

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2022

Findings Date: February 2, 2022

Project Analyst: Gregory F. Yakaboski

Co-Signer: Gloria C. Hale

COMPETITIVE REVIEW

Project ID #: O-12112-21

Facility: Novant Health New Hanover Regional Medical Center

FID #: 943372

County: New Hanover

Applicants: Novant Health New Hanover Regional Medical Center, LLC
Novant Health, Inc.

Project: Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of 6 units of fixed cardiac cath equipment

Project ID #: O-12121-21

Facility: Wilmington ASC

FID #: 170523

County: New Hanover

Applicant: Wilmington ASC, LLC

Project: Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

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 2021 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 catheterization 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 2021 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 29 of the 2021 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 29 of the 2021 SMFP states:

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

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

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

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
Acquire no more than one unit of fixed cardiac cath equipment pursuant to
the need determination in the 2021 SMFP for a total of 6 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”, proposes to acquire one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of 6 units of fixed cardiac cath equipment at the main campus of Novant Health New Hanover Regional Medical Center (NHNHRMC) located at 2131 S. 17th Street, Wilmington.

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.2, pages 27-28, and in Section Q, the applicant explains why it believes its application is conforming to Policy GEN-3.

Policy GEN-4. The proposed capital expenditure is between \$2 million and \$5 million. In Section B.2, pages 29-30, and Exhibit B.2, 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.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Wilmington ASC, LLC, hereinafter referred to as "the applicant" or "WASC", proposes to change the scope of Project ID #O-11441-17 by acquiring one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of three multispecialty GI endoscopy rooms, one new operating room (OR) and one unit of fixed cardiac cath equipment at Wilmington ASC (WASC), which is currently approved to be developed at 1201 Glen Meade Road, Wilmington.

Wilmington Health, PLLC, which does business as Wilmington Health, is the sole member of Wilmington ASC, LLC.

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.2, 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 between \$2 million and \$5 million. In Section B.2, page 31, the applicant describes the project's plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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.

Decision

The applications submitted by each of the applicants are conforming to the need determination and to the applicable policies in the 2021 SMFP. The limit on the number of units of fixed cardiac cath equipment that can be approved is one (1). Collectively, the applicants propose a

total of two units of fixed cardiac cath equipment. Therefore, all the applications cannot be approved.

- (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

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
 Acquire no more than one unit of fixed cardiac cath equipment pursuant to
 the need determination in the 2021 SMFP for a total of 6 units of fixed
 cardiac cath equipment**

Patient Origin

On page 314, the 2021 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.

The following table illustrates historical and projected patient origin.

NHNHRMC: Cardiac Cath

County	Historical (CY2020)		Third Full FY of Operation following Project Completion (CY2025)	
	Patients	% of Total	Patients	% of Total
New Hanover	1,587	33.0%	1,891	33.0%
Brunswick	1,409	29.3%	1,679	29.3%
Pender	532	11.1%	634	11.1%
Onslow	416	8.6%	496	8.6%
Columbus	415	8.6%	495	8.6%
Other*	457	9.5%	545	9.5%
Total	4,816	100.0%	5,740	100.0%

Source: Tables on pages 41 and 42 of the application.

*Other includes 48 counties from North Carolina and other states.

In Section C.3, page 42, and Section Q, pages 128-132, 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 identifies 5 counties: New Hanover, Brunswick, Pender, Onslow and Columbus as comprising its primary service area (See page 46).
- The applicant bases projected patient origin on the historic patient origin for cardiac catheterization services stating *“NHRMC assumes that its 5-county service area will remain consistent in the future. The 5-county serviced area represents 89.5 percent of the cardiac catheterization cases.”*

Analysis of Need

In Section C.4, pages 44-51, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- Population growth trends in New Hanover County and the cardiac cath service area. (pages 45-46).
- Life expectancy in New Hanover County (page 47).
- NHRMC Physician Group Growth (pages 48-49).
- Cardiac Service Line (page 50).
- NHRMC Utilization (page 51).

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

- The 2021 SMFP identifies the need for one additional unit of fixed cardiac cath equipment in New Hanover County.
- NHRMC is scheduled to add additional physicians to its physician network which will increase the number of referrals to NHRMC services. NHRMC's medical staff has grown in the last decade from 470 to 621.
- Historical cardiac cath cases at NHRMC experienced a 12.3% growth from FY2016 to FY2020, increasing from 4,660 patients to 5,232 patients.
- The population projections by the (North Carolina Office of State Budget and Management (NCOSBM) indicate that New Hanover County is projected to grow by 7.0%, with the population aged 65 and older projected to increase by 14.9% from 2021 through 2026. NHRMC's 5-county cardiac cath service area (New Hanover, Brunswick, Columbus, Onslow and Pender counties) is expected to grow by 6.6% from 2021 to 2026, with the population aged 65 and older projected to increase by 15.9%.
- NHNHRMC was the only provider of fixed cardiac cath services in New Hanover County which generated the need for one additional unit of fixed cardiac cath equipment in New Hanover County.

Projected Utilization

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

NHNHRMC: Cardiac Cath-Historical and Interim

	Historical: Last Full FY (CY2020)	Interim Full FY (CY2021)	Interim Full FY (CY2022)
# of Units	5	5	5
# of Diagnostic Procedures	2,567	2,671	2,734
# of Therapeutic (Interventional) Procedures	2,249	2,561	2,621
# of Diagnostic Equivalent Procedures*	6,503	7,153	7,320

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

NHNHRMC: Cardiac Cath-Projected

	1st Full FY (CY2023)	2nd Full FY (CY2024)	3rd Full FY (CY2025)
# of Units	6	6	6
# of Diagnostic Procedures	2,798	2,863	2,930
# of Therapeutic (Interventional) Procedures	2,682	2,745	2,810
# of Diagnostic Equivalent Procedures*	7,492	7,667	7,847

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

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

Step 1. Determine the five-year compound annual growth rate (CAGR) from 2016 through 2021 (annualized), resulting in a CAGR of 2.34%.

- Data on historical cardiac cath cases (therapeutic, diagnostic, total, diagnostic equivalent and cardiac cath systems) comes from the NHRMC Manager of Planning and Business Development and based on five cardiac cath systems.
- Capacity = 1,500 diagnostic-equivalent cases per cardiac cath system as identified in the 2021 SMFP.
- Utilization calculation: Diagnostic-equivalent cases/ (cardiac cath systems x capacity or 5 x 1,500 = 7,500)
- Systems needed calculation: Diagnostic-equivalent cases/ (80% of 1,500 or 1,200)

Step 2 & 3. Project cardiac cases through CY2025, the third full fiscal year of operation following project completion.

- The projection is based on applying the five-year CAGR of 2.34% to CY2021 annualized cases and assumes six cardiac cath systems, the five existing cardiac cath systems and the one additional unit of fixed cardiac cath equipment proposed in this application.
- Therapeutic cases are converted to diagnostic equivalent cases at a conversion of one therapeutic case equates to 1.75 diagnostic case.

NHNHRMC: Fixed Cardiac Cath Utilization

	Annualized	Interim	1 st FFY	2 nd FFY	3 rd FFY
	CY2021	FY2022	CY2023	CY2024	CY2025
Fixed Cardiac Cath Systems	5	5	6	6	6
# Cases*	7,153	7,320	7,492	7,667	7,847
Capacity**	7,500	7,500	9,000	9,000	9,000
Utilization***	95.40%	97.60%	83.24%	85.19%	87.19%

*Cases equal diagnostic-equivalent cases.

**Capacity equates to the number of units of fixed cardiac cath equipment (systems) x 1500

***Utilization equates to the # of cases divided by the capacity of the cardiac cath equipment.

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

- The applicant’s utilization projections are supported by an increase in historical cardiac cath cases at NHRMC over a five-year period.
- The applicant projects utilization for the four-year period of CY2021 through CY2025, the third full fiscal year following project completion, based on the five-year CAGR from CY2016 through CY2021 (annualized) or 2.34%.
- The six units of fixed cardiac cath equipment/systems are projected to be well utilized by CY2025, the third full fiscal year of operation.

Access to Medically Underserved Groups

In Section C.6, page 57, the applicant states that services are available to all persons including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved persons, including the medically indigent referred by their attending physicians. On page 58, the applicant provides the estimated percentage for each medically underserved group, as summarized in the following table.

Medically Underserved Groups	Percentage of Total Patients During the Third Full Fiscal Year
Low income persons	4.5%
Racial and ethnic minorities	13.4%
Women	35.2%
Persons with Disabilities	*
The elderly	61.8%
Medicare beneficiaries	64.9%
Medicaid recipients	4.5%

*Not tracked

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

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

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 for all the reasons described above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Patient Origin

On page 314, the 2021 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.

The following table illustrates projected patient origin.

WASC: Cardiac Cath Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	(CY 2024)		(CY 2025)		(CY 2026)	
New Hanover	297	37.2%	301	37.2%	305	37.2%
Brunswick	224	28.1%	227	28.1%	230	28.1%
Pender	111	13.9%	112	13.9%	114	13.9%
Onslow	79	9.9%	80	9.9%	81	9.9%
Columbus	24	3.0%	25	3.0%	25	3.0%
Duplin	20	2.5%	20	2.5%	21	2.5%
Bladen	16	2.0%	16	2.0%	17	2.0%
Other*	26	3.3%	27	3.3%	27	3.3%
Total	797	100.0%	808	100.0%	818	100.0%

Source: Section C, Page 40.

*Other includes Cabarrus, Cumberland, Guilford, Robeson, and Sampson counties in North Carolina, as well as other states.

In Section C.3, page 40, 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 bases projected patient origin on the historical patient origin for cardiac cath procedures performed by Wilmington Health cardiologists.

Analysis of Need

In Section C.4, 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 cath equipment in New Hanover County (page 42).
 - New Hanover County Population Growth (43-44).
 - Aging of New Hanover County Population (page 45).
 - Cardiovascular Disease (45-47).
 - Existing Cardiac Cath Services in the Region (pages 47-49).
- Need for Cardiac Cath capacity at WASC (pages 49-54).

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

- The 2021 SMFP identifies the need for one unit of fixed cardiac cath equipment in New Hanover County.
- Population growth, particularly among the elderly is occurring in New Hanover County.

- The ability to provide certain diagnostic and interventional cardiac cath procedures in an out-patient setting at a non-hospital licensed ASF at a lower cost than in a hospital licensed facility.

Projected Utilization

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

WASC: Cardiac Cath-Projected

	1 st Full FY (CY2024)	2 nd Full FY (CY2025)	3 rd Full FY (CY2026)
# of Units	1	1	1
# of Diagnostic Procedures	631	640	648
# of Therapeutic (Interventional) Procedures	166	168	170
# of Diagnostic Equivalent Procedures*	922	934	946

Source: Section Q, Form C.2b and Form C Assumptions and Methodology, page 6.

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

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

Background:

- WASC’s fiscal year corresponds to the Calendar Year. The first three full fiscal years after project completion are projected to be CY2024, CY2025 and CY2026.
- WASC is projecting to perform only diagnostic and elective interventional cardiac cath procedures that are included in CMS’s list of Medicare-covered ASF procedures for patients that are determined to be clinically appropriate for an ASF.
- Wilmington Health states its physicians have referred patients for cardiac cath procedures for decades and that its cardiologists perform thousands of cardiac cath each year.
- Wilmington Health has data regarding the number of procedures (cardiac cath) both referred by its physicians and performed by its physicians.

Projected Utilization

Step #1: Identified the historical number of cardiac cath procedures performed or referred by Wilmington Health Providers (CY2018 – CY2021) [See Table on page 2 of Form C Assumptions and Methodology in Section Q].

Step #2: Identified the number of historical cardiac cath procedures performed or referred by Wilmington Health Providers (CY2018 – CY2021) that potentially could have been performed at WASC. [See Table on page 3 of Form C Assumptions and Methodology in Section Q].

- As WASC is projecting to perform only diagnostic and elective interventional cardiac cath procedures that are included in CMS's list of Medicare-covered ASF procedures for patients that are determined to be clinically appropriate for an ASF, Step #2 is a subset of Step #1.

Step #3: Identified the percent of historical cardiac cath procedures from Step #2 that were performed as outpatient procedures by Wilmington Health Cardiologists as a percent of the total (CY2018 – CY2021). [See Table on page 4 of Form C Assumptions and Methodology in Section Q].

- WASC relied on internal data for this calculation.

Step #4: Estimated the number of Wilmington Health (referred or performed) potential cardiac cath procedures that were outpatient by applying the percentages identified in Step #3 to the historical number of cardiac cath procedures identified in Step #2 and also identified a CAGR from CY2018 – CY2021 of total cardiac cath total procedures of 1.3% and a CAGR for diagnostic-equivalent cardiac cath for the same time period of 2.0%. The applicant also identified that an average of 20.8% of total cardiac cath procedures would be interventional (therapeutic) procedures. [See Table on page 5 of Form C Assumptions and Methodology in Section Q].

Step #5: Identified potential cardiac cath procedures outpatient only for CY2022 through CY2027 by applying an annual growth rate of 1.3% starting with CY2021 as a base year.

Step #6: Projected WASC fixed cardiac cath utilization by projecting 75% of the projected total cardiac cath procedures identified in Step #5 would “shift” to WASC. Then the applicant grouped those total cardiac cath procedures as either diagnostic or interventional based on the average of 20.8% of total cardiac cath procedures are interventional (see Step #4). Then the applicant calculated diagnostic-equivalent procedures based on the formula of [diagnostic cardiac cath + (interventional x 1.75) = diagnostic-equivalent cardiac procedures]. [See Table on page 6 of Form C Assumptions and Methodology in Section Q].

2021 New Hanover County Cardiac Cath Review

Project ID #'s: O-12112-21 and O-12121-21

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Historical WASC Potential Cardiac Cath Utilization- Outpatient Only

Row		CY2018	CY2019	CY2020	CY2021*	CAGR (CY18-CY21)
A	Total WASC Potential Diagnostic Cardiac Cath Procedures	1,401	1,713	1,422	1,410	
B	Outpatient Wilmington Health Diagnostic Caths as a % of Total	56.2%	55.8%	48.8%	55.6%	
C	WASC Potential Diagnostic Cath Procedures- Outpatient Only	787	956	693	784	
D	Total WASC Potential Interventional Cardiac Cath Procedures	548	675	502	694	
E	Outpatient Wilmington Health Interventional Caths as a % of Total	35.9%	41.3%	28.9%	34.4%	
F	WASC Potential Interventional Cath Procedures- Outpatient Only	197	279	145	239	
G	Total WASC Potential Cardiac Cath Procedures- Outpatient Only (Row C + Row F)	984	1,234	839	1,023	1.3%
H	Total WASC Potential Diagnostic Equivalent Cardiac Cath Procedures- Outpatient Only (Row C + Row F)	1,131	1,443	947	1,202	2.0%

Source: Section Q, Form C Assumptions and Methodology, page 5

*CY 2021 data was seasonalized based on actual January through May 2021 data and utilizing January through May 2019 data as a percentage of total patient days based on CY 2019 internal data. WASC believes seasonalizing CY 2021 data based on the seasonal distribution of volume from CY 2019, prior to the onset of the COVID-19 pandemic, results in a more accurate representation of the expected seasonal distribution in CY2021 and beyond.

Projected WASC Potential Cardiac Cath Procedures- Outpatient Only

	CY21	CY22	CY23	CY24	CY25	CY26
	COVID Adjusted	Interim	Interim	OY1	OY2	OY3
Cardiac Cath Procedures (See Row G from Table above)	1,023	1,036	1,050	1,063	1,077	1,091
% Growth (See Row G from Table above)	na	1.3%	1.3%	1.3%	1.3%	1.3%

Projected WASC Fixed Cardiac Cath Utilization

	OY1 (CY2024)	OY2 (CY2025)	OY3 (CY2026)
Total WASC Potential Cardiac Cath Procedures- Outpatient Only	1,063	1,077	1,091
Percent of Cardiac Cath Procedures to Shift to WASC	75.0%	75.0%	75.0%
Total WASC Potential Cardiac Cath Procedures- Outpatient Only to Shift	797	808	818
Diagnostic Cardiac Cath Procedures to Shift	631	640	648
Interventional Cardiac Cath Procedures to Shift	166	168	170
Total Diagnostic Equivalent Cardiac Cath Procedures to Shift	922	934	946

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

- The applicant’s utilization projections are supported by historical cardiac cases either performed by or referred by Wilmington Health physicians adjusted for outpatient only with a projected shift to WASC of 75% of all potential outpatient cases.
- The applicant projects utilization for the four-year period of CY2022 through CY2026, the third full fiscal year following project completion, based on the four-year CAGR from CY2018 through CY2021 (adjusted for COVID) or 1.3%.
- 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.
- In response to comments: The applicant projects that 170, or 20.8%, of its total cardiac cath procedures would be interventional which is reasonable given one interventional cardiologist on staff and as stated in Section L.5, page 112, *“The Medical staff will have an open panel, and any qualified physician can apply for membership.”*

Access to Medically Underserved Groups

In Section C.6, page 61, 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, sex, creed, age, national origin, handicap, or ability to pay ... Further, WASC has interpretation and communication assistance services to ensure the provision of the utmost in culturally competent care, particularly for non-native English speakers.”

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

Medically Underserved Groups	Percentage of Total Patients during the Third Full Fiscal Year
Low income persons*	
Racial and ethnic minorities	31.9%
Women	67.0%
Persons with disabilities*	
Persons 65 and older	36.2%
Medicare beneficiaries	65.0%
Medicaid recipients	2.4%

Source: Table on page 62 of the application.

*Not tracked.

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- As stated in the proformas, a significant proportion of the facility's proposed services will be provided to Medicare recipients.
- As required by the Americans with Disabilities Act, the proposed new spaces will be accessible to persons with disabilities.
- WASC has policies designed to ensure access to services, including financial assistance.

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 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

O-12112-21/ Novant Health New Hanover Regional Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of 6 units of fixed cardiac cath equipment

In Section E, pages 73-75, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*-The applicant determined that doing nothing would not meet the need for one additional unit of fixed cardiac cath equipment in New Hanover County identified in the 2021 SMFP. In addition, maintaining the status quo would not enable the applicant to address neither the demand on the existing cardiac cath systems nor the expanding demand for cardiac cath services. Therefore, the applicant determined that this was not the most effective alternative.
- *Increase Cardiac Cath Lab Hours of Operation*- The applicant states that the cardiac cath labs are already currently operating nearly 12 hours per day which places a tremendous burden on the physicians, cardiologists, nurses and technologists. Expanding hours of operation into the weekends and evenings would severely limit the time of the care providers to rejuvenate and relax. Further, the patients are often elderly and driving in the dark would be problematic for both them and their caregivers. Therefore, the applicant determined that this would be a less effective alternative.
- *Contract with a Mobile Cardiac Cath Provider*- The applicant states that utilizing a mobile provider creates scheduling issues, reduced patient comfort and accessibility, focuses on diagnostic procedures for low risk patients and not interventional procedures and is more costly. Therefore, the applicant determined that this was a less effective alternative.

On pages 73-75, the applicant states that its proposal is the most effective alternative because:

- The proposed project would meet the need for one additional fixed unit of cardiac cath equipment in New Hanover County identified in the 2021 SMFP.
- The proposal would allow the applicant to address severe capacity constraints and accommodate utilization growth including both diagnostic and interventional catheterizations.

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

- Maintaining the status quo would not address the need in the 2021 SMFP for an additional fixed unit of cardiac cath equipment in New Hanover County.
- The applicant provides credible 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
- 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 the reasons stated above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

In Section E, pages 80-81, 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:

- *Contract with a Mobile Cardiac Cath Provider-* The applicant states that utilizing a mobile provider creates scheduling issues, is insufficient to serve the growing patient population in New Hanover County and would not meet the need for one additional fixed unit of cardiac cath equipment in New Hanover County identified in the 2021 SMFP. Therefore, the applicant determined that this was a less effective alternative.
- *Develop the Fixed Cardiac Cath Equipment at a Different Site-* The applicant states that WASC is the only existing or approved ASF owned by WASC or a related entity and WASC does not have the ability to develop another ASF in New Hanover County at this time. Further, developing the new unit of fixed cardiac cath equipment at the ASF being constructed minimizes construction costs. In addition, the ASF being developed is only less than one mile from NHHNHRMC, which has open-heart surgical support, in case of an emergency. Therefore, the applicant determined that this alternative would be a less effective alternative.

On pages 80-81, the applicant states that its proposal is the most effective alternative because:

- The proposed project would meet the need for one additional fixed unit of cardiac cath equipment in New Hanover County identified in the 2021 SMFP.
- The proposal would allow ease of access and scheduling at a lower cost than hospital based cardiac cath equipment.

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

- Maintaining the status quo would not address the need in the 2021 SMFP for an additional fixed unit of cardiac cath equipment in New Hanover County.
- The applicant provides credible 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
- 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 the reasons stated above.

- (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 Applications

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
Acquire no more than one unit of fixed cardiac cath equipment pursuant to
the need determination in the 2021 SMFP for a total of 6 units of fixed
cardiac cath equipment**

Capital and Working Capital Costs

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

Site Costs	\$0
Construction Costs	\$1,018,750
Miscellaneous Costs	\$1,929,750
Total	\$2,948,500

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibit F-1. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, page 76, Section Q, Form F.1a, and referenced exhibits.

In Section F.3, page 78, the applicant projects that start-up costs will be \$61,545 and that there will be no initial operating expenses for a total working capital of \$61,545. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the information provided in Section F.3, page 78, and Form F.3(b) of the application.

Availability of Funds

In Section F.2, page 76, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing			
Type	Novant Health New Hanover Regional Medical Center, LLC	Novant Health, Inc.	Total
Loans	\$0	\$0	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$0	\$2,948,500	\$2,948,500
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total Financing	\$0	\$2,948,500	\$2,948,500

* OE = Owner's Equity

In Section F.3, page 79, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital	Amount
Loans	\$0
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$61,545
Lines of credit	\$0
Bonds	\$0
Total *	\$61,545

In Section F, pages 76 and 79, the applicant states that the capital costs and working capital costs for the project will be funded by accumulated reserves of Novant Health, Inc. In Exhibit F.2, the applicant provides a funding letter from Novant Health's Senior Vice President,

Operational Finance & Revenue Cycle attesting to Novant Health, Inc.’s intentions to fund the proposed project. Also, in Exhibit F.2, the Novant Health, Inc. and Affiliates Consolidated Financial Statements, as of December 31, 2020, document the availability of adequate accumulated reserves to fund the project.

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

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

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, 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.

NHNHRMC: Cardiac Cath

	1st FFY (CY 2023)	2nd FFY CY 2024)	3rd FFY (CY 2025)
Total Cases	7,492	7,667	7,847
Total Gross Revenues (Charges)	\$372,340,777	\$392,495,055	\$413,740,255
Total Net Revenue	\$91,223,490	\$96,161,288	\$101,366,362
Average Net Revenue per Case	\$12,176	12,542	\$12,918
Total Operating Expenses (Costs)	\$46,373,038	\$48,852,240	\$51,337,349
Average Operating Expense per Case	\$6,190	6,372	\$6,542
Net Income	\$44,850,452	\$47,309,048	\$50,029,013

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

- 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 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.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Capital and Working Capital Costs

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

	Previously Approved Total Capital Costs Project ID#O-11441-17	Proposed New Total Capital Costs	Capital Costs of this Project Project ID#O-12121-21
Site Costs	\$0	\$36,002	\$36,002
Construction Costs	\$5,176,441	\$8,325,865	\$3,149,424
Miscellaneous Costs	\$8,211,509	\$8,868,044	\$656,535
Total	\$13,387,950	\$17,229,911	\$3,841,961

The applicant provides its assumptions and methodology for projecting capital cost in Section Q and Exhibits F-1. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based the information provided in Section F.1, pages 82-83, Section Q and referenced exhibits.

In Section F.3, pages 84-85, the applicant states that there will be no start-up costs and no initial operating expenses as the proposed project is for the development of a unit of fixed cardiac cath at Wilmington ASC which facility will be developed and operational prior to the development of the unit of fixed cardiac cath.

Availability of Funds

In Section F.2, page 83, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Wilmington ASC, LLC	Total
Loans	\$0	\$0
Cash and Cash Equivalents, Accumulated reserves or OE *	\$3,841,961	\$3,841,961
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$3,841,961	\$3,841,961

* OE = Owner's Equity

In Section F, pages 83-84, the applicant states that the capital costs for the project will be funded by accumulated reserves of Wilmington Health, the sole member of Wilmington ASC, LLC.

Exhibit F.2-1 contains a copy of a letter dated August 16, 2021 from the Chief Financial Officer of Wilmington Health documenting that Wilmington Health has the funds available in accumulated reserves and would make the funds available to Wilmington ASC for the proposed project. Exhibit F.2-3 contains a copy of the audited Wilmington Health, PLLC and Subsidiary Consolidated Financial Statements, as of December 31, 2020, documenting the availability of adequate accumulated reserves to fund the proposed project. Exhibit F.2-2 contains a copy of a letter dated August 16, 2021 from the Facility Executive of Wilmington ASC, LLC committing the funds from Wilmington Health for the proposed project.

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

- Wilmington Health officer commits the funding for the project.
- The Wilmington Health financial statements document adequate cash and cash equivalents for the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, 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: Cardiac Cath

	1st Full Fiscal Year (CY2024)	2nd Full Fiscal Year (CY2025)	3rd Full Fiscal Year (CY2026)
Total Procedures*	922	934	946
Total Gross Revenues (Charges)	\$2,881,433	\$3,006,476	\$3,136,945
Total Net Revenue	\$1,223,310	\$1,276,397	\$1,331,788
Average Net Revenue per procedure	\$1327	\$1,337	\$1,408
Total Operating Expenses (Costs)	\$1,199,595	\$1,230,834	\$1,263,273
Average Operating Expense per procedure	\$1,301	\$1318	\$,1335
Net Income	\$23,715	\$45,563	\$68,514

*Procedures = Diagnostic Equivalent Procedures
 Note: Totals might not foot due to rounding.

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
- 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 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 314, the 2021 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 2021 SMFP, page 320, New Hanover Regional Medical Center (now NHNHRMC) is the only facility with fixed cardiac catheterization 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	2019 Procedures (weighted)	# of Machines Needed (80% util.)
NHNHRMC	5	7,549	6.29

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In Section G, page 86, 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:

“The closest hospital that offers cardiac catheterizations is Southeastern Regional Medical Center (76 miles west of Wilmington in Laurinburg)...”

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 2021 SMFP for the proposed fixed cardiac cath equipment.
- The only fixed cardiac cath equipment (5 units) in the New Hanover County fixed cardiac cath service area is owned and operated by NHNHRMC and it was solely the historical utilization of NHNHRMC’s fixed cardiac cath equipment that resulted in a need determination for one new fixed cardiac cath equipment in the New Hanover County fixed cardiac cath service area.

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

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 for all the reasons described above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

In Section G, page 93, 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:

“The proposed project will not result in an unnecessary duplication of the existing or approved health service facilities that provide cardiac cath services in New Hanover County as the 2021 SMFP identifies a need determination for an additional unit of fixed cardiac cath equipment in New Hanover County. Further, as noted previously, the proposed project will result in the development of North Carolina’s first ASF with cardiac capabilities.”

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 2021 SMFP for the proposed fixed cardiac cath equipment.
- The applicant adequately demonstrates that the proposed fixed cardiac cath equipment is needed in addition to the existing or approved fixed cardiac cath equipment in New Hanover County.

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 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

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In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q, Form H. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2 and H.3, pages 88-91, 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 information provided in Section H, pages 88-91, and in Section Q, Form H, as described above.

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 for all the reasons described above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

In Section Q, Form H, the applicant provides projected staffing for the proposed services through the first three operating years of the project.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2 and H.3, pages 95-96, 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 information provided in Section H, pages 95-96, and in Section Q, Form H, as described above.

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 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 Applications**

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
Acquire no more than one unit of fixed cardiac cath equipment pursuant to**

the need determination in the 2021 SMFP for a total of 6 units of fixed cardiac cath equipment

Ancillary and Support Services

In Section I.1, pages 93-94, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 94-95, and in Exhibit I.1, the applicant explains how each ancillary and support service is or will be made available. In Exhibit I.1, the President of Novant Health New Hanover Regional Medical Center states,

“The necessary ancillary and support services required to operate the cardiac catheterization system are provided by Novant Health New Hanover Regional Medical Center staff or Novant Health corporate staff.”

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

Coordination

In Section I.2, pages 95-96, 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 states,

“NHRMC recognizes its role in the health of the community involves more than providing care within the medical center. NHRMC also offers education, outreach, and screening programs to help residents take better care of their health ...” [see page 95.]

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, pages 95-96, and Exhibit I.2, as described above.

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 for all the reasons described above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Ancillary and Support Services

In Section I.1, page 98, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 98-99, and in Exhibit I.1, the applicant explains how each ancillary and support service is or will be made available, the applicant states,

“As part of Wilmington Health, Wilmington ASC will have all ancillary and support services in place to support operations, including the proposed cardiac cath services....”

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

Coordination

In Section I.2, page 99, 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 states,

“WASC, through its sole member, Wilmington Health, has existing and extensive relationships with the local healthcare community, including the Department of Social Services and Health. Wilmington Health surgeons and proceduralists work with North Carolina Division of Medical Assistance and local social service agencies to coordinate follow up care. Further, Wilmington Health has an active and ongoing relationship with Community Care of Lower Cape Fear, a private non-profit that receives support from the Division of Medical Assistance to coordinate care for Medicaid beneficiaries, which will extend to all Wilmington ASC patients.”

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the information provided in Section I.2, page 99, and Exhibit I.2, as described above.

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 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

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In Section K, page 99, the applicant states that the project involves renovating 1,470 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 99, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the project architect's review and estimation of renovation costs. See Exhibit F.1.

On page 100, 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 expertise of the project architect confirming the projected costs are needed in relation to the proposed development of the fixed cardiac cath equipment. See Form F.1a and Exhibit F.1.

In Section B, pages 29-20 and in Section K, page 100, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit B.2.

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 for all the reasons described above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total

of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

In Section K, page 102, the applicant states that the project involves constructing 4,824 square feet of new space. Line drawings are provided in Exhibit C1-2.

On pages 102-103, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the project architects review and estimation of renovation costs. See Exhibit F.1.

On page 103, 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:

- Co-location of the fixed cardiac cath equipment with the services to be offered at Wilmington ASC will obviate the need for duplicative support services and space.
- The proposed project will be the first to offer both diagnostic and elective interventional cardiac cath services in an ASF permitting the services to be offered at lower costs and in an efficient and innovative setting.

In Section B, page 3 and in Section K, pages 103-104, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

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

- (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
Novant

NA
WASC

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In Section L, page 103, the applicant provides the historical payor mix during FY2020 (10/1/2019 to 9/30/2020) for NHNHRMC, as shown in the table below.

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

Source: Table on page 103 of the application.

*Note: Including any managed care plans.

In Section L, page 104, the applicant provides the following comparison.

NHNHRMC Cardiac Cath Services	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	35.2%	52.4%
Male	64.8%	47.6%
Unknown	0.0%	0.0%
64 and Younger	38.2%	81.6%
65 and Older	61.8%	18.4%
American Indian	0.7%	0.6%
Asian	0.3%	1.6%
Black or African American	12.3%	13.4%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	83.4%	82.2%
Other Race	1.7%	2.1%
Declined / Unavailable	1.6%	0.0%

The Agency reviewed the:

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

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Wilmington ASC is an approved facility that is currently under development. Therefore, Criterion (13a) is not applicable to this review.

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

C
NHNHRMC

NA
WASC

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
Acquire no more than one unit of fixed cardiac cath equipment
pursuant to the need determination in the 2021 SMFP for a total of 6
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 105, the applicant states:

- NHNHRMC is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L.2b, 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 NHNHRMC.

The Agency reviewed the:

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

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Wilmington ASC is an approved facility that is currently under development. Therefore, Criterion (13a) is not applicable to this review.

- (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

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
 Acquire no more than one unit of fixed cardiac cath equipment
 pursuant to the need determination in the 2021 SMFP for a total of 6
 units of fixed cardiac cath equipment**

In Section L, page 106, the applicant projects the following payor mix for both NHNHRMC and cardiac cath services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

NHNHRMC: Entire Facility

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

Source: Table on page 106 of the application.

*Note: Including any managed care plans.

NHNHRMC: Cardiac Cath Services

Payor Category	Percent of Total Patients Served
Self-Pay	4.0%
Charity Care	Included in Self-Pay
Medicare*	64.9%
Medicaid*	4.5%
Insurance*	20.6%
Other (Governmental)	6.1%
Total	100.0%

Source: Table on page 106 of the application.

*Note: Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that for cardiac cath services 4.0% of total services will be provided to self-pay patients, 64.9% to Medicare patients and 4.5% to Medicaid patients.

On page 106, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the historical payor mix for NHHHRMC and cardiac catheterization cases at NHHHRMC.

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 based on the reasons stated above.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

In Section L, page 110, the applicant projects the following payor mix for cardiac cath services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

Wilmington ASC: Cardiac Cath

Payor Category	Percent of Total Patients Served
Self-Pay	4.5%
Medicare*	65.0%
Medicaid*	2.4%
Insurance*	25.0%
Other (Governmental)**	3.1%
Total	100.0%

Source: Table on page 110 of the application.

*Note: Including any managed care plans.

**Includes TRICARE and Workers Compensation.

WASC states that its internal data does not include Charity Care as a payor source for patients. See Form F.2 for charity care projections.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that for cardiac cath services 4.5% of total services will be provided to self-pay patients, 65.0% to Medicare patients and 2.4% to Medicaid patients.

On page 110, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the historical payor mix for cardiac catheterization cases performed by Wilmington Health cardiologists.

The project analyst notes, that with respect to Medicaid, on page 110 the applicant states “...WASC is aware that North Carolina’s Medicaid program does not currently reimburse for cardiac cath procedures in an ASF setting. Since CMS only added cardiac cath to its ASF reimbursement in the last few years, and since there are currently no approved ASF providers of cardiac cath , there has previously been no reason for Medicaid to develop reimbursement in this setting. ... With the stated goal of the Medicaid managed care program of lowering the overall cost of care, and given Wilmington Health’s experience developing an ACO, a Clinically Integrated Network (CIN) and working with the Medicare Shared Savings Program, WASC is confident that it can work with Medicaid to obtain reimbursement for cardiac cath procedures provided in an ASF. Regardless of the ultimate decision for Medicaid-coverage, WASC will provide care to Medicaid beneficiaries. However, to be conservative, WASC has assumed for its financial projections that it will not be reimbursed for these services for the first three full fiscal years.”

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- 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 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

Both Applications

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
Acquire no more than one unit of fixed cardiac cath equipment
pursuant to the need determination in the 2021 SMFP for a total of 6
units of fixed cardiac cath equipment**

In Section L.5, page 107, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

In Section L.5, pages 112-113, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

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

- (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

BOTH APPLICATIONS. In Section M, the applicants describe the extent to which health professional training programs in the area have or will have access to the facility for training purposes and provide supporting documentation in the referenced exhibits.

The Agency reviewed the:

- Applications
- Exhibits to the applications

Based on that review, the Agency concludes that all the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, all the applications are conforming to this criterion.

- (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 314, the 2021 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 2021 SMFP, page 320, New Hanover Regional Medical Center (now NHNHRMC) is the only facility with fixed cardiac catheterization 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	2019 Procedures (weighted)	# of Machines Needed (80% util.)
NHNHRMC	5	7,549	6.29

**O-12112-21/ Novant Health New Hanover Regional Medical Center/
Acquire no more than one unit of fixed cardiac cath equipment pursuant to
the need determination in the 2021 SMFP for a total of 6 units of fixed
cardiac cath equipment**

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 111, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 111, the applicant states:

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

...

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

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

Regarding the impact of the proposal on quality, in Section N, pages 113-114, the applicant states:

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

...

NHRMC will strive to meet Novant Health’s high level of quality when it operates the cardiac catheterization system.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 114, the applicant states:

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

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 117, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to cardiac cath services at the first freestanding ASF with cardiac cath capabilities in North Carolina.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 117, the applicant states:

“the proposed project will offer the first ASF-based cardiac cath program in the state, which offers considerably lower reimbursement than hospital-based programs.”

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

Regarding the impact of the proposal on quality, in Section B, page 26, the applicant states:

“Wilmington Health is the largest private, fully integrated, multispecialty medical group practice in southeastern North Carolina and has been caring for patients for over 50 years. Wilmington Health is dedicated to providing the highest quality care and is continually recognized locally and nationally for its commitment to delivering efficient, quality care. Over the years, Wilmington Health and its physicians have been recognized by many of the top accrediting and ranking organizations in the industry.”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section B, page 28, 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, sex, creed, age, national origin, handicap, or ability to pay ... Further, WASC has interpretation and communication assistance services to ensure the provision of the utmost in culturally competent care, particularly for non-native English speakers.”

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C Both Applications

O-12112-21/ Novant Health New Hanover Regional Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of 6 units of fixed cardiac cath equipment

In Section Q Form O, the applicant identifies the hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 18 of this type of facility located in North Carolina.

In Section O, page 120, the applicant states that, during the 18 months immediately preceding the submittal of the application, neither NHRMC nor any other Novant Health hospital was found by the Division of Health Service Regulation or CMS to have had any incidents resulting in a finding of immediate jeopardy. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 18 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

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

In Section O, page 121, the applicant states that, during the 18 months immediately preceding the submittal of the application,

“Each of the facilities identified in Form O has continually maintained all relevant licensure, certification, and accreditation ... for the 18 months preceding the submission of this application. ... No facilities identified in Form O have had any situations resulting in a finding of immediate jeopardy during the 18-month look-back period.”

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, there were no incidents related to quality of care. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the one facility, 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.

10A NCAC 14C .1603 PERFORMANCE STANDARDS

(a) *An applicant proposing to acquire cardiac catheterization equipment shall demonstrate that the project is capable of meeting the following standards:*

(1) *each proposed item of cardiac catheterization equipment, including mobile equipment but excluding shared fixed cardiac catheterization equipment, shall be utilized at an annual rate of at least 60 percent of capacity excluding*

procedures not defined as cardiac catheterization procedures in 10A NCAC 14C .1601(5), measured during the fourth quarter of the third year following completion of the project;

- C- **Novant.** The applicant has 5 existing units of fixed cardiac catheterization equipment and is proposing to add a 6th unit of fixed cardiac catheterization equipment. In Section C, page 62, the applicant projects cardiac catheterization equipment utilization during the fourth quarter of the third year following completion of the proposed project. Based on the assumptions and methodology in Section Q, the applicant projects that the proposed unit of cardiac catheterization equipment will operate at 87.2% capacity, as shown in the table below.

Row		Project Year 3 4 th Quarter
		October-December 2025
A	Diagnostic	733
B	Therapeutic (Interventional)*	702
C	Therapeutic x 1.75	1,229
D	Total Procedures (Row A + Row B)	1,435
E	Diagnostic Equivalent Procedures (Row A + Row C)	1,962
F	# of Units	6
G	Capacity (1,500 x # of units)/ 4 x 6 units	2,250
H	% Utilization (Row E / Row G)	87.2%

*Therapeutic procedures are valued at 1.75 diagnostic-equivalent procedures.

- C- **WASC.** The applicant has no existing units of fixed cardiac catheterization equipment. The applicant is proposing to develop one unit of fixed cardiac catheterization equipment at an approved, but undeveloped, ambulatory surgical facility (ASF). In Section C, page 66, the applicant projects cardiac catheterization utilization during the fourth quarter of the third year following completion of the proposed project. Based on the assumptions and methodology in Section Q, the applicant projects that the additional unit of cardiac catheterization equipment will operate at 63.0% capacity, as shown in the table below.

	Project Year 3
	(April – June 2026)
Diagnostic	161
Therapeutic (Interventional)	42
Total Procedures	203
Diagnostic Equivalent Procedures	235
# of Units	1
Capacity	375
% Utilization	63%

- (2) *if the applicant proposes to perform therapeutic cardiac catheterization procedures, each of the applicant's therapeutic cardiac catheterization teams shall be performing at an annual rate of at least 100 therapeutic cardiac catheterization procedures, during the third year of operation following completion of the project;*
- C- **Novant.** In Section C, page 62 and in Section Q, Form C, the applicant projects to perform 2,810 therapeutic cardiac catheterization procedures during the third year of operation following completion of the project with 6 teams. Therefore, each team will perform 468 therapeutic cardiac catheterization procedures ($2,810/6 = 468$) which exceeds the performance standard. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **WASC.** In Section C, pages 66-67 and in Section Q, Form C, page 4, the applicant projects to perform 169 therapeutic cardiac catheterization procedures during the third year of operation following completion of the project. The applicant will utilize one team. Therefore, the team will perform 169 therapeutic cardiac catheterization procedures which exceeds the performance standard. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (3) *if the applicant proposes to perform diagnostic cardiac catheterization procedures, each diagnostic cardiac catheterization team shall be performing at an annual rate of at least 200 diagnostic-equivalent cardiac catheterization procedures by the end of the third year following completion of the project;*
- C- **Novant.** In Section C, page 63, and in Section Q, Form C, the applicant projects to perform 2,930 diagnostic-equivalent cardiac catheterization procedures during the third year of operation following completion of the project which is equivalent to 488 procedures per cardiac catheterization team ($2,930/6 = 488$), exceeding the performance standard. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- C- **WASC.** In Section C, page 67 and in Section Q, Form C, the applicant projects to perform 643 diagnostic-equivalent cardiac catheterization procedures during

the third year of operation following completion of the project which equates to 643 diagnostic cardiac catheterizations for the one team proposed by the applicant, exceeding the performance standard. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

(4) *at least 50 percent of the projected cardiac catheterization procedures shall be performed on patients residing within the primary cardiac catheterization service area;*

-C- Novant. In Section C.3, page 42, the applicant projects that 90.5% of cardiac catheterization procedures will be performed on patients residing within its defined primary service area: New Hanover, Brunswick, Pender, Columbus and Onslow counties. The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.

-NA- WASC. In Section C.3, page 68, the applicant states that as WASC is neither a comprehensive cardiac services program nor a diagnostic-only cardiac catheterization provider as included in the definition of “cardiac catheterization service area”, this Rule is not applicable.

(b) *An applicant proposing to acquire mobile cardiac catheterization equipment shall:*

(1) *demonstrate that each existing item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall have been operated at a level of at least 80 percent of capacity during the 12 month period reflected in the most recent licensure form on file with the Division of Health Service Regulation;*

(2) *demonstrate that the utilization of each existing or approved item of cardiac catheterization equipment, excluding mobile equipment, located in the proposed primary cardiac catheterization service area of each host facility shall not be expected to fall below 60 percent of capacity due to the acquisition of the proposed mobile cardiac catheterization equipment;*

(3) *demonstrate that each item of existing mobile equipment operating in the proposed primary cardiac catheterization service area of each host facility shall have been performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the proposed cardiac catheterization service area in the 12 month period preceding the submittal of the application;*

(4) *demonstrate that each item of existing or approved mobile equipment to be operating in the proposed primary cardiac catheterization service area of each host facility shall be performing at least an average of four diagnostic-equivalent cardiac catheterization procedures per day per site in the*

proposed cardiac catheterization service area in the applicant's third year of operation; and

(5) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- Both Applications: Neither of the applicants propose to acquire mobile cardiac catheterization equipment.

(c) *An applicant proposing to acquire cardiac catheterization equipment excluding shared fixed and mobile cardiac catheterization shall:*

(1) *demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, located in the proposed cardiac catheterization service area operated at an average of at least 80 percent of capacity during the twelve month period reflected in the most recent licensure renewal application form on file with the Division of Health Service Regulation;*

-C- Novant. The most recent NHNHRMC Licensure Renewal Application (LRA) on file with the Division of Health Service Regulation is for the year 2021 which covers October 1, 2019 through September 30, 2020. The 2021 LRA, page 10, documents that during that time period the existing items of cardiac catheterization equipment performed 2,723 diagnostic and 2,309 therapeutic cardiac catheterizations which equates to 6,703 diagnostic-equivalent procedures $[2,723 + (2,309 \times 1.75 = 4,040) = 6,763]$. The capacity of the 5 units of fixed cardiac catheterization equipment is 7,500 diagnostic-equivalent procedures $[5 \times 1,500 = 7,500]$. Therefore, utilization during the twelve-month period reflected in the 2021 LRA was 90.17% of capacity $[6,763 / 7,500 = 0.9017$ or 90.17%] which exceeds the 80% utilization of capacity required by the Rule.

The project analyst notes that that the total diagnostic and therapeutic cardiac catheterizations included 522 diagnostic and 305 interventional (therapeutic) procedures performed on a mobile unit and that this Rule states not to include cardiac catheterizations from mobile equipment. However, on June 14, 2019, NHNHRMC received an exemption to both replace one of its five existing fixed units of cardiac catheterization equipment and to utilize a mobile cardiac catheterization provider during this replacement and renovation. (See Exemption Record # 2968). As this mobile cardiac catheterization unit was “temporarily standing in the place of” an existing unit of fixed cardiac catheterization equipment, the diagnostic and interventional (therapeutic) cardiac catheterization procedures performed on this mobile cardiac catheterization unit are deemed as having been performed on a fixed cardiac catheterization unit for purposes of this Rule.

-NA- WASC. The applicant does not have any existing items of cardiac catheterization equipment located in the proposed cardiac catheterization service area.

(2) *demonstrate that its existing items of cardiac catheterization equipment, except mobile equipment, shall be utilized at an average annual rate of at least 60 percent of capacity, measured during the fourth quarter of the third year following completion of the project; and*

-C- Novant. In Section C, page 64, the applicant demonstrates that its five existing units of fixed cardiac catheterization equipment shall be utilized at an average annual rate of at least 60% of capacity as measured during the fourth quarter of the third year following completion of the proposed project, as shown in the table below.

Based on the assumptions and methodology in Section Q, the applicant projects that the proposed unit of cardiac catheterization equipment will operate at 87.2% capacity, as shown in the table below.

Row		Project Year 3 4 th Quarter
		October-December 2025
A	Diagnostic	733
B	Therapeutic (Interventional)*	702
C	Therapeutic x 1.75	1,229
D	Total Procedures (Row A + Row B)	1,435
E	Diagnostic Equivalent Procedures (Row A + Row C)	1,962
F	# of Units	6
G	Capacity (1,500 x # of units)/ 4 x 6 units	2,250
H	% Utilization (Row E / Row G)	87.2%

*Therapeutic procedures are valued at 1.75 diagnostic-equivalent procedures.

-NA- WASC. The applicant does not have any existing items of cardiac catheterization equipment located in the proposed cardiac catheterization service area.

(3) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-C- Novant. In Section C, pages 62-65 and in Section Q, Form C, the applicant documents all the assumptions and data used in the development of these projections in this Rule.

-NA- WASC. The applicant does not have any existing items of cardiac catheterization equipment located in the proposed cardiac catheterization service area. However, in Section Q, Form C, the applicant documents all the assumptions and data used in the development of these projections in this Rule.

(d) *An applicant proposing to acquire shared fixed cardiac catheterization equipment as defined in the applicable State Medical Facilities Plan shall:*

(1) *demonstrate that each proposed item of shared fixed cardiac catheterization equipment shall perform a combined total of at least 225 cardiac catheterization and angiography procedures during the fourth quarter of the third year following completion of the project; and*

(2) *provide documentation of all assumptions and data used in the development of the projections required in this Rule.*

-NA- Both Applications: Neither of the applicants propose to acquire shared fixed cardiac catheterization equipment.

(e) *If the applicant proposes to perform cardiac catheterization procedures on patients age 14 and under, the applicant shall demonstrate that it meets the following additional criteria:*

(1) *the facility has the capability to perform diagnostic and therapeutic cardiac catheterization procedures and open heart surgery services on patients age 14 and under; and*

(2) *the proposed project shall be performing at an annual rate of at least 100 cardiac catheterization procedures on patients age 14 or under during the fourth quarter of the third year following initiation of the proposed cardiac catheterization procedures for patients age 14 and under.*

-NA- Both Applications: Neither of the applicants propose to offer pediatric cardiac catheterization procedures on patients age 14 and under.

COMPARATIVE ANALYSIS

Pursuant to G.S. 131E-183(a)(1) and the 2021 State Medical Facilities Plan, no more than one unit of fixed cardiac cath equipment may be approved for New Hanover County in this review. Because the two applications in this review collectively propose to develop two additional units of fixed cardiac cath equipment to be located in New Hanover County, both the applications cannot be approved for the total number of units of fixed cardiac cath equipment proposed. 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.

O-12112-21/ Novant Health New Hanover Regional Medical Center/ Acquire no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of 6 units of fixed cardiac cath equipment

NOVANT proposes to acquire one fixed unit of cardiac cath equipment to be located at the main campus of Novant Health New Hanover Regional Medical Center (NHNHRMC) located at 2131 S. 17th Street, Wilmington for a total of 6 units of fixed cardiac cath equipment. The applicant proposes to perform 7,847 diagnostic equivalent cardiac cath procedures on the 6 units of fixed cardiac cath equipment [1,308 diagnostic equivalent procedures per unit of fixed cardiac cath equipment] from January 1 – December 31, 2025, the third full year of operation following completion of the project.

O-12121-21/ Wilmington ASC/ Change the scope of Project ID #O-11441-17 by acquiring no more than one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of a total of total of three multispecialty GI endoscopy rooms, one new operating room and one unit of fixed cardiac cath equipment at Wilmington ASC

WASC proposes to change the scope of Project ID #O-11441-17 by acquiring one unit of fixed cardiac cath equipment pursuant to the need determination in the 2021 SMFP for a total of three multispecialty GI endoscopy rooms, one new operating room (OR) and one unit of fixed cardiac cath equipment at WASC, which is currently approved to be developed at 1201 Glen Meade Road, Wilmington. The applicant proposes to perform 946 diagnostic equivalent cardiac cath procedures from January 1 – December 31, 2026, the third full year of operation following completion of the project.

Conformity with Statutory and Regulatory Review Criteria

The applications submitted by Novant and WASC are conforming with all applicable statutory and regulatory review criteria.

Therefore, regarding this comparative factor, the applications submitted by **Novant** and **WASC** are equally effective alternatives.

Scope of Services

The following table compares the scope of services proposed to be offered. Generally, the application offering the greater scope of services is the more effective alternative for this comparative factor.

Applicant	Equipment	Hospital Based or Freestanding*	Type of Cardiac Cath Procedures
Novant	Fixed Cardiac Cath	Hospital	All
WASC	Fixed Cardiac Cath	Freestanding	Limited*

*Freestanding means not operating under a hospital license.

*WASC is projecting to perform only diagnostic and elective interventional cardiac cath procedures that are included in CMS’s list of Medicare-covered ASF procedures for patients that are determined to be clinically appropriate for an ASF.

Both applicants propose to acquire and operate a fixed cardiac cath. However, Novant proposes to offer a broader range of cardiac cath procedures than WASC. Therefore, regarding this comparative factor, the application submitted by **Novant** is the more effective alternative.

Historical Utilization

The following table illustrates historical utilization of each applicant as provided in the 2021 SMFP representing FY2019 reported utilization. Generally, regarding this comparative factor, an existing provider with higher historical utilization rates is the more effective alternative based on an assumption that that provider has a greater need for the proposed unit of fixed cardiac cath equipment in order to serve its projected patients.

According to Table 17A-3 in Chapter 17 of the 2021 SMFP, page 320, New Hanover Regional Medical Center (now NHNHRMC) is the only facility with fixed cardiac catheterization 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	2019 Procedures (weighted)	# of Machines Needed (80% util.)
NHNHRMC	5	7,549	6.29

Novant has historically provided cardiac cath services in New Hanover County while WASC has no history of providing cardiac cath services in New Hanover County. Therefore, regarding this comparative factor, the application submitted by **Novant** is the more effective alternative.

Geographic Accessibility (Location within the Service Area)

The 2021 SMFP identifies the need for one unit of fixed cardiac cath equipment in New Hanover County.

Both applications are proposing to locate the fixed unit of cardiac cath equipment in Wilmington. Novant is proposing to locate the fixed unit of cardiac cath equipment at its existing hospital located at 2131 S. 17th Street and WASC is proposing to locate the fixed unit of cardiac cath equipment at a facility under development located at 1201 Glen Meade Road, Wilmington. Per Google Maps the two locations are less than a mile apart (4 min drive).

Thus, with respect to geographic accessibility, the **Novant** and **WASC** are equally effective alternatives.

Access by New Hanover County Fixed Cardiac Catheterization Equipment Service Area Residents

On page 314, the 2021 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.

Generally, regarding this comparative factor, the application projecting to serve the largest number of service area residents is the more effective alternative based on the assumption that residents of a service area should be able to derive a benefit from a need determination for an additional fixed unit of cardiac cath equipment in the service area where they live.

The following table illustrates access by service area residents during the third full fiscal year following project completion.

Applicant	# of Units of Fixed Cardiac Cath Equipment	New Hanover County Residents Served	New Hanover County Residents per Cardiac Cath Equipment
Novant	6	1,891	315
WASC	1	305	305

As shown in the table above, Novant projects to serve the highest total number of service area residents per each unit of fixed cardiac cath equipment. Therefore, regarding the highest total number of service area residents to be served, **Novant** 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 handicapped persons, 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 access by underserved groups, applications are compared with respect to three underserved groups: charity care patients (i.e., medically indigent or low-income persons), Medicare patients and Medicaid patients. Access by each group is treated as a separate factor.

The Agency may use one or more of the following metrics to compare the applications:

- Total charity care, Medicare or Medicaid patients
- Charity care, Medicare or Medicaid patients as a percentage of total patients
- Charity care, Medicare or Medicaid patients per Cardiac Cath procedure
- Total charity care, Medicare or Medicaid dollars
- Charity care, Medicare or Medicaid dollars as a percentage of total gross or net revenues
- Charity care, Medicare or Medicaid dollars per Cardiac Cath procedure

Which of the above metrics the Agency uses is determined by whether or not the applications included in the review provide data that can be compared as presented above and whether or not such a comparison would be of value in evaluating the alternative factors.

Projected Charity Care

The following table compares projected charity care in the third full fiscal year following project completion for all the applicants as a percentage of gross revenue, and per cardiac cath procedure, as shown below.

Applicant	Gross Revenue	Cardiac Cath Procedures*	Charity Care Dollars	Charity Care as a % of Gross Revenue	Charity Care per Unit of Equipment**	Charity Care / Cardiac Cath Procedure
Novant	\$413,740,255	7,847	\$7,447,325	1.8%	\$1,241,220	\$949
WASC	\$3,136,945	946	\$161,907***	5.2%	\$161,907	\$171

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

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

**Novant has 6 units of fixed cardiac cath equipment (5 existing and 1 proposed). WASC has 1 unit of fixed cardiac cath equipment (1 proposed).

*** Includes Medicaid as stated in assumptions “a” and “c” as described in Section Q, Form F.2 Cardiac Cath Assumptions.

Novant proposes both the highest dollar amount of charity care per unit of equipment and the highest dollar amount per cardiac cath procedure. WASC proposes the highest amount of charity care as a percent of gross revenue. Therefore, with respect to charity care, **Novant** 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 Medicare

The following table compares projected access by Medicare patients in the third full fiscal year following project completion for all the applicants in the review using gross Medicare dollars as a percentage of gross revenue.

The total number of Medicare patients was not provided by the applicants in this review; therefore, total Medicare patients and Medicare patients as a percentage of total patients cannot be compared. Thus, in this review, Medicare is compared as a percentage of gross revenue only.

Applicant	Gross Revenue	Cardiac Cath Procedures*	Medicare Dollars	Medicare as a % of Gross Revenue	Medicare per Unit of Equipment**	Medicare/Cardiac Cath Procedure
Novant	\$413,740,255	7,847	\$268,614,686	64.92%	\$47,769,114	\$34,232
WASC	\$3,136,945	946	\$2,039,403	65.0%	\$2,039,403	\$2,156

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

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

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

**Novant has 6 units of fixed cardiac cath equipment (5 existing and 1 proposed). WASC has 1 unit of fixed cardiac cath equipment (1 proposed).

Novant proposes both the highest dollar amount of Medicare per unit of equipment and the highest dollar amount of Medicare per cardiac cath procedure. Novant and WASC propose equivalent amounts of Medicare as a percent of gross revenue. Therefore, with respect to Medicare, **Novant** is the more 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 Medicaid

The following table compares projected access by Medicaid patients in the third full fiscal year following project completion for all the applicants using gross Medicaid dollars as a percentage of gross revenue.

Applicant	Gross Revenue	Cardiac Cath Procedures	Medicaid*	Medicaid as a % of Gross Revenue	Medicaid per Unit of Equipment**	Medicaid/Cardiac Cath Procedure
Novant	\$413,740,255	7,847	\$18,575,080	4.49%	\$3,095,846	\$2,367
WASC	\$3,136,945	946	\$0	0.00%	\$0	\$0

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

WASC is proposing to perform cardiac cath procedures in an ASF. In its application WASC states that North Carolina's Medicaid program does not currently reimburse for cardiac cath procedures in an ASF setting. WASC does not propose to be reimbursed for Medicaid patients. The project analyst notes, that with respect to Medicaid, on page 110 the applicant states "...WASC is aware that North Carolina's Medicaid program does not currently reimburse for cardiac cath procedures in an ASF setting. Since CMS only added cardiac cath to its ASF reimbursement in the last few years, and since there are currently no approved ASF providers of cardiac cath, there has previously been no reason for Medicaid to develop reimbursement in this setting. ... With the stated goal of the Medicaid managed care program of lowering the overall cost of care, and given Wilmington Health's experience developing an ACO, a Clinically Integrated Network (CIN) and working with the Medicare Shared Savings Program, WASC is confident that it can work with Medicaid to obtain reimbursement for cardiac cath procedures provided in an ASF. Regardless of the ultimate decision for Medicaid-coverage, WASC will provide care to Medicaid beneficiaries. However, to be conservative, WASC has assumed for its financial projections that it will not be reimbursed for these services for the first three full fiscal years.*"

WASC states in its assumptions "*...WASC expects that cardiac caths performed in an ASF will eventually be reimbursed by NC Medicaid but, out of an abundance of caution, WASC has elected to assume that there will not be any reimbursement for Medicaid patients.*" [See assumptions "a" and "c" as described in Section Q, Form F.2 Cardiac Cath Assumptions.]

Therefore, with respect to Medicaid, **Novant** is the more effective alternative.

Competition (Access to a New or Alternative Provider in the Service Area)

Generally, the introduction of a new provider in the service area would be the most effective alternative based on the assumption that increased patient choice would encourage all providers in the service area to improve quality or lower costs in order to compete for patients. However, the expansion of an existing provider that currently controls fewer units of fixed cardiac cath equipment than another provider would also presumably encourage all providers in the service area to improve quality or lower costs in order to compete for patients.

On page 314, the 2021 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.

Novant currently provides cardiac cath procedure services in the service area of New Hanover County. WASC does not currently provide cardiac cath procedure services in the service area of New Hanover County. Therefore, WASC would qualify as a new or alternative provider in the service area. Therefore, regarding this comparative factor, the application submitted by **WASC** is 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 the applicants’ pro forma financial statements (Section Q). 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.

Applicant	Net Revenue	# of Cardiac Cath Procedures*	Average Net Revenue per Cardiac Cath Procedure
Novant	\$101,366,362	7,847	\$12,918
WASC	\$1,331,788	946	\$1,408

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

*Cardiac Cath Procedures are referring to the number of diagnostic equivalent cardiac cath procedures.

As shown in the table above, WASC 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 **WASC**, which proposes the lowest average net revenue per cardiac cath procedure in the third full year following project completion, 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 the applicants’ pro forma financial statements (Section Q). 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.

Applicant	Operating Expense	# of Cardiac Cath Procedures	Average Operating Expense per Cardiac Cath Procedure
Novant	\$51,337,349	7,847	\$6,542
WASC	\$1,263,273	946	\$1,335

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

As shown in the table above, WASC proposes a lower average operating expense per cardiac cath procedure. Therefore, regarding average operating expense per cardiac cath procedure, the proposal by WASC 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

There are currently 5 units of fixed cardiac cath equipment (existing) in the New Hanover County fixed cardiac cath service area. All 5 units of fixed cardiac cath are licensed to, and operated by, NHHHRMC. Fixed units of cardiac cath equipment can be licensed either under a hospital license or an ASF that does not operate under a hospital license. 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 licensed facility using fixed cardiac cath equipment or in an ASF using non-hospital licensed fixed cardiac cath equipment. However, the cost for that same service will often be much higher when the cardiac cath procedure is performed using hospital licensed fixed cardiac cath equipment or, conversely, much less expensive if performed using non-hospital licensed fixed cardiac cath equipment in an ASF.

NHRMC is an existing hospital proposing to locate an additional fixed cardiac cath in its main hospital, offering both inpatient and outpatient cardiac cath services. WASC 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.

Therefore, as to patient access to lower cost outpatient cardiac cath services, WASC is the more effective alternative.

SUMMARY

The following table lists the comparative factors and indicates whether each application was more effective, less effective or equally effective for each factor. The comparative factors are listed in the same order they are discussed in the Comparative Analysis which should not be construed to indicate an order of importance.

Comparative Factor	NHNHRMC	WASC
Conformity with Statutory and Regulatory Review Criteria	Yes	Yes
Scope of Services	More Effective	Less Effective
Historical Utilization of the Facility	More Effective	Less Effective
Geographic Accessibility	Equally Effective	Equally Effective
Access by Service Area Residents	More Effective	Less Effective
Access by Charity Care	Inconclusive	Inconclusive
Access by Medicare	Inconclusive	Inconclusive
Access by Medicaid	More Effective	Less Effective
Competition (Access to New or Alternative Provider)	Less Effective	More Effective
Projected Average Net Revenue per cardiac cath procedure	Inconclusive	Inconclusive
Projected Average Operating Expense per cardiac cath procedure	Inconclusive	Inconclusive
Patient Access to Lower Cost Outpatient cardiac cath services	Less Effective	More Effective

The **Novant** and **WASC** applications are conforming to all applicable statutory and regulatory review criteria, and thus these two applications are approvable standing alone. However, collectively they propose a total of two units of fixed cardiac cath equipment in New Hanover County, but the need determination is for only one unit of fixed cardiac cath equipment in New Hanover County. Therefore, only one unit of fixed cardiac cath equipment can be approved.

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

- Scope of Services
- Historical Utilization
- Access by Service Area Residents
- Access by Medicaid Patients

As shown in the table above, **WASC** was determined to be a more effective alternative for the following factors:

- Competition (Access to New or Alternative Provider)
- Patient Access to Lower Cost Outpatient cardiac cath services

As shown in the table above, **Novant and WASC** were determined to be equally effective alternatives for the following factor:

- Geographic Accessibility

CONCLUSION

Both the applications are conforming to the need determination in the 2021 SMFP for one unit of fixed cardiac cath equipment in New Hanover County. N.C.G.S. 131E-183(a)(1) states that the need determination in the SMFP is the determinative limit on the number of fixed cardiac cath equipment that can be approved by the Agency.

The Agency determined that the application submitted by **Novant** is the more effective alternative proposed in this review for one additional unit of fixed cardiac cath equipment in New Hanover County and is approved. The approval of the other application would result in the approval of fixed cardiac cath equipment in excess of the need determination in the 2021 SMFP and therefore, the application submitted by WASC (Project ID # O-12121-21) is denied.

The application submitted by **Novant (Project ID #O-12112-21)** is approved subject to the following conditions:

- 1. Novant Health New Hanover Regional Medical Center, LLC and Novant Health, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than one unit of fixed cardiac catheterization equipment at the main campus of Novant Health New Hanover Regional Medical Center pursuant to the need determination in the 2021 SMFP for a total of no more than six units of fixed cardiac catheterization equipment upon project completion.**
- 3. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on August 1, 2022 and so forth.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**

- b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**