

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 25, 2024

Findings Date: January 25, 2024

Project Analyst: Ena Lightbourne

Co-Signer: Mike McKillip

### COMPETITIVE REVIEW

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Project ID #: O-12415-23

Facility: Novant Health Scotts Hill Medical Center

FID #: 200732

County: New Hanover

Applicant(s): Novant Health New Hanover Regional Medical Center, LLC  
Novant Health, Inc.

Project: Acquire no more than one unit of fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination which is a change of scope for Project ID# O-11947-20 for a total no more than seven units of cardiac catheterization equipment

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Project ID #: O-12416-23

Facility: Wilmington ASC

FID #: 170523

County: New Hanover

Applicant(s): Wilmington ASC, LLC

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

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Each application was reviewed independently against the applicable statutory review criteria found in G.S. 131E-183(a) and the regulatory review criteria found in 10A NCAC 14C. After completing an independent analysis of each application, the Healthcare Planning and Certificate of Need Section (CON Section) also conducted a comparative analysis of all the applications. The Decision, which can be found at the end of the Required State Agency Findings (Findings), is based on the independent analysis and the comparative analysis.

### 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  
Both Applications

**Need Determination**

The 2023 State Medical Facilities Plan (SMFP) includes a need determination for one unit of fixed cardiac catheterization (cardiac cath) equipment in the New Hanover County fixed cardiac cath service area. Two applications were received by the Healthcare Planning and Certificate of Need Section (CON Section) with each proposing to acquire one unit of fixed cardiac cath equipment. However, pursuant to the need determination, only one unit of fixed cardiac cath equipment can be approved in this review.

**Policies**

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

**Policy GEN-3**

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.”*

**Policy GEN-4**

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.”*

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

Novant Health New Hanover Regional Medical Center, LLC and Novant Health, Inc., hereinafter collectively referred to as “the applicant” or “Novant Health”, propose to develop a new fixed cardiac cath laboratory by acquiring one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP, which is a change of scope for Project ID# O-11947-20 (develop a new hospital by relocating no more than 30 acute care beds and 8 ORs from New Hanover Regional Medical Center (NHNHRMC) and developing 36 acute care beds) for a total of one unit of fixed cardiac cath equipment at the Novant Health Scotts Hill Medical Center (NH Scotts Hill) campus. The NH Scotts Hill Campus will be licensed under NHNHRMC. Upon project completion, NHNHRMC will be licensed for a total of seven units of fixed cardiac cath equipment.

*Need Determination.* The applicant does not propose to develop more units of fixed cardiac cath equipment than are determined to be needed in the New Hanover County fixed cardiac cath service area.

*Policy GEN-3.* In Section B, pages 26-30, the applicant explains why it believes its application is conforming to *Policy GEN-3*.

*Policy GEN-4.* The proposed capital expenditure is over \$5 million. In Section B.2, pages 31-32, and Exhibit B.21, 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to acquire more units of fixed cardiac cath equipment than are determined to be needed in 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 fixed cardiac cath services in New Hanover County;
  - The applicant adequately documents how the project will promote equitable access to fixed cardiac cath services in New Hanover 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.

### **Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

Wilmington ASC, LLC, hereinafter referred to as "the applicant", proposes to develop one unit of fixed cardiac cath equipment at Wilmington ASC, pursuant to the need determination in the 2023 SMFP. Wilmington ASC is an existing ambulatory surgical facility (ASF) located on Glenn Mead road in Wilmington. Upon project completion, Wilmington ASC will be licensed for a total of one unit of fixed cardiac cath equipment.

*Need Determination.* The applicant does not propose to develop more units of fixed cardiac cath equipment than are determined to be needed in the New Hanover County fixed cardiac cath service area.

*Policy GEN-3.* In Section B, pages 26-31, the applicant explains why it believes its application is conforming to *Policy GEN-3*.

*Policy GEN-4*. The proposed capital expenditure is over \$5 million. In Section B, page 32, 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
- Written comments
- Responses to comments
- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to acquire more units of fixed cardiac cath equipment than are determined to be needed in 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 fixed cardiac cath services in New Hanover County;
  - The applicant adequately documents how the project will promote equitable access to fixed cardiac cath services in New Hanover 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 Both Applications

On page 300, the 2023 SMFP defines the cardiac cath 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 New Hanover County as a single county service area. Therefore, the service area for the fixed cardiac cath equipment is New Hanover County. Facilities may also serve residents of counties not included in their service area.

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

**Patient Origin**

NH Scotts Hill is a new facility currently under construction. Therefore, there is no historical patient origin to report. The following table illustrates projected patient origin.

<b>NH Scotts Hill Projected Patient Origin Cardiac Cath</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY</b>		<b>2<sup>nd</sup> Full FY</b>		<b>3<sup>rd</sup> Full FY</b>	
	<b>01/01/27-12/31/27</b>		<b>01/01/28-12/31/28</b>		<b>01/01/29-12/31/29</b>	
	<b>CY2027</b>		<b>CY2028</b>		<b>CY2029</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
New Hanover	328	46%	338	46%	350	46%
Onslow	74	10%	77	10%	79	10%
Pender	312	44%	322	44%	333	44%
<b>Total</b>	<b>715</b>	<b>100%</b>	<b>738</b>	<b>100%</b>	<b>763</b>	<b>100%</b>

Source: Section C. page 38

In Section C, pages 37-39, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin based on the number of clinically appropriate patients residing in the 5-zip code service area expected to shift to the proposed NH Scotts Hill cath lab and distributed by county based on the NHNHRMC patients who were appropriate (zip code and procedural code) to shift in CY2022. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- The applicant combined the number of NH Scotts Hill campus patients projected in the previously approved application Project ID# O-11947-20, to the projected cath lab patients by county.

**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, As summarized below:

- The historical and projected population growth in the NHHHRMC primary service area (New Hanover County) and the secondary service area (Bladen, Brunswick, Columbus, Duplin, Onslow and Pender counties), particularly among the 65+ age group. (pages 40-42)
- The historical growth in volume experienced in NHHHRMC’s existing cath labs. (pages 43-44)
- Physician recruitment and the expansion of services has allowed NHHHRMC to serve more clinically complex patients which has increased the demand for their heart and vascular services. (pages 44-45)
- The applicant states that the previously approved application to develop NH Scotts Hill as a community hospital away from the existing NHHHRMC will improve geographical accessibility and choice. Additionally, it will help shift lower-acuity inpatients and patients from NHHHRMC, a tertiary care provider, to a smaller, more convenient location. (pages 45-46)

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

- The 2023 SMFP identifies the need for one additional unit of fixed cardiac cath equipment in New Hanover County.
- The applicant cites publicly available data to support its conclusions about population growth in the primary and secondary service area.
- The total cardiac cath lab volume (diagnostic, interventional, total cases, and diagnostic equivalents) at NHHHRMC had a FFY 2017-2022 Compound Annual Growth Rate (CAGR) of 3.3% despite the impact of the COVID-19 pandemic.
- NHHHRMC was the only provider of fixed cardiac cath services in New Hanover County which generated the 2023 SMFP need for one additional unit of fixed cardiac cath equipment in New Hanover County.

Projected Utilization

In Section Q, pages 114-115, the applicant provides projected utilization, as illustrated in the following tables.

<b>NH Scotts Hill Projected Utilization</b>				
	<b>Partial FY 10/15/26- 12/31/26</b>	<b>1st Full FY (CY2027)</b>	<b>2<sup>nd</sup> Full FY (CY2028)</b>	<b>3<sup>rd</sup> Full FY (CY2029)</b>
# of Units	1	1	1	1
# of Diagnostic Procedures	98	474	490	506
# of Therapeutic Procedures	50	241	249	257
# of Diagnostic Equivalent Procedures*	185.2	895.5	925.1	955.8

\*Diagnostic Equivalent Procedures equals Diagnostic Procedures + [Therapeutic (Interventional) Procedures x 1.75]

<b>NHNHRMC License Projected Utilization</b>				
	<b>Partial FY 10/15/26- 12/31/26</b>	<b>1st Full FY (CY2027)</b>	<b>2<sup>nd</sup> Full FY (CY2028)</b>	<b>3<sup>rd</sup> Full FY (CY2029)</b>
# of Units	7	7	7	7
# of Diagnostic Procedures	663	3,204	3,310	3,419
# of Therapeutic Procedures	436	2,108	2,178	2,250
# of Diagnostic Equivalent Procedures*	1,425.77	6,892.73	7,120.90	7,356.62

\*Diagnostic Equivalent Procedures equals Diagnostic Procedures + [Therapeutic (Interventional) Procedures x 1.75]

In Section Q, pages 116-126, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

*Step 1: Determine the Historical Growth Rate for Cath Lab Procedures at NHNHRMC*

<b>Historical Volume at NHNHRMC CATH Labs</b>						
<i>LRA Year:</i>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>	<b>2023</b>
<i>Data Year:</i>	<b>FFY2017</b>	<b>FFY2018</b>	<b>FFY2019</b>	<b>FFY2020</b>	<b>FFY2021</b>	<b>FFY2022</b>
Diagnostic Cardiac Cath Cases	2,863	2,789	3,242	2,201	2,462	3,372
Therapeutic Cardiac Cath Cases	1,870	1,768	2,461	2,004	2,719	2,198
Total Cardiac Cath Cases	4,733	4,557	5,703	4,205	5,181	5,570
5-Year CAGR	3.31%					
Cardiac Cath Systems	5	5	5	5	5	5
Diagnostic-Equivalent Cases	6,136	5,883	7,549	5,708	7,220	7,219
Performance Standard	900	900	900	900	900	900
Utilization at Standard	136.3%	130.7%	167.8%	126.8%	160.5%	160.4%
NHNHRMC Need	6.8	6.5	8.4	6.3	8.0	8.0

Source: Section Q, page 117; LRAs for NHNHRMC

	<b>FFY2017- 2022</b>	<b>FFY2018- 2022</b>	<b>FFY2019- 2022</b>	<b>FFY2020- 2022</b>	<b>FFY2021- 2022</b>
CAGR	3.31%	5.15%	-0.78%	9.82%	3.69%

Source: Section Q, page 117; LRAs

The applicant states that the CAGR from FFY2017 to FFY2022 will be applied to project future volumes prior to the projected shift of cases to NH Scotts Hill and Novant Health Brunswick Medical Center (NHBMC). The applicant states that the growth rate is reasonable



because it represents volumes before the pandemic, during the pandemic, and after the pandemic.

*Step 2: Determine the Historical Split Between Diagnostic and Therapeutic Procedures at NHHHRMC*

<b>Distribution of Diagnostic and Therapeutic Cath Lab Cases at NHHHRMC, FY2019-CY2022</b>							
	<b>FFY2017</b>	<b>FFY2018</b>	<b>FFY2019</b>	<b>FFY2020</b>	<b>FFY2021</b>	<b>FFY2022</b>	<b>CY2022</b>
Diagnostic Cases	60%	61%	57%	52%	48%	61%	56%
Therapeutic Cases	40%	39%	43%	48%	52%	39%	44%

Source: Section Q, page 118; LRAs; Form C.2a

*Step 3: Apply Historical Growth Rate and Cath Splits to Project Future Volume, Before Shifts*

The applicant applied the historical CAGR, and the split of diagnostic and therapeutic procedures illustrated in *Step 2* to NHHHRMC CY2022 volumes.

<b>Projected Cardiac Cath Volume at NHHHRMC, CY2022-CY2029 Before Shifts</b>								
	<b>Actual</b>	<b>Projected</b>						
	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>	<b>CY2026</b>	<b>CY2027</b>	<b>CY2028</b>	<b>CY2029</b>
Diagnostic Cases	3,029	3,377	3,489	3,605	3,724	3,847	3,975	4,106
Therapeutic Cases	2,371	2,201	2,274	2,350	2,427	2,508	2,591	2,677
Total Cath Lab Cases	5,400	5,579	5,763	5,954	6,151	6,355	6,565	6,783
Diagnostic-Equivalent Cases	7,178	7,230	7,469	7,716	7,972	8,236	8,508	8,790

Source: Section Q, page 118; *Step 1, Step 2*

*Step 4: Determine Parameters for What Cases will Shift to NH Brunswick Medical Center, if Approved*

The applicant proposes to apply for one shared fixed unit of cardiac cath equipment in Brunswick County at NHBMC, in response to the 2023 SMFP need determination. In this application, the applicant will project a shift of cases from NHHHRMC to NHBMC. The applicant states that if the NHBMC application is denied, more volume would remain on the NHHHRMC license and the projections in the subsequent steps would be higher.

*Step 4a: Determine What Percent of NHHHRMC Cath Lab Volume is Clinically Appropriate for NHBMC and Comes from Within the NHBMC Service Area*

The applicant examines the NHHHRMC CY2022 volume to determine the cath lab volume appropriate to shift NHBMC based on the clinically appropriate CPT and ICD-10 codes and the patient's place of residence. The applicant states that these procedures are also clinically appropriate for NH Scotts Hill.

<b>CY2022 NHHHRMC Cath lab Volume Appropriate to Shift to NHBMC</b>		
	<b>Diagnostic Cath</b>	<b>Therapeutic Cath</b>
Brunswick County Residents-In Code Set	871	647
Columbus County Residents-In Code Set	254	198
Total NHHHRMC Volume	3,029	2,371

Source: Section Q, page 119; Novant Health Internal Data

<b>CY2022 Percentage NHHHRMC Volume in BMC Service Area and Code Set</b>		
	<b>Diagnostic Cath</b>	<b>Therapeutic Cath</b>
Brunswick County Residents-In Code Set	28.8%	27.3%
Columbus County Residents-In Code Set	8.4%	8.4%
Total NHHHRMC Volume	100%	100%

Source: Section Q, page 119; Novant Health Internal Data

*Step 4b: Determine Patient Destination for Services Available at Both Facilities*

The applicant examined CY2022 data of Brunswick and Columbus County inpatients discharges from NHHHRMC or NHBMC to estimate the percentage of patients from each county choosing each hospital for services that both hospitals provide.

<b>Patient Destination for DRGs for which Both Hospitals &gt;=12 Discharges</b>		
	<b>NHHHRMC</b>	<b>NHBMC</b>
Brunswick County Residents	47%	53%
Columbus County Residents	81%	19%

Source: Section Q, page 119; Novant Health Internal Data, CY2022

*Step 4c: Calculate Percentages of Cath Lab Cases Shifting to NHBMC*

To project the total percentage of patients expected to shift to NHBMC, the applicant multiplied the percentage of NHHHRMC cath lab patients appropriate to shift to NHBMC (*Step 4a*) by the percentage of patients who choose to receive services at NHBMC that are available at both facilities (*Step 4b*).

<b>Part C: Total % of Projected Patients Expected at BMC = Step 4A * Step 4B</b>		
	<b>Diagnostic</b>	<b>Therapeutic</b>
Brunswick County Residents	15.15%	14.38%
Columbus County Residents	1.57%	1.57%
Total BMC Service Area	16.72%	15.94%

Source: Section Q, page 120; Novant Health Internal Data, CY2022; *Step 4a, Step 4b*

*Step 5: Calculate NHHHRMC Volume Shifts to NHBMC*

The applicant applies the shift percentages calculated in *Step 4c* to the projected volume calculated in *Step 3*.

<b>Historical Volume at NHHNHRMC CATH Labs</b>						
	<b>2025 Jul-Dec</b>	<b>2026 Jan-Oct 14<sup>th</sup></b>	<b>26 Oct 15<sup>th</sup>-Dec 31<sup>st</sup></b>	<b>CY2027</b>	<b>CY2028</b>	<b>CY2029</b>
Diagnostic Cath Cases	301	490	133	643	665	687
Therapeutic Cath Cases	187	304	83	400	413	427
Total Cath Cases	489	794	216	1,043	1,078	1,113
Diagnostic-Equivalent Cases	629	1,022	278	1,343	1,388	1,433
Cardiac Cath Systems	1	1	1	1	1	1
Performance Standard	113	178	47	225	225	225
Utilization	559%	574%	593%	597%	617%	637%
NHBMC Need at Shared Fixed Standard	5.59	5.74	5.93	5.97	6.17	6.37

Source: Section Q, page 120; Novant Health Internal Data CY2022; Step 4c, Step 3

*Step 6: Calculate Volume Remaining on NHHNHRMC License*

The volume remaining on NHHNHRMC license is calculated by subtracting the volume from Step 5 from the volume from Step 3.

<b>Cath Lab Volume Remaining on NHHNHRMC License after NHBMC</b>						
	<b>2025 Jul-Dec</b>	<b>2026 Jan-Oct 14<sup>th</sup></b>	<b>26 Oct 15<sup>th</sup>-Dec 31<sup>st</sup></b>	<b>CY2027</b>	<b>CY2028</b>	<b>CY2029</b>
Diagnostic Cath Cases	1,501	2,438	663	3,204	3,310	3,419
Therapeutic Cath Cases	988	1,604	436	2,108	2,178	2,250
Total Cath Cases	2,488	4,043	1,099	5,312	5,488	5,669
Diagnostic-Equivalent Cases	3,229	5,246	1,426	6,893	7,121	7,357
Cardiac Cath Systems	6	67	7	7	7	7
Performance Standard	450	713	188	900	900	900
Utilization at Standard	120%	123%	109%	109%	113%	117%
NHHNHRMC Need	7.18	7.36	7.60	7.66	7.91	8.17

Source: Section Q, page 121; Novant Health Internal Data CY2022; Step 3, Step 5

*Step 7: Determine Parameters for Cath Lab Volume Shift to NH Scotts Hill*

The applicant assumes that patients residing in the NH Scotts Hill service area zip codes and farther from the main campus (NHNHRMC) would seek care at NH Scotts Hill. The following table illustrates the CY2022 clinically appropriate diagnostic and therapeutic cath lab cases that resided in the NH Scotts Hill service area zip codes.

<b>% of CY2022 NHNHRMC Cath Lab Encounters for Patients from NH Scotts Hill Proximate ZIP Codes who are Clinically Appropriate for Care at NH Scotts Hill</b>		
	<b>Diagnostic</b>	<b>Therapeutic</b>
Clinically Appropriate Patients from Proximate ZIP Codes	448	271
NHNHRMC Total	3,029	2,371
Percent from Proximate ZIP Codes	14.79%	11.43%

Source: Section Q, page 122; Novant Health Internal Data CY2022

*Step 8: Apply Step 7 Percentages to Step 6 Volume Remaining on NHNHRMC License*

<b>65+ Population Growth in NH Scotts Hill Proximate ZIP Codes, New Hanover County, and NHNHRMC Service Area, 2023-2028</b>	
Area	65+ Populations Growth 2023-2028
28411	12.57%
28429	20.5%
28443	23.69%
28445	13.89%
28457	27.74%
Total NH Scots Hill Proximate ZIP Codes	18.59%
New Hanover County	12.50%
NHNHRMC Primary and Secondary Service Area	14.70%
North Carolina	14.56%

Source: Section Q, page 123; esri; NCOSBM

<b>Projected NH Scotts Hill Cath Lab Volume, Interim and First Three Project Years</b>				
	<b>26 Oct 15<sup>th</sup>- Dec 31<sup>st</sup></b>	<b>CY2027</b>	<b>CY2028</b>	<b>CY2029</b>
Diagnostic Cardiac Cath Cases	98	474	490	506
Therapeutic Cardiac Cath Cases	50	241	249	257
Total Cardiac Cath Cases	148	715	738	763
Diagnostic-Equivalent Cases	185	895	925	956
Cardiac Cath Systems	1	1	1	1
Performance Standard	192	900	900	900
Utilization	96%	99%	103%	106%
System Need	0.96	0.99	1.03	1.06

Source: Section Q, page 123; *Step 6, Step 7*

*Step 9: Determine Volume Remaining on 17<sup>th</sup> Street Main Campus after NH Scotts Hill Opens*

The applicant subtracts volumes calculated in *Step 8* from the volumes calculated in *Step 6* for October 15, 2026, to December 2029, to project the volume remaining at NHHHRMC after NH Scotts Hill and NHBMC open. The applicant evenly distributes volumes across the six cath labs.

<b>Projected Volume at 17<sup>th</sup> Street Main Campus</b>				
<b>Associated Step</b>	<b>Actual</b>	<b>Step 3</b>		<b>Step 3/Step 6*</b>
<b>Period</b>	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>
Diagnostic Cardiac Cath Cases	3,029	3,377	3,489	3,303
Therapeutic Cardiac Cath Cases	2,371	2,201	2,274	2,162
Total Cardiac Cath Cases	5,400	5,579	5,763	5,466
Diagnostic-Equivalent Cases	7,178	7,230	7,469	7,087
Cardiac Cath Systems	5	5	5	6
Performance Standard	900	900	900	900
Utilization At Standard	160%	161%	166%	131%
17 <sup>th</sup> Street Main Campus Need	8.0	8.0	8.3	7.9

Source: Section Q, page 125; Novant Health Internal Data; *Step 3, Step 6, Step 8*  
 \**Step 3* is used for the period (Jan-June 2025) before NHBMC opens and *Step 6* is used for the period after NHBMC opened (July-Dec 2025).

<b>Projected Volume at 17<sup>th</sup> Street Main Campus</b>				
Associated Step	<b>Step 6-Step 8</b>			
Period	<b>CY2026</b>	<b>CY2027</b>	<b>CY2028</b>	<b>CY2029</b>
Diagnostic Cardiac Cath Cases	3,003	2,730	2,820	2,914
Therapeutic Cardiac Cath Cases	1,991	1,867	1,929	1,993
Total Cardiac Cath Cases	4,994	4,457	4,749	4,906
Diagnostic-Equivalent Cases	6,487	5,997	6,196	6,401
Cardiac Cath Systems	6	6	6	6
Performance Standard	900	900	900	900
Utilization At Standard	120%	111%	115%	119%
17 <sup>th</sup> Street Main Campus Need	7.2	6.7	6.9	7.1

Source: Section Q, page 125; Novant Health Internal Data; *Step 3, Step 6, Step 8*  
 \**Step 3* is used for the period (Jan-June 2025) before NHBMC opens and *Step 6* is used for the period after NHBMC opened (July-Dec 2025).

The applicant projects the cath lab volume remaining on the NHHHRMC license without the shifts to NHBMC if the application to develop a cath lab at NHBMC is denied.

<b>Projected Cardiac Cath Volume on NHHHRMC License, CY2022-CY2029 With no Patient Shift</b>								
	<b>Actual</b>	<b>Projected</b>						
	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>	<b>CY2026</b>	<b>CY2027</b>	<b>CY2028</b>	<b>CY2029</b>
Diagnostic Cases	3,029	3,377	3,489	3,605	3,724	3,847	3,975	4,106
Therapeutic Cases	2,371	2,201	2,274	2,350	2,427	2,508	2,591	2,677
Total Cath Lab Cases	5,400	5,579	5,763	5,954	6,151	6,355	6,565	6,783
Diagnostic-Equivalent Cases	7,178	7,230	7,469	7,716	7,972	8,236	8,508	8,790

Source: Section Q, page 126; *Step 3*

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

- There is a need determination in the 2023 SMFP for a unit of fixed cardiac cath equipment in the New Hanover County cardiac cath service area.

- The applicant’s projections of cardiac cath volumes are supported by the historical growth rate of cardiac cath volumes of the existing cardiac cath labs.

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

**Patient Origin**

Wilmington ASC nor Wilmington Health currently own cardiac cath equipment. Therefore, there is no historical patient origin to report. The following table illustrates projected patient origin.

<b>Wilmington ASC Projected Patient Origin Cardiac Cath</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY</b>		<b>2<sup>nd</sup> Full FY</b>		<b>3<sup>rd</sup> Full FY</b>	
	<b>01/01/26-12/31/26</b>		<b>01/01/27-12/31/27</b>		<b>01/01/28-12/31/28</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
New Hanover	339	41.2%	343	41.2%	347	41.2%
Brunswick	183	22.2%	185	22.2%	187	22.2%
Pender	115	14.0%	117	14.0%	118	14.0%
Onslow	85	10.3%	86	10.3%	87	10.3%
Columbus	38	4.6%	38	4.6%	39	4.6%
Duplin	16	1.9%	16	1.9%	16	1.9%
Bladen	11	1.3%	11	1.3%	11	1.3%
Sampson	10	1.2%	10	1.2%	10	1.2%
Other^	26	3.2%	26	3.2%	27	3.2%
<b>Total</b>	<b>822</b>	<b>100.0%</b>	<b>832</b>	<b>100.0%</b>	<b>843</b>	<b>100.0%</b>

Source: Section C, page 40

^Other Includes Alamance, Carteret, Chatham, Cleveland, Craven Duplin, Granville, Guilford, Henderson, Jones, Robeson, Rockingham, Rowan, Scotland, Wake, and Wilkes counties, as well as other states.

In Section C, page 40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported by the historical patient origin of cardiac cath procedures performed by Wilmington Health cardiologists at other facilities and practices in New Hanover County. The applicant does not expect this proposal to change the patient origin because Wilmington Health cardiologists are expected to perform procedures using the proposed unit of fixed cardiac cath equipment.

**Analysis of Need**



In Section C, pages 42-54, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, As summarized below:

*Need for Additional Fixed Cardiac Catheterization Services in the Service Area*-The applicant states that there is a need for additional fixed cardiac cath services in the service area for several reasons. Using data from NCOSBM, the applicant demonstrates New Hanover County as one of the fastest growing counties in North Carolina. Additionally, New Hanover County is projected to be among the top ten counties to experience the highest percentage of growth over the next five years. In addition to population growth, NCOSBM projects that one-fifth of New Hanover County residents will be aged 65 by 2028. The applicant states that the growth and aging of the population demonstrates the need to expand access to cardiac cath services.

Furthermore, the applicant states that the concentration of interventional cardiac cath services at one acute care hospital in New Hanover County limits access to services and patient choice. All six units of cardiac cath equipment located in the service area, are operated at NHHHRMC. Historically, acute care hospitals were the only facilities allowed to provide diagnostic and interventional cardiac cath services with fixed cardiac cath equipment. The applicant states that although the 2021 SMFP included language indicating the ability for ASFs to apply for cardiac cath equipment pursuant to a need determination, NHHHRMC remains the only full-time provider of interventional cardiac cath services. Patients from Wilmington are expected to drive for more than an hour to access the nearest cardiac cath provider.

*Need to Promote Safety and Quality, Access and Value Through Cardiac Catheterization Services for Wilmington ASC Patients*-The applicant states that Wilmington Health's experience as a provider "has resulted in improved quality, better accessibility, lower risk, lower cost, and enhanced continuity of care." The applicant describes how advancements in the performance of cardiac cath procedures have led to expanding services to ambulatory settings, which has demonstrated the same level of safety and quality in its performance outcomes. Cardiac cath services available in an ambulatory setting allow patients access to an alternative setting with the same level of quality as a hospital setting but at a lower cost.

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

- The 2023 SMFP identifies the need for one additional unit of fixed cardiac cath equipment in New Hanover County.
- According to NCOSBM population projections, New Hanover County is projected to grow by 6.3% by 2028 and the population aged 65 and older is projected to increase by 12.5%. Brunswick and Pender counties are two counties contiguous to New Hanover County and among the top five fastest growing counties by percentage of growth. Brunswick experienced a 39.8% growth from 2013 to 2023. Pender experienced a 25.0% increase during the same period.

#### Projected Utilization

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

<b>Wilmington ASC Projected Utilization</b>				
	<b>Partial FY 6/2/25- 12/31/25</b>	<b>1st Full FY (CY2026)</b>	<b>2<sup>nd</sup> Full FY (CY2027)</b>	<b>3<sup>rd</sup> Full FY (CY2028)</b>
# of Units	1	1	1	1
# of Diagnostic Procedures	385	668	676	685
# of Therapeutic Procedures	89	153	156	158
# of Diagnostic Equivalent Procedures*	541	935	949	961

\*Diagnostic Equivalent Procedures equals Diagnostic Procedures + [Therapeutic (Interventional) Procedures x 1.75]

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

The applicant begins projections by examining the number of diagnostic and interventional cardiac cath procedures performed by Wilmington Health providers that were referred by another Wilmington Health provider. The applicant includes procedures performed by non-Wilmington providers that were referred by Wilmington providers and identified these procedures as “*potential*” diagnostic procedures or “*potential*” interventional procedures.

<b>Table 1: Wilmington Health Providers Historical Diagnostic and Interventional Cardiac Catheterization Procedures</b>							
	<b>CY18</b>	<b>CY19</b>	<b>CY20</b>	<b>CY21</b>	<b>CY22</b>	<b>CY23*</b>	<b>CAGR**</b>
WH Performed Diagnostic Procedures	729	804	644	872	952	936	6.9%
WH Performed Interventional Procedures	325	358	297	410	348	373	1.7%
Potential Diagnostic Procedures	312	433	373	395	289		-1.9%
Potential Interventional Procedures	163	215	161	187	116		-8.2%
Total WH Performed Procedures	1,054	1,162	941	1,282	1,300		5.4%
Total Potential Procedures	475	648	534	582	405		-3.9%
<b>Total Procedures</b>	<b>1,529</b>	<b>1,810</b>	<b>1,475</b>	<b>1,864</b>	<b>1,704</b>		<b>2.8%</b>

Source: Section Q, Form C-Utilization-*Methodology and Assumptions*, page 2; Wilmington Health internal data. Note that “*Potential*” procedures data is not available for CY23.

\*CY2023 data annualized based on partial year of data.

\*\*Compound annual growth rate.

The applicant states that the Wilmington ASC will perform only CMS-approved diagnostic and elective interventional cardiac cath procedures that are deemed appropriate for a

freestanding facility. The majority of the procedures illustrated in the table above were ASF-appropriate. The following table identifies the number of ASF-appropriate procedures performed by Wilmington Health and non-Wilmington providers of the total number of procedures performed.

	<b>CY18</b>	<b>CY19</b>	<b>CY20</b>	<b>CY21</b>	<b>CY22</b>	<b>CY23*</b>	<b>CAGR**</b>
WH Performed Diagnostic Procedures	729	804	644	868	947	920	6.8%
WH Performed Interventional Procedures	262	303	232	323	272	307	0.9%
Potential Diagnostic Procedures	312	431	371	393	287		-2.1%
Potential Interventional Procedures	135	181	124	123	83		-11.5%
<b>Total Procedures</b>	<b>1,438</b>	<b>1,719</b>	<b>1,371</b>	<b>1,707</b>	<b>1,589</b>		<b>2.5%</b>

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 3; Wilmington Health internal data. Note that "potential" procedures data is not available for CY23.

\*CY2023 data annualized based on partial year.

The applicant states that the majority of ASF-appropriate procedures performed by Wilmington Health providers were performed in an inpatient setting. The following table illustrates the percentage of diagnostic and interventional procedures that were performed in an outpatient setting.

<b>Table 3: Wilmington Health Providers Historical Diagnostic and Interventional CMS-Approved Cardiac Catheterization Procedures Performed in Outpatient Settings</b>						
	<b>CY18</b>	<b>CY19</b>	<b>CY20</b>	<b>CY21</b>	<b>CY22</b>	<b>CY23*</b>
Total WH Performed Diagnostic Procedures	729	804	644	868	947	920
WH Performed Outpatient Diagnostic Procedures	442	470	339	512	632	579
% Performed Outpatient Diagnostic Procedures	60.6%	58.5%	52.6%	59.0%	66.7%	62.9%
Total WH Performed Interventional Procedures	262	303	232	323	272	307
WH Performed Outpatient Interventional Procedures	117	143	94	152	146	201
% Performed Outpatient Interventional Procedures	44.7%	47.2%	40.5%	47.1%	53.7%	65.5%
<b>Total Performed Outpatient Procedures</b>	<b>559</b>	<b>613</b>	<b>433</b>	<b>664</b>	<b>778</b>	<b>780</b>

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 4; Wilmington Health internal data.

\*CY2023 data annualized based on partial year.

As illustrated in the table above, at least 50% of the diagnostic procedures performed annually by Wilmington Health providers that were ASF-appropriate were performed in an outpatient setting. Based on the percentage of ASF-appropriate outpatient procedures performed by Wilmington Health providers from CY2018 to CY2023 (annualized), the applicant assumes that the proposed Wilmington ASC can perform a minimum of 52.6% diagnostic and 40.5% interventional procedures.

<b>Table 4: Wilmington Health Providers Percentage of Cardiac Catheterization Procedures Performed in Outpatient Settings</b>						
	<b>CY18</b>	<b>CY19</b>	<b>CY20</b>	<b>CY21</b>	<b>CY22</b>	<b>CY23</b>
Diagnostic Outpatient Procedures %	60.6%	58.5%	52.6%	59.0%	66.7%	62.9%
Interventional Outpatient Procedures %	44.7%	47.2%	40.5%	47.1%	53.7%	65.5%

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 4; Wilmington Health internal data.

To account for the “potential” diagnostic and interventional procedures, the applicant multiplies the “potential” diagnostic and interventional procedures performed in CY2022 by the lowest percentage value stated in the Table above (52.6%). During CY2020, 52.6% of

diagnostic procedures and 40.5% of interventional procedures were outpatient. The applicant states that applying the lowest value is reasonable considering the impact the pandemic had on elective ambulatory surgery that has resulted in higher inpatient percentages. The applicant projects that upon approval of the unit of fixed cardiac cath equipment, procedure volumes will increase due to the additional option of an outpatient cardiac cath facility.

The following table demonstrates the projected ASF-approved procedures performed in outpatient facilities. The applicant assumes no growth for CY2023.

<b>Table 5: Wilmington Health Providers Projected CMS Approved Cardiac Catheterization Procedures Performed in Outpatient Facilities</b>		
	<b>CY22</b>	<b>CY23*</b>
WH Performed Diagnostic Procedures	632	632
WH Performed Interventional Procedures	146	146
Potential Diagnostic Procedures	151	151
Potential Interventional Procedures	34	34
Total Procedures	963	963
<b>Total Diagnostic Equivalent Procedures **</b>	<b>1,097</b>	<b>1,097</b>

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 6

\*CY2023 projections are pulled forward from CY22 historical totals, assuming no growth, in order to be appropriately conservative.

\*\* Diagnostic Equivalent Procedures = Diagnostic + (Interventional x 1.75) + (<=14 Years Old x 2.0), as defined in the "Application of the Methodology" for Fixed Cardiac Catheterization Equipment in the 2023 SMFP. Please note that Wilmington ASC will not perform cardiac catheterization procedures for patients under 14 years old.

To project procedure volumes forward, the applicant applied the New Hanover County projected population growth rate of 1.2%. The applicant states that the growth rate is conservative considering the need for cardiovascular services to meet the projected population growth in the service area.

<b>Table 6: New Hanover County Projected Population Growth 2023-2028</b>			
<b>County</b>	<b>2023</b>	<b>2028</b>	<b>CAGR</b>
New Hanover	238,240	253,222	1.2%

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 6;  
 NCOSBM

The applicant states that the majority of the cardiac cath procedures are performed on patients 60 and over. NCOSBM projected population growth rate for the 60+ age group is double the New Hanover County projected population growth rate from CY2023 through CY2028.

<b>Table 7: New Hanover County Projected Population Growth 65 and Older 2023-2028</b>			
<b>County</b>	<b>2023</b>	<b>2028</b>	<b>CAGR</b>
New Hanover	44,974	50,595	2.4%

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 6;  
 NCOSBM

To project utilization for diagnostic and interventional procedures for Wilmington ASC, the applicant applied the 2023-2028 New Hanover County projected population CAGR of 1.2%, as illustrated in the table below.

<b>Table 8: Wilmington Health ASC Projected Cardiac Catheterization Procedures, No Shift</b>							
	<b>CY23</b>	<b>CY24</b>	<b>CY25</b>	<b>CY26 (PY1)</b>	<b>CY27 (PY2)</b>	<b>CY28 (PY3)</b>	<b>CAGR</b>
WH Performed Diagnostic Procedures	632	640	648	656	664	672	1.2%
WH Performed Interventional Procedures	146	148	150	151	153	155	1.2%
Potential Diagnostic Procedures	151	153	155	157	159	161	1.2%
Potential Interventional Procedures	34	34	34	35	35	36	1.2%
Total Procedures	963	975	987	999	1,011	1,024	
<b>Total Diagnostic Equivalent Procedures</b>	<b>1,097</b>	<b>1,111</b>	<b>1,125</b>	<b>1,139</b>	<b>1,153</b>	<b>1,167</b>	

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 7

The applicant assumed that 90% of procedures performed by Wilmington Health cardiologists or referred by Wilmington Health providers will shift to Wilmington ASC based on the assumption that patients will prefer to remain within Wilmington Health facilities. The applicant assumed that only 50% of “potential” procedures will shift to Wilmington ASC based on the assumption that patients may prefer to remain with the facility or their procedural cardiologist.

<b>Table 9: Wilmington ASC Projected Cardiac Catheterization Procedures, Post-Shift</b>					
	<b>CY25*</b>	<b>CY26 (PY1)</b>	<b>CY27 (PY2)</b>	<b>CY28 (PY3)</b>	<b>Assumed Shift</b>
WH Performed Diagnostic Procedures, Shifted**	340	590	597	605	90.0%
WH Performed Interventional Procedures, Shifted**	79	136	138	140	90.0%
Potential Diagnostic Procedures, Shifted^	45	78	79	80	50.0%
Potential Interventional Procedures, Shifted^	10	17	18	18	50.0%
Total Diagnostic Procedures	385	668	676	685	
Total Interventional Procedures	89	153	156	158	
<b>Total Procedures</b>	<b>474</b>	<b>822</b>	<b>832</b>	<b>843</b>	

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 8

\* CY25 is a partial year, with projected cases from the table above denoted so as to be performed from June 2, 2025 (the anticipated start date of the proposed project) to the end of the calendar year.

\*\* WH Performed Procedures, Shifted = (Performed Procedures x 0.90)

^ "Potential" procedures, Shifted = ("potential" procedures X 0.50)

The applicant projects weighted diagnostic and weighted interventional procedures, as defined in the 2023 SMFP.

<b>Table 10: Wilmington ASC Projected Diagnostic Equivalent Cardiac Catheterization Procedures, Post-Shift</b>				
	<b>CY25*</b>	<b>CY26 (PY1)</b>	<b>CY27 (PY2)</b>	<b>CY28 (PY3)</b>
Total Diagnostic Procedures	385	668	676	685
Total Weighted Diagnostic Procedures**	385	668	676	685
Total Interventional Procedures	89	153	156	158
Total Weighted Interventional Procedures^	156	267	273	276
<b>Total Diagnostic Equivalent Procedures</b>	<b>541</b>	<b>935</b>	<b>949</b>	<b>961</b>

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 8

\* CY25 is a partial year, with projected cases from the table above denoted so as to be performed from June 2, 2025 (the anticipated start date of the proposed project) to the end of the calendar year.

\*\* Diagnostic procedures are not weighted when calculating diagnostic equivalent cardiac catheterization procedures, as defined in the 2023 SMFP.

^ Weighted (diagnostic equivalent) interventional procedures = (Interventional Procedures x 1.75)

The applicant projects that Wilmington ASC will perform a total of 961 diagnostic equivalent procedures per unit by the third full fiscal year, exceeding the performance standards for cardiac cath equipment.

<b>Table 11: Wilmington ASC Total Projected Cardiac Catheterization Procedures per Cardiac Catheterization Unit</b>				
	<b>CY25*</b>	<b>CY26 (PY1)</b>	<b>CY27 (PY2)</b>	<b>CY28 (PY3)</b>
Total Procedures	474	822	832	843
Total Diagnostic Equivalent Procedures	541	935	949	961
Cardiac Catheterization Units	1	1	1	1
<b>Total Diagnostic Equivalent Procedures per Unit</b>	<b>541</b>	<b>935</b>	<b>949</b>	<b>961</b>

Source: Section Q, Form C-Utilization-Methodology and Assumptions, page 9

\* CY25 is a partial year, with projected cases from the table above denoted so as to be performed from June 2, 2025 (the anticipated start date of the proposed project) to the end of the calendar year.

The applicant states that the projections are conservative considering Wilmington Health’s historical utilization. Wilmington Health providers performed or referred a total of 2,053 diagnostic equivalent procedures in CY2022. On page 9, the applicant states:

*“...assuming that there is no growth in the number of procedures Wilmington Health providers perform at partnering facilities between CY22 and CY28, if 961 diagnostic equivalent cardiac catheterization procedures were to shift to Wilmington ASC in CY28, this would account for only 46.8 percent of the diagnostic equivalent procedures Wilmington Health providers are currently performing at partnering facilities.”*

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

- The applicant’s projected utilization is supported by the total number of procedures performed or referred by Wilmington Health cardiologists and adjusted for outpatient only with a projected shift of 50% of all “potential” procedures to Wilmington ASC.
- The applicant projects utilization for the three project years (CY2026-CY2028), based on the New Hanover County projected population five-year CAGR of 1.2% from CY2023 through CY2028.
- The applicant adjusts for only diagnostic and elective interventional cardiac cath procedures included in CMS’s list of Medicare-covered ASF procedures that are clinically appropriate for an ASF.

**Access to Medically Underserved Groups**

In Section C, page 65, the applicant states:

*“The proposed project will improve access to cardiac catheterization services in the service area, including to historically medically underserved groups. Wilmington Health, the sole member of WASC, has long promoted economic access to its services as it historically has provided services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment. Please see the previously referenced Exhibit B.20-4 for Wilmington Health’s Language and Communication Assistance Policy. This policy also establishes Wilmington Health’s interpretation and communication assistance services to ensure*



*the provision of the utmost in culturally competent care, particularly for non-native English speakers.*

*In addition, WASC will accept various insurance plans, including Medicare and Medicaid, and will provide financial assistance to patients with financial hardships.”*

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*	
Racial and ethnic minorities	5.6%
Women	6.4%
Persons with disabilities*	
Persons 65 and older	71.6%
Medicare beneficiaries	72.8%
Medicaid recipients	0.6%

Source: Section C, page 66

\*Applicant does not maintain data.

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:

- As stated in the proformas, a significant proportion of the facility’s proposed services will be provided to Medicare recipients.
- The applicant is an established provider in the service area currently serving those identified as underserved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion 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 [persons with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA  
Both Applications

None of the applications in this review propose to reduce or eliminate a service, or to 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.

C  
Both Applications

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section E, pages 64-65, 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:

*Do Not Apply for New Cath Lab*-The applicant states that not applying for a new cath lab is not an effective alternative because of the historical and projected utilization of the existing and approved units of fixed cardiac cath equipment. The applicant projects that by 2032, the six units of fixed cardiac cath equipment will perform 1,615 annual weighted procedures per cath lab. This is significantly higher than the performance standard for cardiac cath equipment. The applicant states that operating at high capacity will cause scheduling problems and service interruptions.

*Add a Cath Lab at the Main Campus*-The applicant determined that the proposed cath lab is needed at NH Scotts Hill. Adding capacity to the main campus will cause an increase in the emergency department volume resulting in an increase in the demand for acute care beds.

*Build an Outpatient Cath Lab*-The applicant states that this alternative was dismissed because an outpatient cath lab would not be accessible to hospital inpatients and emergency patients. Also, duplicating support services would result in additional costs.

On page 64, the applicant states that its proposal is the most effective alternative because of the high utilization of the existing units of cardiac cath equipment on the main campus. Additionally, locating the proposed unit on the NH Scott Hill campus was the best option since there will be no cardiac cath units on the campus upon completion of the facility.

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

- Not applying for a new cath lab would not address the need in the 2023 SMFP for an additional unit of cardiac cath equipment in New Hanover County.
- Adding the proposed cath lab to the main campus will exceed capacity and interrupt services.
- 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.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

### **Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section E, pages 78-79, 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:

*Develop the Fixed Cardiac Catheterization Equipment at a Different Site*-The applicant states that the only other location available in New Hanover County is currently under construction. In order to develop the project at the alternative location, the applicant would be required to submit a change of scope and cost overrun certificate of need application which can result in the capital expenditure exceeding 115% of previously approved capital expenditure.

*Contract for Mobile Cardiac Catheterization Services*-The applicant states that mobile cardiac equipment would not meet the need identified in the 2023 SMFP for one unit of fixed cardiac cath equipment in New Hanover County. Additionally, the limited access of mobile cardiac cath services will not meet the need of the growing patient population in the service area. The applicant also states that contracting with another entity would increase the cost to provide care.

On page 78, the applicant states that its proposal is the most effective alternative because developing the project in an operational facility will minimize any additional costs. Moreover, Wilmington ASC is conveniently located less than one mile from NHHHRMC in the event of an emergency that requires transfer to the hospital.

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’s proposal to develop the cardiac cath equipment in an existing and operational ASF proves to be the more cost effective alternative.
  - 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.
- (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  
Both Applicants

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

**Capital and Working Capital Costs**

In Section Q, page 128, the applicant projects the total capital cost of the project, as shown in the table below.

<b>NH Scotts Hill Capital Costs</b>			
	<b>Previously Approved Capital Cost</b>	<b>New Total Capital Cost</b>	<b>Difference</b>
	O-11947-20	O-11947-20 and Proposed Cath Lab	
Construction/Renovation Contract (s)	\$136,429,298	\$139,923,538	\$3,494,240
Architect/Engineering Fees	\$11,559,600	\$11,839,139	\$279,539
Medical Equipment	\$20,505,753	\$22,428,260	\$1,922,507
Non-Medical Equipment	\$7,550,531	\$7,627,471	\$76,940
Furniture	\$5,684,358	\$5,719,300	\$34,942
Consultant Fees	\$1,392,000	\$1,467,000	\$75,000
Financing Costs	\$1,560,805	\$1,560,805	\$0
Interest during Construction	\$13,284,855	\$13,284,855	\$0
Other	\$11,979,048	\$12,567,365	\$588,317
<b>Total Capital Costs</b>	<b>\$209,946,248</b>	<b>\$216,417,733</b>	<b>\$6,471,485</b>

In Section Q, page 129, 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 information provided in Section Q, page 129, and referenced exhibits.

In Section F, page 68, the applicant does not project initial operating costs because as part of an existing acute care hospital, NH Scotts Hill will be profitable in the first year of operation. The applicant projects start-up costs will be \$552,129 for a total working capital of \$552,129. On page 68, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The projected working capital needs of the project are based on two months of expenses incurred during the first project year.

### **Availability of Funds**

In Section F, pages 66 and 68, the applicant states that the capital and working capital cost will be funded by Novant Health, Inc.

In Exhibit F-2.1, the applicant provides a letter from the Senior Vice President, Operational Finance & Revenue Cycle, documenting Novant Health's commitment to fund the capital and working capital costs of the project through accumulated reserves. Exhibit F-2.2 contains the 2022 consolidated balance sheets for Novant Health Inc, and affiliates, documenting sufficient funds available to fund the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of 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, 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.

NH Scotts Hill	Partial Project Year	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
	10/15/26- 12/31/26	CY2027	CY2028	CY2029
Total Procedures	185.2	895.5	925.1	955.8
Total Gross Revenues (Charges)	\$6,743,688	\$33,556,681	\$35,675,210	\$37,990,232
Total Net Revenue	\$1,326,094	\$6,598,662	\$7,015,254	\$7,470,485
Average Net Revenue per Visit	\$7,160	\$7,369	\$7,583	\$7,816
Total Operating Expenses (Costs)	\$815,518	\$3,963,718	\$4,118,361	\$4,283,754
Average Operating Expense per Visit	\$4,403	\$4,426	\$4,452	\$4,482
Net Income	\$510,576	\$2,634,944	\$2,896,893	\$3,186,732

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, pages 133 and 137. 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
- Written comments
- Remarks made at the public hearing
- Responses to comments

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.

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

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

<b>Wilmington ASC Capital Costs</b>	
Construction/Renovation Contract (s)	\$4,892,708
Landscaping	\$45,063
Architect/Engineering Fees	\$2,500
Medical Equipment	\$1,506,999
Non-Medical Equipment	\$150,000
Furniture	\$95,000
Interest during Construction	\$151,158
Total Capital Costs	\$6,843,427

In Section Q, Form F.1a, and Exhibit F.1, 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.

In Section F, page 82, the applicant states there will be no start-up costs or initial operating expenses because the applicant is proposing to locate the unit at an existing facility that is currently operational.

In Section F, page 80, the applicant states that the capital cost will be funded by Wilmington ASC, LLC.

In Exhibit F-2.1, the applicant provides a letter from the chief financial officer of Wilmington Health stating that the project will be funded through a commercial loan from Truist Bank. Exhibit F-2.1, also contains a letter from the senior vice-president of Truist Bank stating their interest in financing the project.

The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of 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, 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.

Wilmington ASC	Partial Fiscal Year	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
	06/02/25- 12/31/25	CY2026	CY2027	CY2028
Total Procedures	541	935	949	961
Total Gross Revenues (Charges)	\$3,277,843	\$5,856,903	\$6,107,095	\$6,367,975
Total Net Revenue	\$1,395,232	\$2,493,023	\$2,599,519	\$2,710,564
Average Net Revenue per Visit	\$2,579	\$2,666	\$2,739	\$2,821
Total Operating Expenses (Costs)	\$1,121,520	\$1,921,921	\$1,867,306	\$1,806,868
Average Operating Expense per Visit	\$2,073	\$2,055	\$1,968	\$1,880
Net Income	\$273,712	\$571,102	\$732,213	\$903,696

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

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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 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 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  
Both Applications

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 New Hanover County as a single county Acute Care Bed Service Area. Therefore, the service area is New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 17A-3 in Chapter 17 of the 2023 SMFP, page 306, NHNHRMC is the only facility with fixed cardiac cath equipment located in New Hanover County. Information about the facility is shown in the table below.

Fixed Cardiac Catheterization Equipment New Hanover County			
Facility	Current Inventory	2021 Procedures (weighted)	# of Machines Needed (80% util.)
NHNHRMC	5	7,220	6.02

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section G, pages 75-76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed cardiac cath equipment in New Hanover County. The applicant states:

*“NHNHRMC now has five operational laboratories equipped to perform cardiac catheterization procedures... All of the existing and approved labs are on the 17th Street Campus, which is in central Wilmington. This project proposes to establish the first cath lab in northern New Hanover County, away from central Wilmington.*

*Developing one cath lab at NH Scotts Hill is necessary in order for NH to better meet the needs of the population that currently relies on NHNHRMC, as well as residents living closer to the Pender County line...*

*This application is in response to a published need determination in the 2023 SMFP. There is an established need for another cath laboratory in New Hanover County. Therefore, establishing a cath lab at NH Scotts Hill will not be a duplication of services, but instead will be a necessary expansion of needed services.”*

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

- There is a need determination in the 2023 SMFP for the proposed fixed unit of cardiac cath equipment in New Hanover County.
- The applicant is proposing to develop the unit of fixed cardiac cath equipment in the northern part of county, a distance from the existing cardiac cath equipment, to enhance access to services for those residents.
- The applicant adequately demonstrates that the proposed cardiac cath equipment is needed in addition to the existing or approved cardiac cath equipment.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

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

### **Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section G, page 90, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved fixed cardiac cath equipment in New Hanover County. The applicant states:

*“...this application is in response to a need determination in the 2023 SMFP for one unit of fixed cardiac catheterization equipment in New Hanover County. As such, the proposed project is necessary based on the high utilization of the existing equipment in the county and will not duplicate existing resources.”*

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 fixed unit of cardiac cath equipment in New Hanover County.
- The applicant adequately demonstrates that the proposed cardiac cath equipment is needed in addition to the existing or approved cardiac cath equipment.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

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

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section Q, page 139, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

NH Scotts Hill	Projected FTE Staff		
	1 <sup>st</sup> Full FY CY2027	2 <sup>nd</sup> Full FY CY2028	3 <sup>rd</sup> Full FY CY2029
Registered Nurses	5.0	5.0	5.0
Cardiac/Cardiovascular Tech	10.2	10.2	10.2
Supervisor	1.0	1.0	1.0
Nurse Manager	0.4	0.4	0.4
<b>TOTAL</b>	<b>16.6</b>	<b>16.6</b>	<b>16.6</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 140. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 78-81, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant recruits appropriate staff through Novant Health’s established corporate and regional human resources, online advertisement, trade journals and Novant Health’s website.
- The applicant adequately demonstrates Novant Health’s achievements regarding diverse working environments and workplace satisfaction.
- The facility will offer training and educational seminars to physicians and a continuing medical education program for area physicians.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

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

Wilmington ASC	Projected FTE Staff		
	1 <sup>st</sup> Full FY CY2026	2 <sup>nd</sup> Full FY CY2027	3 <sup>rd</sup> Full FY CY2028
Registered Radiologist Technician	1.0	1.0	1.0
Registered Cardiovascular Invasive Specialist	1.0	1.0	1.0
Registered Nurse	1.0	1.0	1.0
LPN-Prep/Recovery	1.0	1.0	1.0
<b>TOTAL</b>	<b>4.0</b>	<b>4.0</b>	<b>4.0</b>

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 Section Q, Form F.3b. In Section H, pages 92-93, 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:

- Wilmington Health recruits staff through print advertising, online applications, and contacts with clinical training programs.
- The applicant offers competitive salaries, benefit packages and identifies as an equal opportunity employer.
- The applicant's training program includes infection prevention and control, sedation competency and pre-operative and post-operative patient care.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

Both Application

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

Project ID# O-11947-20 was conforming to this criterion and the applicant proposes no changes in the current application as submitted that would affect that determination. Therefore, the application is conforming to this criterion.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

**Ancillary and Support Services**

In Section I, page 94, the applicant identifies the necessary ancillary and support services for the proposed services. On page 94, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because Wilmington ASC is an existing provider with ancillary and support services already in place that will support the proposed unit of fixed cardiac cath equipment.

**Coordination**

In Section I, page 95, 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.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

Both Applications

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

Both Applications

None of the applicants is an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

Both Applications

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section K, page 88, the applicant states that the project involves constructing 2,985 square feet of new space. Line drawings are provided in Exhibit K-1. The additional square footage proposed in this application will accommodate the fixed cardiac cath lab.

On pages 90-91, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits K-4.1 through K-4.4. The site appears to be suitable for the proposed fixed cardiac cath lab based on the applicant's representations and supporting documentation.

On page 92, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant's proposal involves adding a cardiac cath lab to a space already under construction.
- The applicant's proposal will be developed alongside the development of NH Scotts Hill which can reduce the project timeline, thereby reducing construction costs.

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 based on the following:

- The project cost incurred will be spread over the total patient volume at NH Scotts Hill and across the larger healthcare system.
- Major payor payments are not based on the cost of a specific hospital.

On pages 89-90 and pages 92-93, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section K, page 98, the applicant states that the project involves constructing 4,824 square feet of new space. Line drawings are provided in Exhibit C.1-1.



On pages 98-99, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The proposal to expand the existing facility will allow the staff to utilize existing services and eliminate the need for additional staff.
- In Exhibit F.1, the applicant provides the architect's construction estimate.
- Upon project completion, the applicant will offer a cost-effective alternative for patients accessing cardiac cath services.

On page 99, 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. Upon project completion, Wilmington ASC would be the first ASF to offer diagnostic and elective interventional cardiac cath services in North Carolina, thereby, offering patients an accessible and cost-effective alternative to cardiac cath services in a hospital setting.

On page 99, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

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

C  
Wilmington ASC

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

NH Scotts Hill is not an existing facility in New Hanover County. Therefore, Criterion (13a) is not applicable.

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section L, page 102, the applicant provides the historical payor mix during CY2022 for the proposed services, as shown in the table below.

<b>Payor Category</b>	<b>Percent of Total</b>
Self-Pay	1.2%
Charity Care*	
Medicare	74.3%
Medicaid	0.5%
Insurance	20.9%
Other (Worker's Comp, TRICARE)	3.5%
<b>Total</b>	<b>100.0%</b>

Source: Section L, page 102

\*Internal data does not include charity care. Any payor category can receive charity care.

In Section L, page 103, the applicant provides the following comparison.

Wilmington ASC	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	64.2%	52.2%
Male	35.8%	47.8%
Unknown	0.0%	0.0%
64 and Younger	28.4%	80.6%
65 and Older	71.6%	19.4%
American Indian	0.0%	0.6%
Asian	0.0%	1.6%
Black or African American	3.7%	12.7%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	71.0%	82.6%
Other Race	1.85%	2.4%
Declined / Unavailable	23.46%	0.0%

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was publicly available during the review and used by the Agency

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

Both Applications

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need**

**determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 96, the applicant states:

*“NHNHRMC fulfilled its Hill-Burton obligation many years ago and does not have any related 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, NHNHRMC 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, NHNHRMC-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 97, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina in the last five years.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 104, the applicant states:

*“Neither WASC nor Wilmington Health has any obligation to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons. However, as stated earlier, WASC does and will continue to provide services to all persons in need of medical care, regardless of race, color, religion, national origin, sex, age, disability, or source of payment...”*

In Section L, page 105, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information which was 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.

- (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  
Both Applications

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section L, page 98, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>NH Scotts Hill                      Projected Payor Mix                      3<sup>rd</sup> Full FY, CY2029                      Cardiac Cath</b>	
<b>Payor Category</b>	<b>% of Total</b>
Self-Pay	1.11%
Charity Care	1.95%
Medicare*	64.39%
Medicaid*	2.64%
Insurance *	24.76%
Tricare	0.97%
Other (VA, other)	4.17%
<b>Total</b>	<b>100.00%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.11% of total services will be provided to self-pay patients, 1.95% to charity care patients, 64.39% to Medicare patients and 2.64% to Medicaid patients.

In Section Q, page 98, 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 following:

- The applicant projects payor mix for cardiac cath services based on the actual payor mix of patients served by NHNHRMC during CY2022.
- The applicant limited its projections to patients who reside in the five zip codes that are near NH Scotts Hill.
- The applicant adjusts the projected payor mix to account for patients deemed clinically appropriate to be served by NC Scotts Hill.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section L, page 106, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

<b>Wilmington ASC Projected Payor Mix 3<sup>rd</sup> Full FY, CY2028 Cardiac Cath</b>	
<b>Payor Category</b>	<b>% of Total</b>
Self-Pay	0.9%
Charity Care	
Medicare*	58.6%
Medicaid*	1.4%
Insurance *	26.1%
Other	13.0%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.9% of total services will be provided to self-pay patients, 58.6% to Medicare patients and 1.4% to Medicaid patients.

In Section Q, page 105, 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 because it is based on the facility's historical experience providing surgical services and Wilmington Health's historical payor mix of cardiac cath procedures performed by Wilmington Health cardiologists.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section L, pages 100-101, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section L, pages 107-108, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

Both Applications



**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

Project ID# O-11947-20 was conforming to this criterion and the applicant proposes no changes in the current application as submitted that would affect that determination. Therefore, the application is conforming to this criterion.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

In Section M, page 110, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- Wilmington Health currently partners with nursing programs and a certified medical assistant program in the area for training purposes.
- Clinical training opportunities will be extended to include cardiac cath services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Remarks made at the public hearing
- Responses to comments

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

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C  
Both Applications

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 New Hanover County as a single county Acute Care Bed Service Area. Therefore, the service area is New Hanover County. Facilities may also serve residents of counties not included in their service area.

According to Table 17A-3 in Chapter 17 of the 2023 SMFP, page 306, New Hanover Regional Medical Center (NHNHRMC) is the only facility with fixed cardiac cath equipment located in New Hanover County. Information about the facility is shown in the table below.

Fixed Cardiac Catheterization Equipment New Hanover County			
Facility	Current Inventory	2021 Procedures (weighted)	# of Machines Needed (80% util.)
NHNHRMC		7,220	6.02

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 103, the applicant states:

*“Adequate cath lab capacity is necessary to attract more cardiologists to the service area to give the population better access and better choice of providers. The addition of a cath lab at NH Scotts Hill will give all invasive cardiologists an expanded, level playing field. NH hospitals and cath labs have an open staff model. This model allows all qualified physicians to obtain privileges in the 17th Street Main Campus and NH Scotts Hill. This applies to physicians employed by NH and to physicians practicing independently. By*

*making adequate cath lab capacity available to all physicians, NH supports competition among cardiologists for patients.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 103, the applicant states:

*“Further, the proposed project will be cost-effective for most patients because NH has provider agreements and negotiated rates with most health plans and is a participating provider with Medicare and Medicaid and with their managed care organizations.”*

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, page 103, the applicant states:

*“The proposed cath lab will improve the quality of services to medically underserved groups by making cardiology services available to uninsured and underinsured patients at a reduced charge or no charge. They will not need to wait for an emergency to consult a cardiologist or to receive invasive cardiology procedures. Cath lab services, like all services at NH Scotts Hill, will be covered under NH’s charity care policy.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 104, 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. NH is a participating provider with traditional Medicare and Medicaid and with their managed care organizations.”*

See also Sections B, 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
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

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

### **Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 103, the applicant states:

*“The proposed project will enhance competition in the service area by promoting cost effectiveness, quality, and access to cardiac catheterization services as the first freestanding ASF with cardiac catheterization capabilities in North Carolina.”*

Regarding the impact of the proposal on cost effectiveness, in Section B, page 29, the applicant states:

*“In a freestanding ASF, there are no other hospital-based expenses allocated to surgery services; the only expenses are those generated directly by services provided by the ASF. As a result, patients and payors do not incur the charges associated with hospital based care. For all payors, the lower charge structure associated with an ASF increases the affordability of the services offered in the facility.”*

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

Regarding the impact of the proposal on quality, in Section B, page 27, the applicant states:

*“Further, WASC recognizes the value of innovative approaches to enhancing patient safety and the quality of care. The proposed project will result in North Carolina’s first ASF capable of offering cardiac catheterization services. As discussed in Section C.1, the proposed unit of fixed cardiac catheterization equipment will include state-of-the-art technology to improve accuracy and reduce recovery times, thus enhancing the safety, quality, and efficiency of the care provided.”*

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 104, the applicant states:

*“Further, WASC recognizes the value of innovative approaches to enhancing patient safety and the quality of care. The proposed project will result in North Carolina’s first ASF capable of offering cardiac catheterization services. As discussed in Section C.1, the proposed unit of fixed cardiac catheterization equipment will include state-of-the-art technology to improve accuracy and reduce recovery times, thus enhancing the safety, quality, and efficiency of the care provided.”*

See also Sections 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
- Written comments
- Remarks made at the public hearing
- Responses to comments
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on 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  
Both Applications

**Project ID# O-12415-23/ Novant Health Scotts Hill Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of 7 units of fixed cardiac cath equipment**

In Section Q, page 142, the applicant identifies the acute care hospitals providing cardiac cath services 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 facility located in North Carolina.

In Section O, pages 107-108, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to a finding of immediate jeopardy occurred at NHHHRMC. A complaint investigation survey was concluded on June 29, 2022. After a follow-up survey on August 11, 2022, CMS determined the facility was in compliance. According to the files in the Acute and Home Care Licensure and Certification Section, DHR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred had not occurred in any of these facilities. 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 six facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

**Project ID# O-12416-23/ Wilmington ASC/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2023 SMFP for a total of one unit of fixed cardiac cath equipment**

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

In Section O, page 115, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents resulting in a finding of immediate jeopardy have not occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred had not occurred in any of these facilities. 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 both 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.

C  
Both Applications

The Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10A NCAC 14C .1600 are applicable to this review. The application is conforming to all applicable criteria. 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;*

-C- **Novant Health**-In Section C, page 33, the applicant identifies five existing units of fixed cardiac cath equipment at NHHHRMC owned and operated by the applicant or a related entity in the proposed service area.

-NA- **Wilmington ASC**-The applicant does not own or operate any fixed cardiac cath equipment in the proposed 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;*

-C- **NH Scotts Hill**-In Section C, page 33, the applicant identifies one approved unit of fixed cardiac cath equipment at NHHHRMC owned and operated by the applicant or a related entity in the proposed service area.

-NA- **Wilmington ASC**-The applicant does not own or operate any approved fixed cardiac cath equipment in the proposed 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;*

- C- **NH Scotts Hill**-In Section Q, Forms C.2a and C.2b, the applicant provides projected utilization of the existing, approved, and proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in New Hanover County during each of the first three full fiscal years of operation following completion of the project.

<b>NHNHRMC</b>				
<b>Projected Utilization</b>				
	<b>Partial FY 10/15/26- 12/31/26</b>	<b>1st Full FY (CY2027)</b>	<b>2<sup>nd</sup> Full FY (CY2028)</b>	<b>3<sup>rd</sup> Full FY (CY2029)</b>
# of Units	7	7	7	7
# of Diagnostic Procedures	663	3,204	3,310	3,419
# of Therapeutic Procedures	436	2,108	2,178	2,250
# of Diagnostic Equivalent Procedures*	1,425.77	6,892.73	7,120.90	7,356.62

\*Diagnostic Equivalent Procedures equals Diagnostic Procedures + [Therapeutic (Interventional) Procedures x 1.75]

- C- **Wilmington ASC**-In Section Q, Form C.2b, the applicant provides projected utilization of the proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in New Hanover County during each of the first three full fiscal years of operation following completion of the project.

<b>Wilmington ASC</b>				
<b>Projected Utilization</b>				
	<b>Partial FY 6/2/25- 12/31/25</b>	<b>1st Full FY (CY2026)</b>	<b>2<sup>nd</sup> Full FY (CY2027)</b>	<b>3<sup>rd</sup> Full FY (CY2028)</b>
# of Units	1	1	1	1
# of Diagnostic Procedures	385	668	676	685
# of Therapeutic Procedures	89	153	156	158
# of Diagnostic Equivalent Procedures*	541	935	949	961

\*Diagnostic Equivalent Procedures equals Diagnostic Procedures + [Therapeutic (Interventional) Procedures x 1.75]

- (4) *provide the assumptions and methodology used to project the utilization required by Subparagraph (3) of this Paragraph; and*

- C- **Novant Health**-In Section Q, pages 116-126, the applicant provides the assumptions and methodology used to project utilization of the existing, approved, and proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in New Hanover County during each of the first three full fiscal years of operation following completion of the project.



- C- **Wilmington ASC**-In Section Q, Form C Utilization-*Methodology and Assumptions* pages 1-10, the applicant provides the assumptions and methodology used to project utilization of the proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in New Hanover County during each of the first three full fiscal years of operation following completion of the project.
- (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.*
- C- **Novant Health**-In Section Q, page 115, the applicant projects that the existing, approved, and proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in New Hanover County will perform a total of 1,051 diagnostic-equivalent procedures per unit of cardiac cath equipment during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **Wilmington ASC**-In Section Q, Form C.2b, the applicant projects that the proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in New Hanover County will perform a total of 961 diagnostic-equivalent procedures per unit of cardiac cath equipment during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference
- (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;*
  - (2) *provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and*
  - (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.*
- NA- **Novant Health**-The applicant does not propose to acquire shared fixed cardiac cath equipment.
- NA- **Wilmington ASC**-The applicant does not propose to acquire shared fixed cardiac cath equipment.

(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- **Novant Health**-The applicant does not propose to acquire mobile cardiac cath equipment.

-NA- **Wilmington ASC**-The applicant does not propose to acquire mobile cardiac cath equipment.

## COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2023 SMFP, no more than one unit of fixed cardiac cath equipment may be approved for New Hanover County in this review. Because both applications in this review collectively propose to acquire two units of fixed cardiac cath equipment, both applications cannot be approved. Therefore, after considering all the information in each application and reviewing each application individually against all applicable statutory and regulatory review criteria, the Project Analyst conducted a comparative analysis of the proposals to decide which proposal should be approved.

Below is a brief description of each project included in this review.

- Project ID# O-12415-23/**Novant Health**/Acquire one unit of fixed cardiac cath equipment
- Project ID# O-12416-23/**Wilmington ASC**/ Acquire one unit of fixed cardiac cath equipment

### **Conformity with Statutory and Regulatory Review Criteria**

All applications are conforming to all applicable statutory and regulatory review criteria. Therefore, regarding this comparative factor, all applications are equally effective alternatives.

### **Scope of Services**

Generally, the application proposing to provide the broadest scope of services is the more effective alternative with regard to this comparative factor. Both of the applicants propose to acquire one fixed unit of cardiac cath equipment in New Hanover County. Each applicant is proposing to perform diagnostic and interventional catheterizations. **Wilmington ASC** proposes to provide only procedures that are included in CMS's most current list of Medicare-covered ASF procedures for patients that are appropriate for a freestanding setting. As such, **Wilmington ASC** will be limited to serving elective outpatient procedures, while **Novant Health** proposes to serve inpatients and outpatients, both elective and emergent. Therefore, with regard to scope services, the application submitted by **Novant Health** is the more effective alternative.

### **Geographic Accessibility**

NHNHRMC is the only facility with fixed cardiac cath equipment located in New Hanover County. **Novant Health** proposes to develop the unit of fixed cardiac cath equipment at NH Scotts Hill, approximately 17 miles from the existing fixed cardiac cath equipment at NHHRMC. **Wilmington ASC** proposes to develop the unit less than one mile from the existing fixed cardiac cath equipment at NHHRMC. The introduction of a new fixed unit of cardiac cath equipment at a greater distance from the existing cardiac cath equipment would do more to expand geographic access to cardiac cath services for those residing in the area. Therefore, with regard to geographic accessibility, the application submitted by **Novant Health** is the more effective alternative.

### **Access by Underserved Groups**

Underserved groups are defined in G.S. 131E-183(a)(13) as follows:

*“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.”*

*Projected Medicaid*

The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicaid patients and the number of Medicaid patients to be served in each applicant’s third full fiscal year of operation following project completion, based on information provided in each applicant’s pro forma financial statements in Section Q. Generally, the application proposing to serve the highest number of Medicaid patients and provide a higher percentage of services to Medicaid patients is the more effective alternative with regard to this comparative factor.

Services to Medicaid Patients - 3 <sup>rd</sup> Full Fiscal Year				
Applicant	Medicaid Patients	Medicaid Gross Revenue	Total Gross Revenue	Medicaid % of Total Gross Revenue
Novant Health	20	\$1,003,914	\$37,990,232	2.6%
Wilmington ASC	12	\$90,036	\$6,367,975	1.4%

Source: Form F.2 for each applicant.

As shown in the table above, the application submitted by **Novant Health** projects that 2.6% of its cardiac cath services will be provided to Medicaid patients, and that it will serve 20 Medicaid patients, in the third year of the project. The application submitted by **Wilmington ASC** projects that 1.4% of its cardiac cath services will be provided to Medicaid patients and that it will serve 12 Medicaid patients, in the third year of the project. Therefore, with regard to service to Medicaid patients, the application submitted by **Novant Health** is the more effective alternative.

*Projected Medicare*

The following table shows each applicant’s percentage of gross revenue (charges) projected to be provided to Medicare patients and the number of Medicare patients to be served in each applicant’s third full fiscal year of operation following project completion, based on information provided in each applicant’s pro forma financial statements in Section Q. Generally, the application proposing to serve the highest number of Medicare patients and provide a higher percentage of services to Medicare patients is the more effective alternative with regard to this comparative factor.

Services to Medicare Patients - 3 <sup>rd</sup> Full Fiscal Year				
Applicant	Medicare Patients	Medicare Gross Revenue	Total Gross Revenue	Medicare % of Total Gross Revenue
Novant Health	492	\$24,463,807	\$37,990,232	64.4%
Wilmington ASC	494	\$3,732,387	\$6,367,975	58.6%

Source: Form F.2 for each applicant.

As shown in the table above, the application submitted by **Novant Health** projects to serve 492 Medicare patients and that 64.4% of its cardiac cath services will be provided to Medicare patients in the third year of the project. The application submitted by **Wilmington ASC** projects to serve 494 Medicare patients and that 58.6% of its cardiac cath services will be provided to Medicare patients. As such, **Novant Health** and **Wilmington ASC** propose to serve comparable numbers of Medicare patients in the third operating year. Therefore, with regard to service to Medicare patients, the applications submitted by **Novant Health** and **Wilmington ASC** are equally effective alternatives.

**Competition**

Generally, the application proposing to increase competition in the service area is the more effective alternative with regard to this comparative factor. The introduction of a new provider in the service area would be a more effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality and/or lower costs for services in order to compete for patients. **Novant Health** currently is the only provider of fixed cardiac cath services in the service area. **Wilmington ASC** does not currently provide fixed cardiac cath services in the service area. Therefore, **Wilmington ASC** would introduce a new provider of fixed cardiac cath services in the service area. Thus, with regard to increasing competition for fixed cardiac cath services in the New Hanover County fixed cardiac cath service area, the application submitted by **Wilmington ASC** represents the more effective alternative.

**Projected Average Net Revenue per Cardiac Cath Procedure**

The following table compares the projected average net revenue per cardiac cath procedure for the third year of operation following project completion for all the applicants, based on the information provided in Section Q, Form C.2b and Form F.2b of the respective applications. Generally regarding this factor, the application proposing the lowest average net revenue per cardiac cath procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor.

3 <sup>rd</sup> Full Fiscal Year			
Applicant	Net Revenue	# of Cardiac Cath Procedures*	Average Net Revenue per Cardiac Cath Procedure
Novant Health	\$7,470,485	763	\$9,791
Wilmington ASC	\$2,710,564	843	\$3,215

Source: Section Q Form C.2b and Form F.2b of the respective applications

As shown in the table above, **Wilmington ASC** proposes the lower average net revenue per cardiac cath procedure in the third full fiscal year following project completion. Therefore, regarding this comparative factor, the proposal by **Wilmington ASC** is the more effective alternative.

However, differences in the types of facilities and the types of cardiac cath procedures proposed by each of the applicants may impact the averages shown in the table above. Therefore, the result of this analysis is inconclusive.

**Projected Average Total Operating Cost per Cardiac Cath Procedure**

The following table compares the projected average operating expense per cardiac cath procedure for the third year of operation following project completion for both the applicants, based on the information provided in Section Q, Form C.2b and Form F.2b. Generally regarding this factor, the application proposing the lowest average operating expense per cardiac cath procedure is the more effective alternative since a lower average may indicate a lower cost to the patient or third-party payor or a more cost-effective service.

3 <sup>rd</sup> Full Fiscal Year			
Applicant	Operating Expense	# of Cardiac Cath Procedures	Average Operating Expense per Cardiac Cath Procedure
Novant Health	\$4,283,754	763	\$5,614
Wilmington ASC	\$1,806,868	843	\$2,143

Source: Section Q Form C.2b and Form F.2b of the respective applications

As shown in the table above, **Wilmington ASC** proposes a lower average operating expense per cardiac cath procedure. Therefore, regarding average operating expense per cardiac cath procedure, the proposal by **Wilmington ASC** is the more effective alternative.

However, differences in the types of facilities and the types of cardiac cath procedures proposed by each of the applicants may impact the averages shown in the table above. Therefore, the result of this analysis is inconclusive.

**Patient Access to Lower Cost Outpatient Cardiac Cath Services**

According to Table 17A-3 in Chapter 17 of the 2023 SMFP, page 306, NHNHRMC is the only facility with fixed cardiac cath equipment located in New Hanover County. **Novant Health** proposes to develop one additional unit of fixed cardiac cath equipment in a new hospital currently under development, offering both inpatient and outpatient cardiac cath services. **Wilmington ASC** is proposing to locate the fixed unit of cardiac cath equipment, and offer outpatient cardiac cath services, in an approved ASF which is under development.

Based on the applications, written comments and response to comments, many, but not all, outpatient cardiac cath services can either be performed in a hospital or in an ASF. However, the cost for that same service will often be higher when the cardiac cath procedure is performed in a hospital. In fact,

**Wilmington ASC** projects a lower average operating cost and lower average net revenue per cardiac cath procedure in the third operating year of the project.

Therefore, with regard to patient access to lower cost outpatient cardiac cath services, **Wilmington ASC** is the more effective alternative.

### Summary

The following table lists the comparative factors and indicates whether each application was determined more effective, equally effective or less effective with regard to the factor.

Comparative Factor	Novant Health	Wilmington ASC
Conformity with Statutory and Regulatory Review Criteria	Equally Effective	Equally Effective
Scope of Services	<b>More Effective</b>	Less Effective
Geographic Accessibility	<b>More Effective</b>	Less Effective
Access by Medicaid Recipients	<b>More Effective</b>	Less Effective
Access by Medicare Recipients	Equally Effective	Equally Effective
Competition	Less Effective	<b>More Effective</b>
Projected Average Net Revenue per Cardiac Cath Procedure	Inconclusive	Inconclusive
Projected Average Total Operating Cost per Cardiac Cath Procedure	Inconclusive	Inconclusive
Patient Access to Lower Cost Outpatient Cardiac Cath Services	Less Effective	<b>More Effective</b>

As shown in the table above, **Novant Health** was determined to be the more effective alternative for the following three comparative factors:

- Scope of Services
- Geographic Accessibility
- Access by Medicaid Recipients

As shown in the table above, **Wilmington ASC** was determined to be the most effective or more effective alternative for the following two comparative factors:

- Competition
- Patient Access to Lower Cost Outpatient Cardiac Cath Services

### DECISION

Each application is individually conforming to the need determination in the 2023 SMFP for unit of fixed cardiac catheterization equipment in New Hanover County. However, G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of units of fixed cardiac catheterization equipment that can be approved by the Healthcare Planning and Certificate of Need Section.

Based upon the independent review of each application and the Comparative Analysis, the Agency determined that the application submitted by **Novant Health** is the most effective alternative proposed in this review for the development of one unit of fixed cardiac cath equipment and is approved.

While the application submitted by **Wilmington ASC** is approvable standing alone, the approval of both applications would result in the approval of more units of fixed cardiac cath equipment than are determined to be needed, and therefore, the applications submitted by **Wilmington ASC** is denied.

The application submitted by **Novant Health** Project ID# O-12415-23, is approved subject to the following conditions:

1. **Novant Health New Hanover Regional Medical Center and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with the representations in this application and the representations in Project ID #O-11947-20. Where representations conflict, the certificate holder shall materially comply with the last made representation.**
2. **The certificate holder shall acquire no more than one unit of fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination which is a change of scope for Project ID# O-11947-20 for a total no more than seven units of fixed cardiac catheterization equipment.**
3. **Upon completion of the project, Novant Health Scotts Hill Medical Center shall be licensed for no more than one unit of fixed cardiac catheterization equipment.**
4. **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 September 2, 2024.**
5. **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.**



- 6. 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.**
- 7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**