant assumes that payor mix for the proposed diagnostic center will be consistent with this historical payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated 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 110, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

In Section M, page 112, 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 adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on Novant Health's existing and established Radiologic Technology program and its agreements with clinical education programs that will be incorporate in the proposed diagnostic center.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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.

NC

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 SMFP does not define a service area for diagnostic centers, nor are there any applicable rules adopted by the Department that define the service area for diagnostic centers. Thus, the service area in this review is as defined by the applicant. The applicant proposes locating the diagnostic center in an existing building space in Buncombe County. The applicant is also proposing to serve Henderson County. Thus, the service area is Buncombe and Henderson counties. Facilities may also serve residents not included in the defined service area.

Diagnostics centers are not regulated by the Division of Health Service Regulation. In Section G, page 87, the applicant provides a list of facilities that currently provide imaging services similar to the services proposed.

County	Facility
Buncombe	Emerge-Ortho-Blue Ridge Division
Buncombe	Mission Imaging Services
Buncombe	Mission Hospital
Buncombe	Open MRI Asheville
Buncombe	Providence Imaging Services
Buncombe	AdventHealth Hendersonville
Buncombe	Providence Imaging Services
Buncombe	UNC Pardee Hospital

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 114, the applicant states:

“NH Asheville Imaging Center expects the development of the IDTF/diagnostic center to have a positive effect on competition in the service area because it will increase the current capacity of imaging services in the service area. It will also increase access to imaging services for Buncombe and Henderson counties’ residents. Additionally, as an alternative to hospital-based and HOPD-based imaging services, the IDTF/diagnostic center at NH Asheville Imaging Center will have lower costs for both patients and insurers.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 114, 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 what makes healthcare affordable and more sustainable. It is Novant Health’s approach to delivering remarkable healthcare, so that people can get better and stay healthy.

As previously established, NH Asheville Imaging Center will be part of the Novant Health system which provides many system-wide policies and initiatives which will support the proposed project, including revenue cycle process improvements, value-based care programs, and tactics to save money in a way that will not impact patients.”

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 116, the applicant states:

“The Novant Health Utilization Review Plan will be used at NH Asheville Imaging Center. Utilization Review consists of interdisciplinary professionals and supporting team members providing a wide range of functions for patients and the organization. This includes the patients, their caregivers, internal and external partners, and the healthcare community. The UR team strives to ensure the achievement of quality and the most effective level(s) of care. The UR team performs evaluations for medical necessity using either InterQual or payor specific criteria for patients in the acute care, observation, and outpatient setting.

The Novant Health Risk Management Plan will also be used at NH Asheville Imaging Center. The Risk Management program covers Novant Health entities and team members, including medical staff, licensed independent practitioners, volunteers, students, and contracted workers. Risk Management identifies and presents risk exposures and assures pro-active risk assessments are conducted.”

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 117 and 119, the applicant states:

“NH Asheville Imaging Center will provide services to all persons regardless of race, sex, age, religion, creed, disability, national origin, or ability to pay.

...

Novant Health has implemented strategies aimed at removing barriers to health care, closing health equity gaps and improving the overall health and wellness of all its communities, including equitable COVID-19 vaccine distribution, compassionate care designation for LGBTQ care on its online Physician Finder, education in culturally and linguistically sensitive care, and achievement of its long-term breast cancer screening goal.”

See also Section L of the application and any exhibits.

However, the applicant does not adequately demonstrate the proposal would have a positive impact on cost-effectiveness, because the applicant does not adequately demonstrate:

- the need the population to be served has for the proposal because projected utilization is not reasonable and adequately supported. The discussion regarding projected utilization, found in Criterion (3) is incorporated herein by reference;
- that projected revenues and operating costs are reasonable. The discussion regarding projected revenues and operating costs found in Criterion (5) is incorporated herein by reference.
- that the proposal would not result in an unnecessary duplication of existing and approved health services. The discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion based on 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.

The applicant proposes to develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

In Section Q, Form O, the applicant identifies all diagnostic centers located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of 15 diagnostic centers located in North Carolina. Diagnostic centers are not subject to DHSR license requirements.

After reviewing and considering information provided by the applicant regarding the quality of care provided at all diagnostic centers identified in Form O, the applicant provided sufficient evidence that quality of 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 develop a diagnostic center by acquiring no more than one CT scanner, two ultrasound units, three mammography units and one DXA unit in an upfitted medical office building in Buncombe County.

The Criteria and Standards for Diagnostic Centers were repealed, effective March 16, 2017. The proposed new diagnostic center includes acquiring a computed tomography (CT) scanner. The Criteria and Standards for Computed Tomography Equipment (CT scanners) were repealed, effective January 1, 2022. The applicant proposes no additional equipment for which performance standards apply. Therefore, no performance standards apply to this review.