

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 27, 2023

Findings Date: November 27, 2023

Project Analyst: Gregory F. Yakaboski

Co-Signer: Lisa Pittman

Project ID #: F-12403-23

Facility: Novant Health Ballantyne Medical Center

FID #: 180518

County: Mecklenburg

Applicants: Novant Health Ballantyne Medical Center, LLC

Novant Health, Inc.

Project: Acquire a fixed MRI scanner pursuant to Policy TE-3

### 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 Ballantyne Medical Center, LLC and Novant Health, Inc., herein after collectively referred to as “the applicant”, proposes to acquire one fixed MRI scanner at Novant Health Ballantyne Medical Center (NH Ballantyne) pursuant to Policy TE-3 of the 2023 State Medical Facilities Plan (SMFP). NH Ballantyne is in Ballantyne, Mecklenburg County.

#### **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 2023 SMFP. Therefore, there are no need determinations applicable to this review.

## **Policies**

There are two policies in the 2023 SMFP which are applicable to this review: *Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners*; and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

### **Policy TE-3**

*Policy TE-3: Plan Exemption for Fixed Magnetic Resonance Imaging Scanners*, on page 28 of the 2023 SMFP, states:

*“The applicant proposing to acquire a fixed magnetic resonance imaging (MRI) scanner shall demonstrate in its certificate of need (CON) application that it is a licensed North Carolina acute care hospital or a hospital campus:*

- 1. that has licensed acute care beds; and*
- 2. that provides emergency care coverage 24 hours a day, seven days a week.*

*The applicant shall demonstrate that the proposed fixed MRI scanner will perform at least 850 weighted MRI procedures during the third full operating year.*

*The performance standards in 10A NCAC 14C .2703 would not be applicable.*

*The proposed fixed MRI scanner:*

- 1. must be located on the main campus of the hospital as defined in G.S. § 131E-176(14n); or*
- 2. must be located at another acute care hospital on a campus that operates under the main hospital’s license.*

*The proposed fixed MRI scanner cannot be located at a site where the inventory in the SMFP reflects that there is an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application.*

*The proposed scanner may operate as part of the hospital, a diagnostic center, or an independent diagnostic testing facility (IDTF) location that does not currently provide fixed MRI services.”*

In Section B, page 24, and in Exhibit B.19 (Tab 2), the applicant explains why it believes its application is conforming with Policy TE-3. The applicant adequately demonstrates that NH Ballantyne is a facility:

- with licensed acute care beds,
- provides emergency care 24 hours a day, seven days a week

- will perform at least 850 weighted MRI procedures during the third full operating year;
- will be located on the main campus of the hospital; and
- will be located at a site where the inventory of the SMFP reflects that there has not been an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application.

#### **Policy GEN-4**

*Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*, on page 30 of the 2023 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 for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”*

The proposed capital expenditure for this project is greater than \$5 million. In Section B, page 25, and in Exhibit B.21 (Tab 3), the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

#### **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 the following reasons:

- The applicant adequately demonstrates that the proposal is consistent with Policy TE-3 and Policy GEN-4 for the following reasons:
  - The applicant adequately documents that NH Ballantyne is a facility with licensed acute care beds that provides an operational emergency department that is open 24 hours per day, seven days per week;
  - The applicant adequately documents that the proposed site for the fixed MRI scanner will perform at least 850 weighted MRI procedures in the third operating year and that the fixed MRI scanner will be located on a site that has not had an existing or approved fixed MRI scanner in the last five years and will be located on the main campus of a hospital.
  - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

(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

The applicant proposes to acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

### **Patient Origin**

In Chapter 17, page 331, the 2023 SMFP defines the service area for a fixed MRI scanner as *“the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1”*. In Chapter 5, page 31, the 2023 SMFP defines the service area for Acute Care Beds as *“...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.”* In Figure 5.1 on page 36 of the 2023 SMFP Mecklenburg County is shown as a single county service area. The applicant proposes to locate the fixed MRI scanner at NH Ballantyne in Mecklenburg County. Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

NH Ballantyne is a new facility, approved in March 2019 [Project ID# F-11625-18], and only started providing services on June 19, 2023. The application for this proposed project was submitted on June 15, 2023. The following table illustrates projected patient origin for fixed MRI services.

**NH Ballantyne: MRI Services**

County	1 <sup>st</sup> Full FY		2 <sup>nd</sup> Full FY		3 <sup>rd</sup> Full FY	
	(CY2024)		(CY2025)		(CY2026)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Mecklenburg	1,048	49.6%	1,245	49.6%	1,439	49.6%
Union	727	34.4%	863	34.4%	998	34.4%
Other	338	16.0%	402	16.0%	464	16.0%
Total	2,113	100.0%	2,510	100.0%	2,901	100.0%

Source: Table on page 34 of the application.

In Section C.3, page 34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported as the applicant states

*“NH Ballantyne assumes that its MRI service area will continue to be the six zip codes (28134, 28173, 28226, 28277, 29707 and 29720) identified in the 2018 NH Ballantyne CON application (Project ID # F-11625-18) approved to develop the medical center. Mecklenburg County and Union County represent 84.0 percent of the MRI patients.”*

**Analysis of Need**

In Section C.4, pages 36-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Fixed MRI Benefits and Policy TE-3 (See pages 36-37).
- Population Growth and Aging Trends in Mecklenburg County (See page 38).
- Mecklenburg County Life Expectancy (See page 39).
- Mecklenburg County MRI Utilization (See page 40).

The information is reasonable and adequately supported based on the application and exhibits to the application, including, but not limited to, the highlighted points listed below:

- The benefits, including improved clinical outcomes, cost efficiency and timely access to MRI services, of having MRI services available 24 hours per day/ 7 days per week at an acute care hospital that provides emergency services 24 hours per day/ 7 days per week.
- The applicant uses clearly cited and reasonable historical and demographic data to identify the population to be served, its projected growth, and the need the identified population has for the proposed services.
- Historical growth of MRI scans in Mecklenburg County.
- Letters from physicians who have expressed support for the proposed project. See Exhibit I.2.

**Projected Utilization**

In Section Q, Form C.1a and C.2b, the applicant provides interim and projected utilization, as illustrated in the following tables.

**NH Ballantyne: Projected MRI Utilization**

	<b>Interim CY2023*</b>	<b>Interim CY2024</b>	<b>OY1 CY2025</b>	<b>OY2 CY2026</b>	<b>OY3 CY2027</b>
# of Mobile MRI scanners	1	1	0	0	0
# of Fixed MRI scanners	0	0	1	1	1
Unweighted Procedures	765	1,720	2,113	2,510	2,901
Weighted Procedures	892	2,006	2,737	3,251	3,757

Source: Section Q, Form C.1a and Form C.2b.

\*6/12/2023 to 12/31/2023.

In Section C.5, pages 43-44, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: The applicant identified projected MRI volumes for the original approval of NH Ballantyne (Project ID# F-11625-18) for project years 1-3 of that project [CY2023, CY2024 and CY2025]. See application page 43.

Step 2: The applicant calculated the 2-year Compound Annual Growth Rate (CAGR) based on the three project years from the original NH Ballantyne approval (Project ID# F-11625-18). See application page 43.

Step 3: Apply 50% of the 2-year CAGR (11.5%) [ $23.0\% / 2 = 11.5\%$ ] to project MRI volume for CY2026 and CY2027 (Project Years 2 and 3 for the current proposed project). See application pages 43-44.

The project analyst notes that even though the applicant is only using 50% of the CAGR the CAGR was based off an initial “ramp up year”. In this case, that skews the CAGR to a higher percentage, and is not reasonable. However, the project analyst also notes that even if the historical CAGR of 5.0% for MRI scans in Mecklenburg County for the period of FY2017-FY2022 (see application page 40) was utilized the projected number of weighted MRI scans easily exceeds the 850 weighted MRI scans required pursuant to Policy TE-3. The project analyst further notes that the projected MRI scans for CY2025 (third project year in the original project and first full project year in this proposed project) at NH Ballantyne, approved as part of Project ID# F-11625-18, with no growth from CY2025 to CY2027, exceeds the 850 weighted MRI scans required pursuant to Policy TE-3.

Step 4: Divided each projected annual MRI volume in half to account for MRI volume starting in a partial year. See application page 44.

Steps 5 & 6: Calculated the projected MRI volume starting with the interim partial year through Project Year Three (CY2027). See application page 44.

Projected utilization is reasonable and adequately supported based on the application and exhibits to the application, including, but not limited to, the highlighted points listed below:

- Pursuant to Policy TE-3 NH Ballantyne needs to reasonably project 850 weighted scans in the third project year. The third project year in the proposed project is CY2027. NH Ballantyne, the facility, was approved on March 29, 2019 (Project ID# F-11625-18). As part of that initial approval the applicant proposed mobile MRI services two days per week with projected MRI scans in CY2025 of 2,315 which exceeds the minimum number of MRI scans required pursuant to Policy TE-3. CY2025 is the first full project year in this proposed project. Therefore, even with no growth from CY2025 to CY2027, the projected utilization exceeds the 850 weighted MRI scans required to be compliant with Policy TE-3.
- The applicant relied on population growth and aging trend projections from the NC Office of State Budget and Management as well as the NC State Center for Health Statistics.
- The historical Compound Annual Growth Rate (CAGR) of MRI scans in Mecklenburg County from FY2015-FY2022 was 5.0%.

**Access to Medically Underserved Groups**

In Section C.6, page 47, the applicant states,

*“Services are available to all persons including: (a) low income persons, (b) racial and ethnic minorities, (c) women, (d) handicapped persons, (e) the elderly, and (f) other underserved persons, including the medically indigent referred by their attending physicians.*

*NH Ballantyne is a not-for-profit organization that does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. NH Ballantyne actively participates in both the Medicaid and Medicare programs.”*

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

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients</b>
Low-income persons	8.5%
Racial and ethnic minorities	43.0%
Women	51.0%
Persons with Disabilities*	na
Persons 65 and older	42.9%
Medicare beneficiaries	42.9%
Medicaid recipients	5.2%

Source: Table on page 49 of the application.

\*NH Ballantyne does not track this information.

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.

**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.

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.

CA

The applicant proposes to acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

In Section E, page 58, 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 of providing emergency care 24 hours per day, seven days per week in addition to operating 36 acute care beds with no fixed MRI scanner does not allow NH Ballantyne to meet patient need including providing MRI services for non-ambulatory patients. Therefore, the applicant states that this is not the most effective alternative.
- *Rely on a Mobile MRI scanner*- The applicant states that there is a shortage of available mobile MRI scanner days across the state. In addition, relying on a mobile MRI scanner is insufficient to meet projected patient volumes as well as difficulty in serving non-ambulatory patients. Therefore, the applicant states that this alternative is more costly.

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

- The applicant provides reasonable 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

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Novant Health Ballantyne Medical Center, LLC and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire no more than one fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP to be located at Novant Health Ballantyne Medical Center.**
- 3. Upon completion of the project Novant Health Ballantyne Medical Center shall be licensed for no more than one fixed MRI scanner.**
- 4. The certificate holder shall 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.**
- 5. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder 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 holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder 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 July 1, 2024.**

6. **The certificate holder 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.**
  7. **The certificate holder 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 acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

**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.

Site Costs	\$0
Construction Costs	\$2,895,622
Miscellaneous Costs	\$4,463,877
<b>Total</b>	<b>\$7,359,499</b>

The applicant provides its assumptions and methodology for projecting capital cost in Section Q, Form F.1a Capital Cost Assumptions, Form F.1a Capital Cost and Exhibit F.1. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, page 60, Section Q and Exhibit F.1 (Tab 7).

In Section F.3, page 62, the applicant projects that start-up costs will be \$124,592 and initial operating expenses will be \$0 for a total working capital of \$124,592. On page 63, 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.

**Availability of Funds**

In Section F.2, page 60, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	<i>Novant Health Ballantyne Medical Center, LL</i>	<i>Novant Health, Inc.</i>	Total
Loans	\$0	\$0	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$0	\$7,359,499	\$7,359,499
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$0</b>	<b>\$7,359,499</b>	<b>\$7,359,499</b>

\* OE = Owner's Equity

In Section F.3, page 63, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

<b>Sources of Financing for Working Capital: Novant Health, Inc.</b>	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$124,592
Lines of credit	\$0
Bonds	\$00
<b>Total *</b>	<b>\$</b>

In Exhibit F-2 (Tab 8) and Exhibit F-3 (Tab 9) the applicant provides a letter dated June 10, 2023, from the Senior Vice President, Operational Finance and Revenue Cycle for Novant Health, Inc. (Novant Health) confirming Novant Health's commitment of \$7,359,499 for the capital costs and \$124,592 for the working capital costs from its accumulated reserves to fund the proposed project.

Exhibit F-2 (Tab 8) contains a copy of the audited Consolidated Financial Statements for Novant Health, Inc. and Affiliates for the year ending December 31, 2021. According to the financial report, as of December 31, 2021, Novant Health, Inc. had adequate accumulated reserves to fund the projected capital and working capital requirements of the proposed project. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project based the information provided in Section F and Exhibits F-2 (Tab 8) and F-3 (Tab 9) of the application.

**Financial Feasibility**

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

**NH Ballantyne-MRI Services**

	<b>1<sup>st</sup> Full FY (CY2025)</b>	<b>2<sup>nd</sup> Full FY (CY2026)</b>	<b>3<sup>rd</sup> Full FY (CY2027)</b>
Total MRI Scans*	2,737	3,251	3,757
Total Gross Revenues (Charges)	\$8,711,899	\$10,659,192	\$12,689,237
Total Net Revenue	\$2,570,010	\$3,144,462	\$3,743,325
Average Net Revenue per MRI Scan	\$939	\$967	\$996
Total Operating Expenses (Costs)	\$1,251,696	\$1,292,427	1,334,704
Average Operating Expense per MRI Scan	\$457	\$398	\$355
Net Income	\$1,318,314	\$1,852,035	\$2,408,621

\*Total MRI Scans represents weighted scans.

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:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

The applicant proposes to acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

In Chapter 17, page 331, the 2023 SMFP defines the service area for a fixed MRI scanner as “the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1”. In Chapter 5, page 31, the 2023 SMFP defines the service area for Acute Care Beds as “...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.” In Figure 5.1 on page 36 of the 2023 SMFP Mecklenburg County is shown as a single county service area. The applicant proposes to locate the fixed MRI scanner at NH Ballantyne in Mecklenburg County. Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The applicant is proposing to acquire one fixed MRI scanner pursuant to Policy TE-3. Policy TE-3 requires that the fixed MRI scanner

*“be located at a site where the inventory in the SMFP reflects that there is an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application.”*

NH Ballantyne is not listed as a facility having a fixed MRI scanner according to Table 17E-1: *MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents*, pages 344-346, of the 2023 SMFP. Furthermore, NH Ballantyne is a new acute care hospital that was approved in March 2019 [Project ID# F-11625-18] and started offering service in June 2023. The approved project did not include a fixed MRI scanner. The approved project only included mobile MRI scanner service two days per week.

In Section G, page 70, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed MRI scanner services in Mecklenburg County. The applicant states:

*“No fixed MRI scanner currently exists at NH Ballantyne which operates 35 acute care beds and provides 24 hours per day, seven days per week emergency services.”*

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:

- NH Ballantyne currently has no approved or existing fixed MRI scanner and is an acute care hospital that which provides emergency services seven days per week, 24 hours per day.
- The proposed acquisition of a fixed MRI scanner by NH Ballantyne is permitted by Policy TE-3 of the 2023 SMFP

### **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 acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

In Section Q, Form H, the applicant provides the projected full-time equivalent (FTE) staffing for the proposed MRI services.

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 Form F.3b. In Sections H.2 and H.3, pages 72-74, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibits H-2 (Tab 11) and H.3 (Tab 12) the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 72-74, Exhibits H-2 (Tab 11) and H.3 (Tab 12) and in Section Q, Form H, as described above.

### 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.

### C

The applicant proposes to acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

### **Ancillary and Support Services**

In Section I.1, page 76, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 77-78, and in Exhibit I.1 (Tab 13), the applicant explains how each ancillary and support service is or will be made available.

The applicant adequately demonstrates that the necessary ancillary and support services will be made available and provides supporting documentation in Exhibits I-1 (Tab 13).

### **Coordination**

In Section I.2, page 78, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-2 (Tab 14). The applicant states,

*“Novant Health, the parent company of NH Ballantyne, has established relationships with local health care and social service providers throughout its service area. These relationships extend to NH Ballantyne, which recently opened in 2023.”*

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, page 78, and Exhibit I-2 (Tab 14), as described above.

### **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 acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

In Section K, page 81, the applicant states that the project involves constructing 1,350 square feet of new space. Line drawings are provided in Exhibit K.1 (Tab 15).

On page 81, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on architect review.

On page 82, and Exhibit F.1, 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.

On page 82, 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;

**NA**

NH Ballantyne is a new acute care hospital that only started providing services on June 19, 2023. In Section L, page 87, the applicant states that NH Ballantyne does not have a last full FY of data 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.2, page 87, the applicant states that the facility is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 87, the applicant states that during the last 18 months no patient civil rights equal access complaints have been against NH Ballantyne.

**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.3, page 88, the applicant projects the payor mix for services at NH Ballantyne during the third full fiscal year of operation (CY2027) following completion of the project, as illustrated in the following table.

**NH Ballantyne-Entire Facility  
3<sup>rd</sup> Full FY (CY2027)**

<b>Payor Category</b>	<b>Percent of Total of Total Patients Served</b>
Self-Pay	2.76%
Charity Care	2.71%
Medicare*	57.93%
Medicaid*	7.16%
Insurance*	27.69%
Other (Governmental)	1.75%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 88 of the application.

\*Including any managed care plans.

In Section L.3, page 88, the applicant projects the payor mix for MRI services at NH Ballantyne during the third full fiscal year of operation (CY2027) following completion of the project, as illustrated in the following table.

**NH Ballantyne – MRI Services  
3<sup>rd</sup> Full FY (CY2027)**

<b>Payor Category</b>	<b>Percent of Total of Total Patients Served</b>
Self-Pay	1.7%
Charity Care	na
Medicare*	38.4%
Medicaid*	2.8%
Insurance*	53.6%
Other (Governmental)	3.5%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 88 of the application.

\*Including any managed care plans.

As shown in the table immediately above, during the third full fiscal year of operation following completion of the project, the applicant projects that 1.7 percent of total MRI services will be provided to self-pay patients, 38.4 percent to Medicare patients, and 2.8 percent to Medicaid patients.

On page 88, the applicant provides the assumptions and methodology used to project payor mix during the first three years of operation following completion of the project. The projected payor mix NH Ballantyne is reasonable and adequately supported because it is based on the utilization methodology in the NH Ballantyne CON application (Project ID# F-11625-18) that was conditionally approved on March 29, 2019. The projected payor mix for MRI services is reasonable and adequately supported as it is based on service area MRI patients receiving an MRI scan at NH Matthews.

The Agency reviewed the:

- Application
- Exhibits to the application

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.5, page 89, 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

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 acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1 (Tab 17). The applicant adequately demonstrates that health professional training programs in the area have and will continue to 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 acquire one fixed MRI scanner at NH Ballantyne pursuant to Policy TE-3 of the 2023 SMFP.

In Chapter 17, page 331, the 2023 SMFP defines the service area for a fixed MRI scanner as “*the same as an Acute Care Bed Service area as defined in Chapter 5 and shown in Figure 5.1*”. In Chapter 5, page 31, the 2023 SMFP defines the service area for Acute Care Beds as “*...Counties with at least one licensed acute care hospital that are not grouped with another county are single county service areas.*” In Figure 5.1 on page 36 of the 2023 SMFP Mecklenburg County is shown as a single county service area. The applicant proposes to locate the fixed MRI scanner at NH Ballantyne in Mecklenburg County. Therefore, for the purpose of this review, the fixed MRI service area is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The applicant is proposing to acquire one fixed MRI scanner pursuant to Policy TE-3. Policy TE-3 requires that the fixed MRI scanner

*“be located at a site where the inventory in the SMFP reflects that there is an existing or approved fixed MRI scanner in the five years immediately preceding the filing of the CON application.”*

NH Ballantyne is not listed as a facility having a fixed MRI scanner according to Table 17E-1: *MRI Fixed and Mobile Procedures by MRI Service Area with Tiered Thresholds and Fixed Equivalents*, pages 344-346, of the 2023 SMFP. Furthermore, NH Ballantyne is a new acute care hospital that was approved in March 2019 [Project ID# F-11625-18] and started offering service in June 2023. The approved project did not include a fixed MRI scanner. The approved project only included mobile MRI scanner service two days per week.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

*“NH Ballantyne expects the acquisition of the new MRI scanner to have a positive effect on competition in the service area because it will increase the current capacity of MRI scanner services in the service area.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 93 the applicant states:

*“Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventative care and managing existing conditions to slow or reverse the progression of disease, all while lowering the overall cost of care.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 95-96, the applicant states:

*“The Novant Health Utilization Review Plan is used at NH Ballantyne. ... The UR team strives to ensure the achievement of quality and the most effective level(s) of care. ... Novant Health has a history of receiving strong grades from The Leapfrog Group, a national nonprofit that evaluates the safety, quality and patient experience provided by hospitals across the county.”*

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, page 96, the applicant states:

*“NH Ballantyne provides services to all persons regardless of race, sex, religion, creed, disability, national origin, or ability to pay.”*

See also Section L and C 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
- 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 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

In Section Q, Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of twelve of this type of facility located in North Carolina.

In Section O.5, page 102, the applicant states that, during the 18 months immediately preceding the submittal of the application, *“Novant Health New Hanover Regional Medical Center (“NH New Hanover”) had a finding of immediate jeopardy identified June 24, 2022. The North Carolina State Survey Agency complaint investigation survey was concluded on June 29, 2022. ... The North Carolina State Survey Agency conducted a follow-up survey and on [sic] August 11, 2022 and determined that NH New Hanover is in compliance. A CMS memo dated August 22, 2022, confirmed NH New Hanover to be restored to its “deemed status” as a facility accredited by Det Norske Veritas (DNV).”* Exhibit O.5 (Tab 20) includes a copy of the CMS “deemed status” letter.

According to the files in the Acute and Home Care Licensure Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in any of the applicant’s other facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure Section and considering the quality of care provided at all of the applicant’s facilities, 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 acquire a fixed MRI scanner pursuant to Policy TE-3 in the 2023 SMFP.

The applicant qualifies to acquire a fixed MRI scanner at Novant Health Ballantyne Medical Center pursuant to Policy TE-3. The discussion regarding conformity with Policy TE-3 found in Criterion (1) is incorporated herein by reference. Therefore, pursuant to Policy TE-3, the performance standards found in 10A NCAC 14C .2703 are not applicable to this review.