

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: November 22, 2022

Findings Date: November 22, 2022

Project Analyst: Julie M. Faenza

Co-Signer: Gloria C. Hale

Project ID #: F-12262-22

Facility: Novant Health Matthews Medical Center

FID #: 945076

County: Mecklenburg

Applicants: Presbyterian Medical Care Corporation

Novant Health, Inc.

Project: Develop no more than one additional unit of cardiac catheterization equipment pursuant to the need determination in the 2022 SMFP for a total of no more than two units of cardiac catheterization equipment

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

Presbyterian Medical Care Corporation and Novant Health, Inc. (hereinafter referred to as “Novant” or “the applicant”) propose to develop no more than one unit of fixed cardiac catheterization (cardiac cath) equipment at Novant Health Matthews Medical Center (NH Matthews) for a total of no more than two units of fixed cardiac cath equipment upon project completion.

Need Determination

Chapter 17 of the 2022 State Medical Facilities Plan (SMFP) includes a methodology for determining the need for additional cardiac cath equipment in North Carolina by service area.

Application of the need methodology in the 2022 SMFP did not show a need for any units of fixed cardiac cath equipment anywhere in North Carolina. However, pursuant to a petition submitted to the State Health Coordinating Council (SHCC), the SHCC approved an adjusted need determination for one unit of fixed cardiac cath equipment in Mecklenburg County. NH Matthews does not propose to develop more units of fixed cardiac catheterization equipment than are determined to be needed in Mecklenburg County. Therefore, the application is consistent with the need determination.

Policies

There is one policy in the 2022 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 30 of the 2022 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.”

In Section B, page 25, the applicant explains why it believes its application is consistent with Policy GEN-3. The applicant states it is dedicated to ensuring quality care and patient safety, that it will not discriminate based on a number of characteristics and will provide resources for uninsured patients, and that its projected utilization is based on reasonable and adequately supported assumptions, including the need the population has for the services proposed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- The applicant does not propose to develop more fixed cardiac cath units than are determined to be needed in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-3, 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 Mecklenburg County.
 - The applicant adequately documents how the project will promote equitable access to fixed cardiac cath services in Mecklenburg County.
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

NH Matthews currently has an existing unit of fixed cardiac cath equipment and additionally has a vascular lab with equipment capable of performing cardiac cath procedures, but which does not provide those procedures because it does not have a certificate of need to do so. On August 5, 2015, the Agency approved a request from NH Matthews to use the vascular lab equipment to temporarily perform cardiac cath procedures while it was relocating a different unit of fixed cardiac cath lab equipment from Novant Health Presbyterian Medical Center (NH Presbyterian) to NH Matthews. The applicant provides a copy of this correspondence with the Agency in Exhibit C.1.2. The applicant proposes to develop the proposed fixed cardiac cath equipment by utilizing the existing vascular lab equipment that is capable of performing cardiac cath procedures. The applicant states this will enable immediate operationalization of the equipment with almost no capital expenditure.

Patient Origin

On page 310, the 2022 SMFP defines the cardiac cath equipment service areas as “...*the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.*” Figure 5.1, on page 38, shows Mecklenburg County as a single county service area. Therefore, the service area for the fixed cardiac cath equipment is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates historical and projected patient origin.

Historical & Projected Patient Origin – NH Matthews Cardiac Cath Equipment								
	Historical – CY 2021		FY 1 – CY 2024		FY 2 – CY 2025		FY 3 – CY 2026	
	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients	# Patients	% Patients
Union	678	42.5%	733	42.5%	745	42.5%	756	42.5%
Mecklenburg	624	39.1%	675	39.1%	685	39.1%	696	39.1%
Anson	52	3.3%	56	3.3%	57	3.3%	58	3.3%
Stanly	42	2.6%	45	2.6%	46	2.6%	47	2.6%
Chesterfield (SC)	39	2.4%	42	2.4%	43	2.4%	44	2.4%
Cabarrus	33	2.1%	36	2.1%	36	2.1%	37	2.1%
Lancaster (SC)	29	1.8%	31	1.8%	32	1.8%	32	1.8%
York (SC)	18	1.1%	19	1.1%	20	1.1%	20	1.1%
Other*	78	5.0%	85	5.0%	87	5.0%	88	5.0%
Total	1,593	100.0%	1,724	100.0%	1,751	100.0%	1,778	100.0%

Source: Section C, pages 28 and 30

*Other: Other counties in North Carolina as well as other states

In Section C, page 30, the applicant provides the assumptions and methodology used to project its patient origin. The applicant projects no changes in patient origin because it is an expansion to existing services NH Matthews already provides. The applicant’s assumptions and methodology used to project patient origin are reasonable and adequately supported because they are based on the historical patient origin for the same services already being offered at the same location.

Analysis of Need

In Section C, pages 32-41, the applicant explains why it believes the population projected to utilize the proposed services needs the services, as summarized below.

- The applicant states that the Novant Heart & Vascular Institute at NH Matthews is a national and international leader in cardiovascular research and that it provides advanced diagnostic testing and treatment for numerous services. The applicant lists the numerous services offered at NH Matthews along with recent accreditations and recognitions. (pages 32-34)
- Cardiac cath procedures have been increasing “rapidly” at NH Matthews. The applicant states that between CY 2018 and CY 2021, the cardiac cath procedures which had the lowest compound annual growth rate (CAGR) were diagnostic cath procedures, which grew at a 3.4% CAGR, and diagnostic-equivalent or weighted (the terms mean the same thing) cardiac cath procedures grew at a 6.5% CAGR during the same time period. The applicant states that despite the impact of the COVID-19 pandemic on hospitals and other medical treatments, in CY 2020 the volume at NH Matthews decreased by only 94 procedures (or 6.5%). Even with the decrease in procedures, the applicant’s projected CAGR for CY 2018 to CY 2022 annualized is 6.1%. (pages 34-35)
- NH Matthews currently has only one approved cardiac cath lab. The applicant states that on a typical day there are five outpatient cases scheduled, but several times each week those cases are bumped because an emergency ST-Segment Elevation Myocardial Infarction

(STEMI) case has come into the hospital. STEMI cases, which are also commonly known as “widowmakers,” cannot wait for treatment, and if an outpatient case is in the cardiac cath lab when a STEMI case comes in, the outpatient case must be taken out of the cardiac cath lab and returned once the STEMI case is treated. The applicant states there are times when, because of STEMI cases, patients who are scheduled for a cardiac cath procedure are admitted overnight as observation patients because their cases have been delayed too long to accommodate the same day. (page 35)

- The applicant states that the primary population served by cardiac cath labs are patients age 65 and older, who may face travel or mobility challenges and rely on others to assist them with transportation to cardiac cath procedures. NH Matthews is located in a part of Mecklenburg County with a high population of residents age 65 and older and expecting those patients to travel to other facilities when the procedures they need are available close to home is unreasonable. (pages 36-38)
- The applicant states the demographics of Mecklenburg County will create more need for cardiac cath procedures in the future. The applicant states that, based on the North Carolina Office of State Budget and Management, Mecklenburg County has a projected 2022 – 2026 4-year CAGR of 1.8%, higher than the total statewide projected 2022-2026 4-year CAGR of 1.0%, and the Mecklenburg County population most likely to use cardiac cath procedures – those age 65 and older – have a projected 2022-2026 4-year CAGR of 4.5%. The applicant also states that, according to the North Carolina State Center for Health Statistics, the life expectancy of Mecklenburg County residents has increased in almost every age category, regardless of race or gender, in the last 30 years. The applicant states increases in life expectancy also increase the likelihood of health conditions requiring cardiac cath procedures. (pages 39-41)

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

- The applicant cites trusted and publicly available data to support its conclusions about population growth.
- The applicant provides documentation of growth of cardiac cath procedures at NH Matthews.
- The total cardiac cath procedure volume at NH Matthews has a CY 2018-2021 CAGR of 5.6% and a CY 2018-2022 annualized CAGR of 5.4% even with the impact of the COVID-19 pandemic.
- The applicant provides information to support the need for an additional unit of fixed cardiac cath equipment based on STEMI cases and the impacts of those cases when they arrive at NH Matthews.

Projected Utilization

On Forms C.2a and C.2b in Section Q, the applicant provides historical and projected utilization, as illustrated in the following tables.

NH Matthews Cardiac Cath Historical & Projected Utilization				
	Historical – CY 2021	FY 1 – CY 2024	FY 2 – CY 2025	FY 3 – CY 2026
# of Units	1	2	2	2
# Diagnostic Procedures	1,012	1,082	1,094	1,107
# Interventional Procedures	581	642	657	671
# of Diagnostic-Equivalent Procedures	2,029	2,206	2,243	2,281

Immediately following Forms C.2a and C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant reviewed historical utilization and CAGRs for diagnostic, interventional, total, and weighted cardiac cath procedures for CYs 2018-2021 and CYs 2018-2022 annualized based on January through May 2022 actual utilization). The applicant projected growth of cardiac cath procedures at NH Matthews by using one-fourth of the Mecklenburg County projected 2022-2026 4-year CAGR for the population age 65 and older for diagnostic cardiac cath procedures and by using one-half of the Mecklenburg County projected 2022-2026 4-year CAGR for the population age 65 and older for interventional cardiac cath procedures. (Steps 1-2)
- The applicant began its projections with CY 2022 annualized data and applied the projected growth rate to each type of procedure to project utilization at NH Matthews through the first three full operating years. (Step 3)

A summary of the applicant’s assumptions and calculations are shown in the table below.

NH Matthews Cardiac Cath Projected Utilization Assumptions & Methodology								
	CY 18-21 CAGR	CY 18-22* CAGR	Projected CAGR	CY 2022*	CY 2023	FY 1 CY 2024	FY 2 CY 2025	FY 3 CY 2026
Diagnostic Procedures	3.4%	3.7%	1.1%	1,058	1,070	1,082	1,094	1,107
Interventional Procedures	10.0%	8.9%	2.3%	614	628	642	657	671
Total Procedures	5.6%	5.4%		1,672	1,698	1,724	1,751	1,778
Diagnostic-Equivalent Procedures	6.5%	6.1%		2,133	2,169	2,206	2,243	2,281

*CY 2022 is annualized based on January 2022 – May 2022 actual utilization

Novant Health System

Pursuant to 10A NCAC 14C .1603(a)(5), an applicant proposing to acquire fixed cardiac cath equipment must demonstrate that the existing, approved, and proposed fixed cardiac cath units owned by the applicant or a related entity in a cardiac cath equipment service area will perform 900 or more diagnostic-equivalent cardiac cath procedures per unit during the third full fiscal year following project completion.

Immediately following Forms C.2a and C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization for the entire Novant system in Mecklenburg County, which are summarized below.

- The applicant reviewed historical utilization and CAGRs for diagnostic, interventional, total, and weighted cardiac cath procedures for CYs 2018-2021 and CYs 2018-2022 annualized. The applicant projected the following growth rates for types of cardiac cath procedures at each facility:
 - Novant Health Huntersville Medical Center (NH Huntersville): one-fourth of the Mecklenburg County projected 2022-2026 4-year CAGR for the population age 65 and older for diagnostic cardiac cath procedures and one-third of the Mecklenburg County projected 2022-2026 4-year CAGR for the population age 65 and older for interventional cardiac cath procedures.
 - NH Presbyterian: no growth projected for diagnostic cardiac cath procedures and one-third of the Mecklenburg County projected 2022-2026 4-year CAGR for the population age 65 and older for interventional cardiac cath procedures. (Steps 1-2)
- The applicant began its projections with CY 2022 annualized data and applied the projected growth rate to each type of procedure to project utilization at all Novant facilities through the first three full operating years. (Step 3)

A summary of the applicant's assumptions and calculations are shown in the table below.

Novant Health System Cardiac Cath Projected Utilization Assumptions & Methodology								
	CY 18-21 CAGR	CY 18-22* CAGR	Projected CAGR	CY 2022*	CY 2023	FY 1 CY 2024	FY 2 CY 2025	FY 3 CY 2026
NH Matthews								
Diagnostic Procedures	3.4%	3.7%	1.1%	1,058	1,070	1,082	1,094	1,107
Interventional Procedures	10.0%	8.9%	2.3%	614	628	642	657	671
Total Procedures	5.6%	5.4%		1,672	1,698	1,724	1,751	1,778
Diagnostic Equivalent Procedures	6.5%	6.1%		2,133	2,169	2,206	2,243	2,281
NH Huntersville								
Diagnostic Procedures	9.1%	7.2%	1.1%	559	566	572	578	585
Interventional Procedures	17.9%	15.9%	1.5%	300	305	309	314	318
Total Procedures	11.7%	9.9%		859	870	881	892	903
Diagnostic Equivalent Procedures	12.8%	11.0%		1,084	1,098	1,113	1,127	1,142
NH Presbyterian								
Diagnostic Procedures	-1.2%	0.5%	0.0%	1,142	1,142	1,142	1,142	1,142
Interventional Procedures	4.8%	7.3%	1.5%	984	999	1,014	1,029	1,045
Total Procedures	1.3%	3.4%		2,126	2,141	2,156	2,172	2,187
Diagnostic Equivalent Procedures	2.1%	4.3%		2,864	2,890	2,917	2,943	2,970
Novant System Totals								
Diagnostic Procedures	2.4%	2.9%		2,760	2,778	2,796	2,815	2,834
Interventional Procedures	8.3%	9.0%		1,898	1,931	1,965	1,999	2,034
Total Procedures	4.6%	5.2%		4,658	4,709	4,761	4,814	4,868
Diagnostic Equivalent Procedures	5.4%	6.0%		6,081	6,157	6,235	6,314	6,394
# Fixed Cardiac Cath Units				4	4	5	5	5
Diagnostic-Equivalent Procedures Per Unit of Fixed Cardiac Cath Equip.				1,520	1,539	1,247	1,263	1,279

*CY 2022 is annualized based on January 2022 – May 2022 actual utilization

As shown in the table above, the applicant projects that the entire Novant Health system in Mecklenburg County will perform 6,394 diagnostic-equivalent cardiac cath procedures on five units of fixed cardiac cath equipment, or an average of 1,279 diagnostic-equivalent cardiac cath procedures per unit of fixed cardiac cath equipment during CY 2026. Each facility will also perform at least 900 diagnostic-equivalent cardiac cath procedures per unit of fixed cardiac cath equipment during CY 2026. This meets the requirement promulgated in 10A NCAC 14C .1603(a)(5), requiring the applicant to project that each existing, approved, and proposed unit of fixed cardiac cath equipment owned by the applicant or a related entity perform 900 or more diagnostic-equivalent cardiac cath procedures per unit of fixed cardiac cath equipment in the third full fiscal year following project completion.

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

- The applicant uses lower projected growth rates than the applicant’s historical growth rates at each facility.
- The applicant uses a projected growth rate based on data for projected population growth in Mecklenburg County.

- For NH Presbyterian, where one CAGR for diagnostic procedures showed negative growth and another CAGR for diagnostic procedures showed positive growth, the applicant projected no growth at all in diagnostic procedures.

Access to Medically Underserved Groups

In Section C, pages 46-47, the applicant states that it will not discriminate against individuals on the basis of race, color, national origin, gender, disability, age, or payor, and discusses its charity care policies designed to provide financial assistance for uninsured patients or patients with lower income levels. The applicant states it will provide services in a manner consistent with Title VI of the Civil Rights Act of 1963, Section 504 of the Rehabilitation Act of 1973, The Age Discrimination Act of 1975, and any applicable amendments to those statutes.

On page 47, the applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Low income persons	6.5%
Racial and ethnic minorities	19.7%
Women	52.3%
Persons 65 and older	61.0%
Medicare beneficiaries	61.0%
Medicaid recipients	2.6%

On page 47, the applicant states it does not retain data on the number of disabled persons it serves and states that disabled persons will not be denied access to NH Matthews.

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:

- NH Matthews is part of an established health system in Mecklenburg County that has established policies against discrimination.
- The applicant states it will not discriminate against patients on the basis of a number of categories and describes its policies for assisting uninsured and low-income patients with financial assistance.
- The applicant provides its Patient Accessibility Policies in Exhibit C.6 and its Patient Financial policies in Exhibit L.4.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

- Information publicly available during the review and used by the Agency

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce a service, eliminate a service, or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

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

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

In Section E, pages 58-59, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo – the applicant states maintaining the status quo would mean continuing to only have one unit of fixed cardiac cath equipment at NH Matthews, which is already utilized at more than 1,500 diagnostic-equivalent procedures per year, and in a service area with a growing and aging population; therefore, maintaining the status quo is not an effective alternative.

Increase NH Matthews' Cardiac Cath Lab Hours of Operation – the applicant states increasing the hours of operation for NH Matthews' cardiac cath lab puts stress on patients, staff, and hospital resources, and already occurs several times per week when STEMI patients present to the hospital and need immediate intervention; therefore, increasing the NH Matthews cardiac cath lab hours of operation is not an effective alternative.

Utilize Mobile Cardiac Cath Lab Equipment – the applicant states mobile equipment is not appropriate for interventional procedures, which could mean additional and more costly appointments for diagnostic patients who need intervention; would create critical delays if a patient went into cardiac arrest during a procedure; and is much more expensive than a facility

owning the equipment; therefore, utilizing mobile cardiac cath lab equipment is not an effective alternative.

Develop Cardiac Cath Equipment at a Different Location – the applicant states that, of the three facilities in Mecklenburg County with fixed cardiac cath equipment, two of the facilities are operating below the 1,500 diagnostic-equivalent procedures per year per unit of equipment, and only NH Matthews exceeds that amount. The applicant also states NH Matthews is located in an area of Mecklenburg County with a large population of residents age 65 and older. Therefore, developing cardiac cath equipment at a different location is not an effective alternative.

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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. Therefore, the application is approved subject to the following conditions:

- 1. Presbyterian Medical Care Corporation 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 Novant Health Matthews Medical Center pursuant to the need determination in the 2022 State Medical Facilities Plan for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.**
- 3. 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.**
- 4. Progress Reports:**

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on April 1, 2023.
5. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
- a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project to be \$150,000; \$50,000 for CON consultant and legal fees and \$100,000 of contingency.

Immediately following Form O in Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The equipment and space necessary for a fixed cardiac cath unit is already existing and in place at NH Matthews.
- The applicant does not project to perform any construction or renovation.

In Exhibit F.2, the applicant provides a letter from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc., which states that there are no working capital costs for the proposed project because it is an ongoing operation. The applicant adequately demonstrates that projected working capital cost is based on reasonable and adequately supported assumptions because the applicant currently provides the services it proposes to add.

Availability of Funds

In Section F, pages 60-61, the applicant states that the capital cost will be funded through accumulated reserves. In Exhibit F.2, the applicant provides a letter from the Senior Vice President of Operational Finance and Revenue Cycle for Novant Health, Inc., committing to providing \$150,000 in capital costs for the proposed project. Exhibit F.2 also contains the Novant Health, Inc. and Affiliates Consolidated Financial Statements and Supplemental Information which shows that for the year ending December 31, 2021, the applicant had adequate cash equivalents and assets to fund the proposed 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 during the first three full fiscal years following completion of the project, as shown in the table below.

NH Matthews Projected Revenues and Operating Expenses – Cardiac Cath Equipment			
	FY 1 – CY 2024	FY 2 – CY 2025	FY 3 – CY 2026
Total Procedures	1,724	1,751	1,778
Total Gross Revenues (Charges)	\$87,939,224	\$91,977,234	\$96,220,785
Total Net Revenue	\$18,889,283	\$19,756,644	\$20,668,156
Average Net Revenue per Procedure	\$10,957	\$11,283	\$11,624
Total Operating Expenses (Costs)	\$7,042,840	\$7,318,467	\$7,606,500
Average Operating Expense per Procedure	\$4,085	\$4,180	\$4,278
Net Income	\$11,846,442	\$12,438,177	\$13,061,656

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:

- The applicant based its projected patient services gross revenue on CY 2021 gross charges and accounted for inflation in projections.
- The applicant’s projected payor mix is based on the applicant’s historical payor mix.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital 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

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

On page 310, the 2022 SMFP defines the cardiac cath equipment service areas as “...*the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.*” Figure 5.1, on page 38, shows Mecklenburg County as a single county service area. Therefore, the service area for the fixed cardiac cath equipment is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to Table 17A-3 in Chapter 17 of the 2022 SMFP, there are five facilities with a combined total of 16 units of fixed cardiac cath equipment in Mecklenburg County. Information about the facilities and equipment is shown in the table below.

Fixed Cardiac Cath Equipment Inventory – Mecklenburg County				
Facility	# Units	2020 Weighted* Procedures	Machines Required (80% Utilization)	# of Add'l Machines Required by Facility
Atrium Health Pineville	3	2,215	1.85	0
Carolinas Medical Center	9	4,334	3.61	0
Novant Health Huntersville Medical Center	1	813	0.68	0
Novant Health Matthews Medical Center	1	1,833	1.53	1
Novant Health Presbyterian Medical Center	2	2,225	1.85	0
Total	16	11,420	9.52 (10)	1

*Weighted and Diagnostic-Equivalent mean the same thing.

In Section G, page 69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Mecklenburg County. The applicant states:

“The proposed project will not result in unnecessary duplication of existing facilities in Mecklenburg County.

The robust growth of cardiac catheterization procedures at [sic] cases (both diagnostic and interventional) at NHMMC supports the need to develop additional capacity in Mecklenburg County at NHMMC. The proposed project effectively expands and enhances access to Novant Health cardiac catheterization in Mecklenburg County via immediate utilization of existing equipment with minimal capital expenditure at NHMMC.

..., Novant Health facilities have the highest cardiac catheterization utilization per unit in Mecklenburg County. NHMMC has the highest cardiac catheterization utilization per unit in Mecklenburg County.”

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 2022 SMFP for the proposed unit of fixed cardiac catheterization equipment.
- The applicant adequately demonstrates that the proposed cardiac catheterization equipment is needed in addition to the existing or approved cardiac catheterization equipment.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

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

NH Matthews Historical & Projected FTE Staffing				
	Historical (as of 12/31/2021)	FY 1 – CY 2024	FY 2 – CY 2025	FY 3 – CY 2026
Registered Nurses	5.0	7.0	13.2	13.2
Cardiac Cath/Cardiovascular Tech	10.2	13.2	13.2	13.2
Supervisor	1.0	1.0	1.0	1.0
Nurse Manager	0.4	0.4	0.4	0.4
TOTAL	16.6	21.6	27.8	27.8

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 Section H, pages 70-71, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant is an existing provider of fixed cardiac cath services which already employs staff necessary to offer fixed cardiac cath services.
- The applicant is part of a large and established healthcare system in Mecklenburg County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

Ancillary and Support Services

In Section I, page 73, the applicant identifies the necessary ancillary and support services for the proposed services. On page 73, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because NH Matthews currently provides the ancillary and support services that will be necessary for the additional unit of fixed cardiac cath equipment.

Coordination

In Section I, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant is an existing provider with established relationships with healthcare and social services providers in the service area.
- In Exhibit I.2, the applicant provides letters of support from Novant physicians supporting the addition of an additional unit of fixed cardiac cath equipment.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

NA

The applicant does not propose to construct any new space or make any renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic

minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, pages 80-81, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

NH Matthews Historical Payor Mix CY 2021		
Payor Category	% of Total – Entire Facility	% of Total – Cardiac Cath
Self-Pay	1.9%	1.6%
Charity Care	4.4%	2.3%
Medicare*	32.9%	61.0%
Medicaid*	9.1%	2.6%
Insurance*	48.5%	29.9%
Workers Compensation	0.4%	0.0%
TRICARE	1.1%	0.4%
Other Gov't/Institutional	1.7%	2.2%
Total	100.0%	100.0%

*Including any managed care plans

In Section L, page 81, the applicant provides the following comparison.

	% of Total Patients Served by NH Matthews during CY 2021	% of the Population of Mecklenburg County
Female	65.0%	51.7%
Male	34.9%	48.3%
Unknown	0.0%	0.0%
64 and Younger	67.6%	88.1%
65 and Older	32.4%	11.9%
American Indian	0.3%	0.9%
Asian	3.0%	6.5%
Black or African-American	20.2%	33.3%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	65.5%	45.3%
Other Race	7.8%	2.6%
Declined / Unavailable	3.1%	0.0%

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 82, the applicant states it has no such obligation.

In Section L, page 82, the applicant states that during the five years immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, pages 82-83, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

NH Matthews Projected Payor Mix FY 3 – CY 2026		
Payor Category	% of Total – Entire Facility	% of Total – Cardiac Cath
Self-Pay	1.9%	1.6%
Charity Care	4.4%	2.3%
Medicare*	32.9%	61.0%
Medicaid*	9.1%	2.6%
Insurance*	48.5%	29.9%
Workers Compensation	0.4%	0.0%
TRICARE	1.1%	0.4%
Other Gov't/Institutional	1.7%	2.2%
Total	100.0%	100.0%

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.9% of total services and 1.6% of cardiac cath services will be provided to self-pay patients, 4.4% of total services and 2.3% of cardiac cath services to charity care patients, 32.9% of total services and 61% of cardiac cath services to Medicare patients, and 9.1% of total services and 2.6% of cardiac cath services to Medicaid patients.

On page 82, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the historical payor mix for the same services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 85, the applicant adequately describes the range of means by which patients will have access to the proposed services.

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.

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

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

In Section M, page 87, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant has existing clinical education agreements with area health education programs in Mecklenburg County.
- The applicant states all educational programs that have clinical agreements with NH Matthews will have the same access upon completion of the proposed project.
- The applicant states it is always open to considering new agreements with other clinical education training programs.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive

impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

On page 310, the 2022 SMFP defines the cardiac cath equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 38, shows Mecklenburg County as a single county service area. Therefore, the service area for the fixed cardiac cath equipment is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to Table 17A-3 in Chapter 17 of the 2022 SMFP, there are five facilities with a combined total of 16 units of fixed cardiac cath equipment in Mecklenburg County. Information about the facilities and equipment is shown in the table below.

Fixed Cardiac Cath Equipment Inventory – Mecklenburg County				
Facility	# Units	2020 Weighted* Procedures	Machines Required (80% Utilization)	# of Add'l Machines Required by Facility
Atrium Health Pineville	3	2,215	1.85	0
Carolinas Medical Center	9	4,334	3.61	0
Novant Health Huntersville Medical Center	1	813	0.68	0
Novant Health Matthews Medical Center	1	1,833	1.53	1
Novant Health Presbyterian Medical Center	2	2,225	1.85	0
Total	16	11,420	9.52 (10)	1

*Weighted and Diagnostic-Equivalent mean the same thing.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 89, the applicant states:

“The project will promote cost-effectiveness, quality, and access to services and therefore will promote competition in Mecklenburg County because it will allow Novant Health to expand access services [sic] to cardiovascular services, to better meet the needs of its existing patient population, and to ensure the timely provision of critical diagnostic and therapeutic services.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 89, the applicant states:

“Novant Health is delivering value and quality in outcomes through its Population Health Management programs. This approach encourages wellness and preventive care and

managing existing conditions to slow or reverse the progression of disease, all while lowering the costs of care. ...

Novant Health is collaborating with payors and partners to identify payment models that match Novant Health's value-based care delivery. ...

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

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

Regarding the impact of the proposal on quality, in Section N, page 90, the applicant states:

"Novant Health is committed to delivering high-quality care at all of its facilities. Novant Health has quality-related policies and procedures that are applicable to NHMMC."

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 90-91, the applicant states:

"..., Novant Health will continue to have a policy to provide services to all patients regardless of income, racial/ethnic origin, gender, physical or mental conditions, age, ability to pay, or any other factor that would classify a patient as underserved. Novant Health's financial assistance policy will apply to the proposed services. By bringing cardiac catheterization services closer to a growing population, it also makes them more accessible for patients with transportation challenges.

Section L.3 includes payor mix projections that demonstrate Novant Health's commitment to ensuring access for medically underserved patients at NHMMC."

See also Sections 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 demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.

- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

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

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

C

The applicant proposes to develop one additional unit of fixed cardiac cath equipment at NH Matthews, pursuant to the adjusted need determination in the 2022 SMFP, for a total of no more than two units of fixed cardiac cath equipment upon project completion.

On Form O in Section Q, the applicant identifies the hospitals with fixed cardiac cath equipment located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of six hospitals with fixed cardiac cath equipment located in North Carolina.

In Section O, page 94, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents resulting in a finding of immediate jeopardy that occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all six facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical

center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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

10A NCAC 14C .1603 PERFORMANCE STANDARDS

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

(1) *identify the existing fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*

-C- In Section C, page 50, the applicant identifies the existing fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in Mecklenburg County. The applicant identifies four existing units of fixed cardiac cath equipment: two at NH Presbyterian and one each at NH Huntersville and NH Matthews.

(2) *identify the approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in the proposed fixed cardiac catheterization equipment service area;*

-C- In Section C, page 50, the applicant states it has no approved but not yet operational units of fixed cardiac cath equipment owned or operated by the applicant or a related entity located in Mecklenburg County.

(3) *provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*

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

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

-C- Immediately following Form C.2b in Section Q, the applicant provides the assumptions and methodology used to project utilization of the existing, approved, and proposed

fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in Mecklenburg County during each of the first three full fiscal years of operation following completion of the project.

(5) *project that the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed fixed cardiac catheterization equipment shall perform 900 or more diagnostic-equivalent cardiac catheterization procedures per unit of cardiac catheterization equipment during the third full fiscal year of operation following completion of the project.*

-C- On Form C.2b in Section Q, the applicant projects that the existing, approved, and proposed fixed cardiac cath equipment owned or operated by the applicant or a related entity and located in Mecklenburg County will perform 900 or more diagnostic-equivalent procedures per unit of cardiac cath equipment during the third full fiscal year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

- (1) *provide projected utilization of the proposed shared fixed cardiac catheterization equipment during each of the first three full fiscal years of operation following completion of the project;*
- (2) *provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and*
- (3) *project that the proposed shared fixed cardiac catheterization equipment shall perform 225 or more diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of the project.*

-NA- The applicant does not propose to acquire shared fixed cardiac cath equipment.

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

- (1) *identify the existing mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that provides cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;*
- (2) *identify the approved mobile cardiac catheterization equipment owned or operated by the applicant or a related entity that will provide cardiac catheterization services at host sites located in the proposed mobile cardiac catheterization equipment service area;*
- (3) *provide projected utilization of the cardiac catheterization equipment identified in Subparagraphs (1) and (2) of this Paragraph and the proposed mobile cardiac*

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

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