

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 24, 2024

Findings Date: January 24, 2024

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: O-12443-23

Facility: Novant Health Brunswick Medical Center

FID #: 061342

County: Brunswick

Applicants: Brunswick Community Hospital, LLC

Novant Health, Inc.

Project: Acquire no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination

## 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

Brunswick Community Hospital, LLC and Novant Health, Inc. (hereinafter collectively referred to as “Novant” or “the applicant”) propose to develop no more than one unit of shared fixed cardiac catheterization (cardiac cath) equipment at Novant Health Brunswick Medical Center (NHBMC) pursuant to the 2023 State Medical Facilities Plan (SMFP) need determination.

### **Need Determination**

Chapter 17 of the 2023 State Medical Facilities Plan (SMFP) includes a need determination for one unit of shared fixed cardiac catheterization equipment in the Brunswick County cardiac catheterization service area.

The applicant does not propose to develop more units of shared fixed cardiac catheterization equipment than are determined to be needed in the 2023 SMFP for the Brunswick County cardiac catheterization service area. Therefore, the application is consistent with the need determination.

### **Policies**

There are two policies in the 2023 SMFP applicable to this review: *Policy GEN-3: Basic Principles*, and *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-3, on page 30 of the 2023 SMFP states:

*“A certificate of need applicant applying to develop or offer a new institutional health service for which there is a need determination in the North Carolina State Medical Facilities Plan shall demonstrate how the project will promote safety and quality in the delivery of health care services while promoting equitable access and maximizing healthcare value for resources expended. A certificate of need applicant shall document its plans for providing access to services for patients with limited financial resources and demonstrate the availability of capacity to provide these services. A certificate of need applicant shall also document how its projected volumes incorporate these concepts in meeting the need identified in the State Medical Facilities Plan as well as addressing the needs of all residents in the proposed service area.”*

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 25-27; Section N, pages 102-103; Section O, pages 105-107 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section B, page 28; Section C, pages 45-46; Section L, page 97; Section N, page 102 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section B, pages 28-29; Section F, pages 71-78; Section K, pages 91-93, Section N, page 102-103; the applicant’s pro forma financial statements in Section Q and referenced exhibits.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize health care value and that the applicant’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2023 SMFP. Therefore, the application is consistent with policy GEN-3.

Policy GEN-4, 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 \$4 million. In Section B, pages 29-31, 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

Based on that review, the Agency concludes that the application is conforming to this criterion based on the following:

- The applicant does not propose to acquire more shared fixed cardiac catheterization units than are determined to be needed in the 2023 SMFP for the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3 and Policy GEN-4 based on the following:

- The applicant adequately documents how the project will promote safety and quality in the delivery of cardiac catheterization services in Brunswick County.
  - The applicant adequately documents how the project will promote equitable access to cardiac catheterization services in Brunswick County; and
  - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
  - 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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination. In Section C.1, pages 32-33, the applicant describes the project as follows:

*“Pursuant to the need determination in the 2023 SMFP, the applicants propose to acquire one unit of shared fixed cardiac catheterization equipment to be installed in renovated space at NHBMC. If approved, this will be the first time Brunswick County residents will have access to both diagnostic and interventional cardiac catheterization procedures on a full-time basis in Brunswick County...NHBMC is currently the host site for a DLP Cardiac Partners’ mobile cardiac catheterization laboratory, which is onsite two days per month, for a few hours each day...In July 2022, NHBMC submitted a petition to the 2023 SMFP requesting an adjustment to the need determination to add one unit of shared fixed cardiac catheterization equipment in Brunswick County. That petition, included in Exhibit C-1.3, pointed out the limitations of the mobile cath lab and the need for more comprehensive cardiac catheterization services in Brunswick County. Ultimately, the petition was approved and a need for one unit of shared fixed cardiac catheterization equipment in Brunswick County was published in the final 2023 SMFP...This project proposes to add one unit of shared fixed cardiac catheterization equipment to the NHBMC campus. Upon completion of the project, NHBMC will no longer serve as a mobile site for the DLP Cardiac Partners’ mobile cardiac catheterization laboratory.”*

### **Patient Origin**

On page 300, the 2023 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 36, shows Brunswick County as a single county service area. Bolivia is in

Brunswick County. Thus, the service area for this proposal is Brunswick County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 35, the applicant states that 100% of the historical (CY2002) patients served on the DLP Cardiac Partners’ mobile cardiac catheterization equipment were from Brunswick County.

In Section C, page 36, the applicant provides historical patient (CY2022) origin for NHBMC, as illustrated in the following table:

Entire Facility of Campus	Novant Health Brunswick Medical Center	
	Last Full FY	
	01/01/2022 to 12/31/2022	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Brunswick	82,834	90.5%
Columbus	2,099	2.3%
New Hanover	1,017	1.1%
Mecklenburg	236	0.3%
Pender	258	0.3%
Wake	18	0.2%
Bladen	174	0.2%
Other	4,753	5.2%
<b>Total</b>	<b>91,556</b>	<b>100.0%</b>

Source: Section C, page 36

In Section C, page 40, the applicant provides projected patient origin for the shared fixed cardiac cath lab at NHBMC for the first full three years of full operation (CY 2026-2028), as shown in the following table:

**Novant Health Brunswick Medical Center**

Shared Fixed Cardiac Cath Lab	1 <sup>st</sup> Full FY CY 2026		2 <sup>nd</sup> Full FY CY 2027		3 <sup>rd</sup> Full FY CY 2028	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Brunswick County	913	90.4%	943	90.4%	975	90.4%
Columbus County	97	9.6%	100	9.6%	103	9.6%
<b>Total</b>	<b>1,010</b>	<b>100.0%</b>	<b>1,043</b>	<b>100.0%</b>	<b>1,078</b>	<b>100.0%</b>

Source: Section C, page 40

In Section C, pages 36-40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because it is based on historical utilization of cardiac catheterization services at NHBMC and Novant Health New Hanover Regional Medical Center (NHNHRMC) by residents of the proposed service area.

**Analysis of Need**

In Section C, pages 40-45, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states the cath lab is needed to accommodate the area’s growing population and the growing cardiac catheterization lab use rates by patients in the service area.
- The applicant states that Brunswick County was the fastest growing county in North Carolina, with a 5.5% growth rate. The service area’s total population is expected to increase by over 40,000 residents in the next ten years, and the population 65 and over is expected to increase by over 20,000.
- The applicant states adding a cardiac cath lab at NHBMC will increase accessibility to residents in Brunswick County, particularly those living in the southern, central, and western parts of the county. NHBMC is not only more readily accessible to a larger part of the county from a geographical perspective, but also NHBMC is within 30-minute of more Brunswick County residents than NHHNHRMC.
- The applicant states that while Brunswick County has mobile cardiac catheterization equipment, its availability is extremely limited, and it can only be used to perform diagnostic procedures. The mobile cath lab does not have 24/7 availability like a fixed cath lab and is only in operation two days per month, for a few hours each day. The limited availability of the mobile cath lab means it cannot provide the volume of cath procedures Brunswick County residents need. The current volume of the mobile cath lab shows it is not meeting the needs of service area residents.
- Providing fixed cardiac catheterization services at NHBMC, with the ability to provide both diagnostic and interventional procedures, will allow inpatients and outpatients to be served at a more accessible location.

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

- The applicant’s projected utilization is supported by its historical experience providing cardiac catheterization services utilizing the leased DLP mobile cardiac catheterization unit.
- The applicant provides information regarding current and projected population for Brunswick County from the North Carolina Office of State Budget and Management.

Projected Utilization

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

<b>Projected Utilization of NHBMC Shared Fixed Cardiac Catheterization</b>	<b>Partial FY 7/1/25 to 12/31/25</b>	<b>1<sup>st</sup> Full FY 1/1/26 to 12/31/26</b>	<b>2<sup>nd</sup> Full FY 1/1/27 to 12/31/27</b>	<b>3<sup>rd</sup> Full FY 1/1/28 to 12/31/28</b>
# of Units	1	1	1	1

# of Diagnostic Procedures	301	623	643	655
# of Therapeutic Procedures	187	387	400	413
# of Diagnostic Equivalent Procedures	629.18	1,300.01	1,343.05	1,387.50

Source: Section Q, Form C.2b, page 113

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

Step 1: The applicant used License Renewal Application (LRA) data to determine the growth rate for cardiac cath procedures at NHHHRMC from federal fiscal year FFY2017 to FFY2022. The compound annual growth rate (CAGR) for FFY2017 to FFY2022 was 3.31 percent.

Step 2: The applicant used LRA data to determine what percentages of cath lab procedures at NHHHRMC were diagnostic or therapeutic procedures.

Step 3: The applicant applied the growth rate from Step 1 and the diagnostic/therapeutic split from Step 2 to CY2022 data to project the number of cardiac catheterization procedures at NHHHRMC before any shifts to CON-proposed cath labs (NHBMC and NH Scotts Hill).

Step 4: The applicant determined parameters for what cases will shift to NHBMC. The applicant determined the percentage of the total CY2022 cath lab cases at NHHHRMC a) that were clinically appropriate shift, and b) were patients living in the NHBMC service area (Brunswick and Columbus counties).

Step 4B: The applicant projects some clinically appropriate patients who live in the NHBMC service area may choose to receive care at NHHHRMC’s 17<sup>th</sup> Street main campus in Wilmington.

Step 5: The applicant projects NHHHRMC volume shifts to NHBMC to project the number of cath lab patients shifting to NHBMC in its first three full fiscal years of operation. The cath lab at NHBMC is assumed to open in July 2025.

Projected utilization is reasonable and adequately supported because it is based on data on utilization of cardiac catheterization services at NHHHRMC by residents of the proposed service area and by letters of support from Novant Health cardiologists.

**Access to Medically Underserved Groups**

In Section C.6, page 57, the applicant states: *“NHBMC 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. NHBMC will actively participate 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	NH does not track this information
Racial and ethnic minorities	13.2%
Women	62.9%
Persons with disabilities	NH does not track this information
Persons 65 and older	44.5%
Medicare beneficiaries	47.6%
Medicaid recipients	14.5%

Source: Section C, page 59

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 this information provided on pages 58-59 of the application.

### **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

- (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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

In Section E, page 69, the applicant describes the alternative it considered and explains why this alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The applicant states maintain the status quo was the only



alternative to the proposed project. If NHBMC did not add a fixed shared cardiac cath lab, it would have to continue serving the population through the mobile cath lab. NHBMC is currently a host site for DLP Cardiac Partners' mobile cardiac catheterization laboratory, which is onsite two days per month. On page 69, the applicant states that its proposal is the most effective alternative because offering cardiac cath services two days per month for only a few hours is not sustainable for the growing number of cardiac catheterization procedures in Brunswick County.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

### **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. Brunswick Community Hospital, 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 one unit of shared fixed cardiac catheterization equipment at Novant Health Brunswick Medical Center (NHBMC) pursuant to the need determination in the 2023 SMFP.**
- 3. Upon completion of the project, Novant Health Brunswick Medical Center shall be licensed for no more than one unit of shared fixed cardiac catheterization equipment.**
- 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 June 1, 2024.**

**6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

#### **Capital and Working Capital Costs**

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

Construction Costs	\$8,817,409
Architect/ Engineering Fees	\$881,740
Medical Equipment	\$3,962,936
Non Medical Equipment	\$434,990
Furniture	\$93,682
Consultant Fees	\$36,000
Contingency	\$1,239,955
<b>Total</b>	<b>\$15,466,712</b>

In Section Q, Form F.1a, 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 documentation from the Novant Health Design and Construction department in Exhibit F-1.1.

In Section F page 73, the applicant projects that start-up costs will be \$630,642 and initial operating expenses will be \$0 for a total working capital of \$630,642. On page 73, the applicant provides the assumptions and methodology used to project the working capital needs

of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- The applicants state NHBMC is an existing, profitable hospital, there will be no initial operating costs, as cash outflow will never exceed cash inflow.
- The applicants state for startup costs they will assume two months of operating expenses prior to opening, based on the first project year’s total operating expenses.

**Availability of Funds**

In Section F.2, page 71, the applicant projects the total capital cost will be funded, as shown in the table below.

Type	Brunswick Community Hospital, LLC	Novant Health, Inc.	Total
Loans	\$	\$	\$
Cash and Cash Equivalents, Accumulated reserves or OE *	\$	\$15,466,712	\$15,466,712
Bonds	\$	\$	\$
Other (Specify)	\$	\$	\$
Total Financing	\$0	\$15,466,712	\$15,466,712

\* OE = Owner’s Equity

In Section F.3, page 74, the applicant states the working capital cost will be funded as shown in the table below.

Type	Brunswick Community Hospital, LLC	Novant Health, Inc.	Total
Loans	\$	\$	\$
Accumulated reserves or OE *	\$	\$630,642	\$630,642
Bonds	\$	\$	\$
Other (Specify)	\$	\$	\$
Total Financing	\$0	\$630,642	\$630,642

\* OE = Owner’s Equity

Exhibit F.2-1 contains a letter dated October 5, 2023 from the Senior Vice President, Operational Finance & Revenue Cycle for Novant Health, Inc. documenting that Novant Health has sufficient cash reserves and would make the funds available to for the capital and working capital costs of the proposed project. Exhibit F.2-2 also contains a copy of Novant Health, Inc. and Affiliates consolidated financial statements demonstrating adequate availability of funds.

**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.2, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

<b>Projected Revenues and Expenses NHBMC Shared Fixed Cardiac Catheterization Lab</b>	<b>1st Full FY CY 2026</b>	<b>2<sup>nd</sup> Full FY CY 2027</b>	<b>3<sup>rd</sup> Full FY CY 2028</b>
Total Procedures	1,300	1,343	1,387
Total Gross Revenues (Charges)	\$47,196,917	\$50,201,164	\$53,442,340
Total Net Revenue	\$8,783,570	\$9,342,675	\$9,945,873
Average Net Revenue per Procedure	\$6,757	\$6,957	\$7,171
Total Operating Expenses (Costs)	\$5,158,990	\$5,349,238	\$5,551,772
Average Operating Expense per Procedure	\$3,968	\$3,983	\$4,003
Net Income	\$3,624,580	\$3,993,437	\$4,394,101

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application.

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 based on the following:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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 costs and charges.

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

The applicant proposes to acquire no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

On page 300, the 2023 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 36 of the 2023 SMFP shows Brunswick County as a single county acute care bed service area. Thus, the service area for this proposal is Brunswick County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 80, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Brunswick County. The applicant states, “*There are currently no fixed cardiac catheterization machines in Brunswick or Columbus counties.*”

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:

- There is a need determination in the 2023 SMFP for the proposed shared fixed cardiac catheterization equipment.
- There are no fixed cardiac catheterization labs in Brunswick County.
- The applicant adequately demonstrates that the proposed unit of shared fixed cardiac catheterization equipment is needed at NHBMC. See discussion 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 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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

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

Positions	1 <sup>st</sup> Full FY FTE	2 <sup>nd</sup> Full FY FTE	3 <sup>rd</sup> Full FY FTE
Registered Nurses	5.0	5.0	5.0
Other (Cardiac Cath/Cardiovascular Tech)	10.2	10.2	10.2
Other (Supervisor)	1.00	1.0	1.0
Other (Nurse Manager)	0.4	0.4	0.4
<b>TOTAL</b>	<b>16.6</b>	<b>16.6</b>	<b>16.6</b>

Source: Section Q, Form H, page 134

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.2.1, and H.3, pages 82-85, and Exhibit H.3, the applicant describes the methods 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 information provided in Section H, pages 82-85, Section Q, Form H and Exhibit 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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

**Ancillary and Support Services**

In Section I.1, page 87, the applicant identifies the necessary ancillary and support services for the proposed services. On page 87, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Exhibit I.1, a letter from the President & CEO of Novant Health Brunswick Medical Center states:

*“In my role I oversee the ancillary and support services at NHBMC. These services include, but are not limited to: laboratory, pathology, radiology, pharmacy, environmental, and laundry services. All ancillary services necessary for providing both inpatient and outpatient care are currently in place at NHBMC. The proposed cardiac catheterization laboratory and its patients will have access to the same services immediately upon its opening.”*

The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

### **Coordination**

In Section I.2, page 88, 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. 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 88, and Exhibit I.2, 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.

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

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

In Section K.2, page 91, the applicant states the project involves renovation of 8,737 square feet of space. Line drawings are provided in Exhibit K-2.

On page 91, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states,

*“The cath lab will be built into an existing courtyard that was designed for expansion when the original hospital was built. The courtyard can be completely separated from hospital operations during construction and will not affect flow on the interior or exterior of the building. There is no sitework expected, which reduced construction costs. Placing the cath lab in the courtyard is the most effective cost and design strategy.”*

On page 92, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states,

*“The project costs incurred by NH will be spread over the total patient volume at NHBMC, and across the larger healthcare system. The costs and charges to the public should not increase due to this project because no major payor bases payment on the costs of a specific hospital.”*



On page 92, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

**C**

In Section L, page 95, the applicant provides the historical payor mix during CY2022 for Novant Health Brunswick Medical Center, as shown in the table below.

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	1.50%
Charity Care	6.90%
Medicare*	47.30%
Medicaid*	14.60%
Insurance*	26.70%
Workers Compensation	0.20%
TRICARE	1.20%
Other (describe)	1.60%

<b>Total</b>	<b>100.00%</b>
--------------	----------------

Source: Table on page 95 of the application  
 \*Including any managed care plans.

In Section L, page 96, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	62.89%	52.90%
Male	37.11%	48.10%
Unknown	0.01%	n/a
64 and Younger	55.5%	66.00%
65 and Older	44.5%	34.00%
American Indian	0.41%	0.80%
Asian	0.31%	0.80%
Black or African American	8.34%	9.30%
Native Hawaiian or Pacific Islander	0.11%	0.10%
White or Caucasian	86.83%	87.00%
Other Race	2.95%	1.90%
Declined / Unavailable	1.06%	0.100%

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.2, pages 97-98 the applicant states that Novant Health Brunswick Medical Center does not have any obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and the handicapped. As a 501(c)(3) tax-exempt entity,

NHBMC is a charitable organization that promotes the health of the community. Accordingly, charity care is provided. However, there are no federal regulations per se applicable that require the provision of uncompensated care. Nevertheless, NHBMC-affiliated entities strive to provide services to all persons in need of health care services, regardless of their ability to pay.

In Section L, page 95, the applicant states that during the 18 months immediately preceding the application deadline, no complaints have been filed against NHBMC.

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, pages 98-99, the applicant projects the following payor mix for Novant Health Brunswick Medical Center overall and for cardiac cath services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

**Novant Health Brunswick Medical Center - CY2028**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	1.50%
Charity Care	6.87%
Medicare*	47.55%
Medicaid*	14.52%
Insurance*	26.58%
Workers Compensation	0.23%

TRICARE	1.15%
Other	1.58%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 98 of the application.

\*Including any managed care plans.

**Novant Health Brunswick Medical Center: Shared Fixed Cardiac Catheterization**

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	0.86%
Charity Care	3.01%
Medicare*	69.32%
Medicaid*	3.50%
Insurance*	19.64%
Workers Compensation	0.00%
TRICARE	0.32%
Other	3.34%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 99 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.86% of total cardiac cath services will be provided to self-pay patients, 3.01% to charity care patients, 69.32% to Medicare patients and 3.50% to Medicaid patients.

On page 96, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the historical payor mix data from FY2022 for cardiac cath services at Novant Health Brunswick Medical Center.

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.

In Section L, page 99, 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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

In Section M.1, page 101, 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 H-2.1. The applicant adequately demonstrates that health professional training programs in the area 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 no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

On page 300, the 2023 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 36 of the 2023 SMFP shows Brunswick County as a single county acute care bed service area. Thus, the service area for this proposal is Brunswick County. Facilities may also serve residents of counties not included in their service area.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 102, the applicant states:

*“Placing a cath lab at NHBMC has better effects on competition in the service area than awarding the cath lab to another provider. Placing a cath lab at NHBMC is more cost-effective because it can serve a wider scope of inpatients and outpatients. Because of Novant Health’s charity care policy it will be more accessible for medically underserved groups.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 102, the applicant states:

*“Placing a cath lab at NHBMC is more cost-effective because it can serve a wider scope in inpatients and outpatients. The proposed cath lab will be cost-effective because it can take advantage of the support services and staffing of NHBMC and of the Novant Health organization. This includes purchasing power for equipment and supplies.”*

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 102 -103, the applicant states:

*“The proposed cath lab will improve the quality of cardiac catheterization services available in Brunswick County by having a lab that is available to both inpatients and outpatients on a 24/7 basis to provide both diagnostic and interventional procedures.”*

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 103, the applicant states:

*“The proposed cath lab will improve access for medically underserved groups by applying the same charity care and financial assistance policies as all other NH facilities and practitioners.”*

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

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**

The applicant proposes to acquire no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

In Section Q, Form O, page 137, 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 six of these types of facilities located in North Carolina.

In Section O, page 104, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in June 24, 2022 at Novant Health New Hanover Regional Medical Center (NHNHRMC) related to the evaluation and supervision of care of two patients. The applicant states that the problems have been corrected as of August 11, 2022 and the facility is back in compliance. 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, 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.

## C

The application is conforming with all applicable Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600. The specific criteria are discussed below.

### **10A NCAC 14C .1603 PERFORMANCE STANDARDS**

(a) An applicant proposing to acquire fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:

- (1) identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;
- (2) identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;
- (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;
- (4) provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and
- (5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.

**-NA-** The applicant does not propose to acquire fixed cardiac catheterization equipment pursuant to a need determination in the 2023 State Medical Facilities Plan.



- (b) An applicant proposing to acquire shared fixed cardiac catheterization equipment pursuant to a need determination in the annual State Medical Facilities Plan in effect as of the first day of the review period shall:
  - (1) provide projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;
- C- In Section Q, Form C.2b, the applicant provides projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the proposed project.
  - (2) provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and
- C- In Section Q, pages 114-120, the applicant provides the assumptions and methodology used to project utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the proposed project.
  - (3) project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of the project.
- C- Upon completion of the proposed project, NHBMC will have one unit of shared fixed cardiac catheterization equipment. In Section Q, the applicant projects that the one unit of shared fixed cardiac catheterization equipment will perform 1,388 diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of this proposed project which exceeds the 225 procedures required by this Rule.
- (c) An applicant proposing to acquire mobile cardiac catheterization equipment pursuant to a need determination in the State Medical Facilities Plan in effect as of the first day of the review period shall:
  - (1) identify the existing mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that provides cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;
  - (2) identify the approved mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that will provide cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;
  - (3) provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;

- 4) provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and
- (5) project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.

-NA- The applicant does not propose to acquire mobile cardiac catheterization equipment.