

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 9, 2021

Findings Date: November 9, 2021

Project Analyst: Celia C. Inman

Co-Signer: Micheala Mitchell

Project ID #: O-12111-21

Facility: Novant Health New Hanover Regional Medical Center

FID #: 943372

County: New Hanover

Applicant(s): Novant Health, Inc.

Novant Health New Hanover Regional Medical Center, LLC

Project: Acquire one Bi-plane System

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 New Hanover Regional Medical Center, LLC and Novant Health, Inc., hereinafter collectively referred to as “the applicant”, proposes to develop a dedicated interventional radiology (IR) room in the Novant Health New Hanover Regional Medical Center (NHRMC) Neuroscience Institute, which is currently under construction, by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

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 2021 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2021 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4, on page 29 of the 2021 SMFP, states:

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

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 \$2 million and less than \$5 million. In Section B, pages 27-28, the applicant describes a plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the applicant’s plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant 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 develop an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

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 2021 SMFP does not define a service area for a bi-plane system, nor are there any applicable rules adopted by the Department that define the service area for a bi-plane system. In Section C.3, page 38, the applicant defines the service area for the proposed interventional radiology services as consisting of New Hanover, Brunswick, Pender, Onslow, Columbus counties, with “Other” including 48 counties in North Carolina and other states. Facilities may also serve residents of counties not included in the service area.

The following table illustrates historical and projected patient origin for IR services at NHRMC.

County	Historical CY2020		Third Full FY of Operation following Project Completion CY2025	
	Patients	% of Total	Patients	% of Total
New Hanover	986	42.6%	1,291	42.6%
Brunswick	477	20.6%	625	20.6%
Pender	292	12.6%	382	12.6%
Onslow	184	8.0%	243	8.0%
Columbus	118	5.1%	155	5.1%
Other*	255	11.0%	333	11.0%
Total	2,312	100.0%	3,032	100.0%

Source: Section C, Tables on pages 37-38.

In Section C, page 38, the applicant provides the assumptions and methodology used to project its patient origin, stating that it assumes its 5-county service area will remain consistent in the future. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 40-46, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 40, the applicant states that it identified the internal medical center need for an additional IR system to be located within the Neuroscience Institute at NHRMC based on the factors summarized below:

- Population growth trends in New Hanover County and the IR service area (pages 41-42)
- New Hanover County life expectancy (page 43)
- NHRMC physician group growth (pages 44-45)
- Comprehensive stroke center (page 46)
- NHRMC utilization (page 46)

The information is reasonable and adequately supported for the following reasons:

- The population projections by the (North Carolina Office of State Budget and Management (NCOSBM) indicate that New Hanover County is projected to grow by 7.0% with the population aged 65 and older projected to increase by 14.9% from 2021 through 2026. NHRMC's 5-county IR service area (New Hanover, Brunswick, Columbus, Onslow and Pender counties) is expected to grow by 6.6% from 2021 to 2026, with the population aged 65 and older projected to increase by 15.9%.
- Life expectancy, per the North Carolina State Center for Health Statistics, is increasing, which the applicant states, increases the chance of health conditions requiring an IR procedure.
- NHRMC is scheduled to add additional physicians to its physician network which will increase the number of referrals to NHRMC services. NHRMC's medical staff has grown in the last decade from 470 to 621.
- NHRMC is the only DNV GL-certified Comprehensive Stroke Center in North Carolina. It received that certification in July 2019, reflecting the highest level of competence for treatment of serious stroke events. NHRMC is also the only hospital in southeastern North Carolina to offer 24/7 neuro-interventional coverage to treat patients suffering cerebrovascular emergencies, including stroke and aneurysms. As such, development of an additional IR Room will expand NHRMC's capability to provide time sensitive care and ensure adequate access and redundancy to support the comprehensive stroke center.
- Historical IR cases at NHRMC experienced a 63.9% growth from FY2016 to FY2020, increasing from 1,411 patients to 2,312 patients.
- In developing future projections for the proposed project, several factors indicate the volume will increase, including:
 - The population growth in NHRMC's IR services area
 - The increase in key age groups in the service area
 - NHRMC's IR cases increased 15.5%, from 1,868 patients in FY2017 to 2,158 patients in FY2021 (annualized)

Projected Utilization

In Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables.

Historical IR Cases: NHRMC

	Historical					Annualized
	CY2016	CY2017	CY2018	CY2019	CY2020	CY2021
IR Cases	1,411	1,868	2,346	2,388	2,312	2,158

Source: Section Q, page 115

Projected IR Cases: NHRMC

	CY2022	CY2023	CY2024	CY2025
IR Cases	2,350	2,558	2,785	3,032

Source: Section Q, pages 114 and 116

In Section Q, pages 115-117, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Step 1. Determine the five-year compound annual growth rate (CAGR) from 2016 through 2021 (annualized), resulting in a CAGR of 8.87%.

- Data on historical IR cases and IR systems comes from the NHRMC Manager of Planning and business development and assumes two IR systems.
- Capacity = (260 days x 10 hours per day) / 2 hours per IR case = 1,300 cases per system = 2,158 / 2,600 = 83% capacity in CY2021.

Step 2. Project IR cases through CY2025, the third full fiscal year of operation following project completion.

- The projection is based on applying the five-year CAGR of 8.87% to CY2021 annualized cases and assumes four IR systems, as identified in Section C, page 30, including the system approved in 2019, Project ID #O-11748-19 and approved for the Neuroscience Institute in the December 15, 2020 Material Compliance Letter.
- Capacity = (260 days x 10 hours per day) / 3 hours per IR case = 866 cases per system = 3,032 / 3,464 = 87.5% capacity in CY2025. The applicant states that the capacity of the individual IR systems is expected to decrease due to the increase of and new performance of complex cases, increasing average case time from two hours to three hours.

				Interim	Interim	Annualized	Interim	Interim	1 st FFY	2 nd FFY	3 rd FFY
	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	J-J 2022	J-D 2022	CY2023	CY2024	CY2025
# Cases	1,411	1,868	2,346	2,388	2,315	2,158	1,175	1,175	2,558	2,785	3,032
CAGR	8.87%										
IR Systems	2	2	2	2	2	2	2	4	4	4	4
IR Capacity	1,300	1,300	1,300	1,300	1,300	1,300	650	433	866	866	866
Utilization*	54.27%	71.85%	90.23%	91.85%	88.92%	83.00%	90.36%	67.82%	73.84%	80.39%	87.52%

*Capacity is expected to decrease due to the increase of and new performance of complex cases. Average case time is assumed to increase from 2 hours per case to 3+ hours per case

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

- The applicant’s utilization projections are supported by an increase in historical IR cases at NHRMC over a five-year period.
- The applicant projects utilization for the four-year period of CY2021 through CY2025, the third full fiscal year following project completion, based on the five-year CAGR from CY2016 through CY2021 (annualized) or 8.87%.
- The increase in the performance of complex cases and the performance of new complex cases will decrease capacity per system.
- The four IR systems are projected to be well utilized by CY2025, the third full fiscal year of operation.

Access to Medically Underserved Groups

In Section C, page 52, the applicant states that services are available to all persons including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved persons, including the medically indigent referred by their attending physicians. On page 53, the applicant provides the estimated percentage for each medically underserved group, as summarized in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	14.5%
Racial and ethnic minorities	20.6%
Women	49.4%
Persons with Disabilities	*
The elderly	54.2%
Medicare beneficiaries	59.6%
Medicaid recipients	12.7%

*Not tracked

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:

- NHRMC is a not-for-profit organization and the applicant states that Novant Health facilities and programs do not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay.
- The applicant provides NHRMC's estimated percentage of total patients for each of the listed medically underserved groups.

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 a reduction or elimination of a service, or the relocation of a facility or a service. Therefore, Criterion (3a) is not applicable to this review.

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

CA

The applicant proposes to develop an interventional radiology room in the Neuroscience Institute, which is under construction at NHRMC, by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

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

- Maintain the status quo – the applicant determined that delaying the acquisition of an additional bi-plane system would be a less effective alternative because the Neuroscience Institute is in the process of being constructed now and would require renovation to add the system at a later date.

- Acquire a bi-plane system, as proposed – the applicant determined that submitting the application as proposed was the most effective alternative because adding the system while the Neuroscience Institute is under construction will result in less staff and patient inconvenience.

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 New Hanover Regional 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 bi-plane system for interventional radiology for a total of no more than four bi-plane systems for interventional radiology upon completion of this project and Project ID # O-11748-19.
3. 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on May 1, 2022. The second progress report shall be due on August 1, 2022 and so forth.
 4. 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.
 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, The certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
 6. 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 develop an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

Capital and Working Capital Costs

In Section Q, page 118, the applicant projects the total capital cost of the project, as shown in the table below.

Construction Costs and A&E	\$1,090,000
Medical Equipment	\$2,133,288
Miscellaneous Costs*	\$231,900
Total	\$3,455,188

*includes non-medical equipment, furniture, consultant and CON fees, owner costs, and contingency

In Section Q, pages 118-119, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- Construction costs are verified by a Licensed Architect
- A Siemens quote is provided for the medical equipment
- Non-medical equipment and furniture costs are developed by NHRMC facilities team and architects

In Section F, page 66, the applicant projects that start-up costs will be \$40,811 and initial operating expenses will be \$0 for a total working capital of \$40,811. On page 66, 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:

- NHRMC will hire 5.0 FTE interventional radiology technicians to develop the IR system
- NHRMC will incur one month of salary and benefits

Availability of Funds

In Section F, page 64, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing		
Type	Novant Health, Inc.	Total
Loans	\$	\$
Accumulated reserves or OE *	\$3,455,188	\$3,455,188
Bonds	\$	\$
Other (Specify)	\$	\$
Total Financing	\$3,455,188	\$3,455,188

* OE = Owner's Equity

In Section F, page 67, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Novant Health, Inc.
Loans	\$
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$40,811
Lines of credit	\$
Bonds	\$
Total *	\$40,811

In Exhibit F.2, the applicant provides a funding letter from Novant Health's Senior Vice President, Operational Finance & Revenue Cycle attesting to Novant Health, Inc.'s intentions

to fund the proposed project. Also in Exhibit F.2, the Novant Health, Inc. and Affiliates Consolidated Financial Statements, as of December 31, 2020, document the availability of adequate accumulated reserves to fund the project.

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

- Novant Health, Inc. officer commits the funding for the project
- The Novant Health, Inc. financial statements document adequate funds for the project

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, page 124, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
Total IR Cases	2,558	2,785	3,032
Total Gross Revenues (Charges)	\$ 213,853,206	\$ 239,804,802	\$ 268,905,686
Total Net Revenue	\$ 52,885,898	\$ 59,303,728	\$ 66,500,376
Average Net Revenue per Case	\$ 20,675	\$ 21,294	\$ 21,933
Total Operating Expenses (Costs)	\$ 43,748,439	\$ 48,906,035	\$ 54,564,569
Average Operating Expense per Case	\$ 17,103	\$ 17,561	\$ 17,996
Net Income	\$ 9,137,459	\$ 10,397,693	\$ 11,935,807

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:

- Gross revenue is projected using the FY2020 actual gross charge by payor
- Average charge inflation is 3% per year
- Contractual adjustments are derived from CY2020 NHRMC experience with interventional radiology
- 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.

C

The applicant proposes to develop an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

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 2021 SMFP does not define a service area for a bi-plane system, nor are there any applicable rules adopted by the Department that define the service area for a bi-plane system. In Section C.3, page 38, the applicant defines the service area for the proposed interventional radiology services as consisting of New Hanover, Brunswick, Pender, Onslow, Columbus counties, with “Other” including 48 counties in North Carolina and other states. Facilities may also serve residents of counties not included in the service area.

In Section G, page 73, the applicant, based on the 2021 Hospital License Renewal Applications, identifies all existing facilities in the proposed service area that provide “other imaging equipment” such as IR equipment as proposed in this application as illustrated in the following table:

Facility	Service Area County
New Hanover Regional Medical Center	New Hanover
J. Arthur Doshier Memorial Hospital	Brunswick
Novant Health Brunswick Medical Center	Brunswick
Pender Memorial Hospital	Pender
Onslow Memorial Hospital	Onslow
Columbus Regional HealthCare System	Columbus

Source: Table on page 73 of the application

On page 73, the applicant states that the data provided on the Hospital License Renewal Applications is too broadly defined for comparative purposes, stating:

“The 2021 Hospital License Renewal Application, Table 10h.-Other Imaging Equipment identifies Special Procedures/Angiography Equipment. This broad description does not allow NHRMC to know for certain if the report volumes are IR procedures, angiography procedures, or other non-IR and non-angiography procedures. Nonetheless, NHRMC is providing the reported data.”

The applicant provides the data from the respective 2021 LRAs in Exhibit G.1. The LRAs show Special Procedures/Angiography Equipment from Table 10 h. for NHRMC with two units and 3,400 procedures and NHRMC Orthopedic Hospital with one unit and 423 procedures for a total of three units and 3,823 procedures. The LRAs for the other hospitals show no Special Procedures/Angiography Equipment in Table 10 h.

In Section G, page 74, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved IR services in the service area. The applicant states:

“As noted in Section G.2, only NHRMC performs Special Procedures/Angiography procedures in the 5-county service area.”

The applicant further states that Southeastern Regional Medical Center, 76 miles west of Wilmington, is the closest hospital that offers such procedures.

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

- The applicant adequately demonstrates that no other providers in the service area provide the proposed services.
- The applicant adequately demonstrates that the proposed bi-plane system for interventional radiology is needed in addition to the existing or approved interventional radiology systems.

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.

- (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 an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

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

Position	Current FTE Staff	Projected FTE Staff		
	As of 7/19/2021	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
Lead Interventional Radiology Technician	1.07	1.07	1.07	1.07
Interventional Radiology Technician	8.24	13.24	13.24	13.24
Imaging Scheduler	1.00	1.00	1.00	1.00
TOTAL	10.31	15.31	15.31	15.31

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 Projected Operating Costs. In Section H, 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:

- NHRMC is an existing facility with positions that will remain in place.
- NHRMC has ongoing recruitment efforts in place to ensure adequate personnel for its service offerings.
- NHRMC offers competitive salaries and benefits to attract and retain qualified personnel.

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 develop an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

Ancillary and Support Services

In Section I, pages 81-83, the applicant identifies the necessary ancillary and support services for the proposed services and explains how each ancillary and support service is 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:

- NHRMC is an existing facility.
- NHRMC is already providing the necessary ancillary and support services.

Coordination

In Section I, page 83, the applicant describes its existing relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- NHRMC is an existing facility.
- NHRMC has existing relationships with numerous other facilities and outreach programs.

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.

- (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

- (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 an interventional radiology room in the Neuroscience Institute, which is under construction at NHRMC, by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

In Section K, page 87, the applicant states that the project involves renovating 625 square feet of existing space. Line drawings are provided in Exhibit K.2.

In Section K, page 88, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- New construction is not needed, only renovation of existing space to include lead shielding, dimmable lighting, ceiling system to accommodate ceiling booms and utility penetrations, and structural steel mounts to accommodate the equipment.
- The project architect estimated the project renovation costs at \$1 million.

On page 88, 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 project will be developed in renovated space in the Neuroscience Institute.
- The project architect estimated the project renovation costs at \$1 million.

In Section K.3(c), pages 88-89, 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.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 91, the applicant provides the historical payor mix during CY2020 for NHRMC, as summarized in the table below.

Payor Category	Entire Facility as Percent of Total Patients
Self-Pay	6.4%
Charity Care	2.8%
Medicare*	40.1%
Medicaid*	16.4%
Insurance*	26.4%
Other (Governmental)	7.9%
Total	100.0%

*Including any managed care plans

In Section L, page 92, the applicant provides the following comparison for NHRMC IR services.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	49.5%	52.4%
Male	50.5%	47.6%
Unknown	0.0%	0.0%
64 and Younger	45.8%	81.6%
65 and Older	54.2%	18.4%
American Indian	0.7%	0.6%
Asian	0.1%	1.6%
Black or African-American	19.8%	13.4%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	76.3%	82.2%
Other Race	0.0%	2.1%
Declined / Unavailable	3.1%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and ... persons [with disabilities] to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L, page 93, the applicant states that NHRMC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L, page 93, the applicant states that, during the 18 months immediately preceding the application, no patient civil rights access complaints have been filed against the facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 94, the applicant provides tables showing the projected payor mix for both NHRMC overall services and the proposed service in the third full fiscal year, as summarized below.

**Projected Payor Mix
CY2025**

Payor Source	NHRMC	NHRMC IR Services
Self-Pay	6.4%	3.5%
Charity Care	2.8%	^
Medicare*	40.1%	59.6%
Medicaid*	16.4%	12.7%
Insurance*	26.4%	18.9%
Other (Governmental)	7.9%	5.4%
Total	100.0%	100.0%

*Including any managed care plan

^Included in Self-Pay

As shown in the table above, during the third full fiscal year of operation, the applicant projects 3.5 percent of IR services will be provided to self-pay patients, 59.6 percent of

IR services will be provided to Medicare patients, and 12.7 percent of IR services will be provided to Medicaid patients.

Exhibit L-4 contains Novant Health's financial policies. The applicant provides the assumptions and methodology used to project payor mix in Section L, page 94. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the historical payor mix of IR cases at NHRMC.
- The applicant assumes that the payor mix will remain consistent through the project years.

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.

- (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.

In Section L, page 95, the applicant describes the range of means by which a person 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 develop an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

In Section M, page 97, the applicant describes the extent to which health professional training programs in the area will 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 the following:

- Novant Health has established relationships with training programs in the area.
- Novant Health, UNC Health and the UNC School of Medicine have reached an agreement to broaden medical education, research, and clinical service through a long-term academic and clinical affiliation in the New Hanover region.

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 develop an interventional radiology room in the NHRMC Neuroscience Institute by acquiring a Siemens Artis icono bi-plane system for IR, including interventional neuroradiology.

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 2021 SMFP does not define a service area for a bi-plane system, nor are there any applicable rules adopted by the Department that define the service area for a bi-plane system. In Section C.3, page 38, the applicant defines the service area for the proposed interventional radiology services as consisting of New Hanover,

Brunswick, Pender, Onslow, Columbus counties, with “Other” including 48 counties in North Carolina and other states. Facilities may also serve residents of counties not included in the service area.

In Section G, page 73, the applicant, based on the 2021 Hospital License Renewal Applications, identifies all existing facilities in the proposed service area that provide “other imaging equipment” such as IR equipment as proposed in this application as illustrated in the following table:

Facility	Service Area County
New Hanover Regional Medical Center	New Hanover
J. Arthur Doshier Memorial Hospital	Brunswick
Novant Health Brunswick Medical Center	Brunswick
Pender Memorial Hospital	Pender
Onslow Memorial Hospital	Onslow
Columbus Regional HealthCare System	Columbus

Source: Table on page 73 of the application

On page 73, the applicant states that the data provided on the Hospital License Renewal Applications is too broadly defined for comparative purposes, stating:

“The 2021 Hospital License Renewal Application, Table 10h.-Other Imaging Equipment identifies Special Procedures/Angiography Equipment. This broad description does not allow NHRMC to know for certain if the report volumes are IR procedures, angiography procedures, or other non-IR and non-angiography procedures. Nonetheless, NHRMC is providing the reported data.”

The applicant provides the data from the respective 2021 LRAs in Exhibit G.1. The LRAs show Special Procedures/Angiography Equipment from Table 10 h. for NHRMC with two units and 3,400 procedures and NHRMC Orthopedic Hospital with one unit and 423 procedures for a total of three units and 3,823 procedures. The LRAs for the other hospitals show no Special Procedures/Angiography Equipment in Table 10 h.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 99, the applicant states:

“NHRMC expects the acquisition of the additional IR system to have a positive effect on competition in the service area because it will increase the current capacity of IR services in the service area. The IR system will also allow more complex IR cases to be performed in the service area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 99, the applicant states:

“The proposed project will increase cost effectiveness, quality, and access to services, as described below.”

...

As previously established, NHRMC is 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 B, C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, pages 101-102, the applicant states:

“Quality at NHRMC is derived from its commitment to excellence in all aspects of care throughout the healthcare system. Quality care at the organization is provided by highly skilled and compassionate teams using advanced technology, treatment protocols, and carefully outlined safety and quality assurance standards based on the tenets that care is patient-centered, safe, timely, effective, efficient, and equitable.

...

NHRM will strive to meet Novant Health’s high level of quality when it operates the IR system.”

See also Sections B, 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 102-103, the applicant states:

“NHRMC is a comprehensive provider to all patients without regard to race, color, religion, creed, national origin, sex, sexual orientation, disability, age, or ability to pay.”

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion 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 18 of this type of facility located in North Carolina.

In Section O, page 108, the applicant states that, during the 18 months immediately preceding the submittal of the application, neither NHRMC nor any other Novant Health hospital was found by the Division of Health Service Regulation or CMS to have had any incidents resulting in a finding of immediate jeopardy. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 18 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 bi-plane system for interventional radiology. There are no administrative rules that are applicable to this proposal.