

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2021

Findings Date: September 27, 2021

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: F-12086-21

Facility: Atrium Health Cabarrus

FID #: 943049

County: Cabarrus

Applicant(s): Charlotte-Mecklenburg Hospital Authority

Project: Develop no more than one unit of fixed cardiac catheterization equipment pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion

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

The Charlotte-Mecklenburg Hospital Authority, hereafter referred to as the “applicant” or “CMHA” proposes to develop no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

Need Determination

The 2021 SMFP includes a need determination for one unit of fixed cardiac catheterization equipment in the Cabarrus County cardiac catheterization service area. Atrium Health Cabarrus does not propose to develop more units of fixed cardiac catheterization equipment than are determined to be needed in the 2021 SMFP for the Cabarrus County cardiac

catheterization service area. Therefore, the application is consistent with the need determination.

Policies

There is one policy in the 2021 SMFP that is applicable to this review: Policy *GEN-3: Basic Principles*, on page 29.

Policy GEN-3: Basic Principles states:

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

Promote Safety and Quality - The applicant describes how it believes the proposed project would promote safety and quality in Section B, pages 27-28; Section N, page 98; Section O, pages 100-102 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote safety and quality.

Promote Equitable Access - The applicant describes how it believes the proposed project would promote equitable access in Section B, page 28; Section C, pages 47-48; Section L, pages 89-94; Section N, page 98 and referenced exhibits. The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal would promote equitable access.

Maximize Healthcare Value - The applicant describes how it believes the proposed project would maximize health care value in Section B, pages 28-29, Section C, pages 30-31; Section F, pages 67-69; Section K, pages 86-87, Section N, page 98; the applicant’s pro forma financial statements in Section Q and referenced exhibits.

The information provided by the applicant is reasonable and adequately supports the determination that the applicant’s proposal will maximize health care value and that the applicant’s projected volumes incorporate the concepts of quality, equitable access and maximum value for resources expended in meeting the need identified in the 2021 SMFP. Therefore. The application is consistent with policy GEN-3.

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 cardiac catheterization units that 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's awards and recognition of its commitment to providing quality care and its existing Quality Assessment, Performance Improvement, Utilization Management and Risk Management plans.
 - The applicant's long history of providing access to care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.
 - The applicant's commitment to containing cost by adding the equipment to an existing Electrophysiology (EP) lab.

(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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

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

The following tables illustrate historical and projected patient origin.

Atrium Health Cabarrus (Cardiac Cath Lab) *		
Historical Patient Origin		
01/01/2020-12/31/2020 (CY 2020)		
County	# of Patients	% of Total
Cabarrus	1,321	41.5%
Stanly	667	20.9%
Mecklenburg	437	13.7%
Rowan	358	11.2%
Other**	408	12.6%
Total	3,186	100.0%

Source: Section C, Page 32

*Includes cardiac cath and EP patients

**Includes 35 other counties and other states

Atrium Health Cabarrus (Cardiac Cath Lab) *						
Projected Patient Origin						
	1st Full FY		2nd Full FY		3rd Full FY	
	01/01/2023-12/31/2023 (CY 2023)		01/01/2024-12/31/2024 (CY 2024)		01/01/2025-12/31/2025 (CY 2025)	
Cabarrus	1,398	41.5%	1,425	41.5%	1,452	41.5%
Stanly	706	20.9%	719	20.9%	733	20.9%
Mecklenburg	463	13.7%	471	13.7%	480	13.7%
Rowan	379	11.2%	386	11.2%	393	11.2%
Other**	426	12.6%	434	12.6%	443	12.6%
Total	3,371	100.0%	3,435	100.0%	3,501	100.0%
	[3,372]					

Source: Section C, Page 35

*Includes cardiac cath and EP patients

**Includes 35 other counties and other states

Note: Project Analyst's calculation in brackets

In Section C, page 34, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported. The applicant states that projected patient origin for patients to receive cardiac catheterization and EP procedures is based on the CY 2020 patient origin associated with cardiac catheterization and EP procedures performed in the two existing cardiac catheterization labs and one existing EP lab located at Atrium Health Cabarrus. The applicant does not project any change to patient origin for cardiac catheterization and EP procedures.

Analysis of Need

In Section C, pages 37-40, the applicant explains why it believes the population projected to utilize the proposed services needs the services. On pages 37-40, the applicant states:

Cabarrus County Demographics (pages 37-38)

The applicant cites data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate the projected population growth in Cabarrus County. The population is projected to grow approximately 1.9% annually from 2021 through 2025. The 65 and older population in Cabarrus County is projected to grow 4.2% annually during the same period of time. In Exhibit C.4, the applicant provides "Leading Cause of Death" statistics

from the North Carolina's State Center for Health Statistics. Heart disease is the leading cause of death in Cabarrus County and North Carolina among the 65 and older population and accounts for approximately 22.3% and 22.2% of total deaths in 2019, respectively. The applicant states that growing demographics of the 65 and older population will require increasing access to services, including cardiac catheterization services. The 65 and older population tends to utilize healthcare services more frequently than younger residents.

Need for Additional Fixed Cardiac Catheterization Capacity in Cabarrus County (pages 38-40)

Need Identified in the 2021 SMFP

The applicant states that the 2021 SMFP need for one unit of fixed cardiac catheterization equipment in Cabarrus County was generated by the highly utilized cardiac catheterization at Atrium Health Cabarrus, the only acute care hospital in Cabarrus County. The need for fixed cardiac catheterization equipment in Cabarrus County prior to the 2021 SMFP was determined in the 1994 SMFP.

Historical Utilization at Atrium Health Cabarrus

The applicant states that Atrium Health Cabarrus experienced a 3-year 5.4% Compound Annual Growth Rate (CAGR) for diagnostic and interventional procedures combined from CY 2017 to CY 2020. From CY 2018 to CY 2020, the two existing units reached above 100% utilization for each year. The applicant states that the facility's cardiac catheterization volumes have increased substantially, resulting in long waits, cancelled procedures and unnecessary overnight stays, further demonstrating the need for a third unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus.

Need to Develop the Proposed Project at Atrium Health Cabarrus to Meet Patient Needs

The applicant states that the facility's current cardiac catheterization capacity is insufficient to meet the needs of its growing number of patients, which can result in delays in patient care. Emergency patients may cause delays in procedures for scheduled patients, resulting in expensive and inconvenient overnight stays, delays in recovery or disruption in the continuity of care if patients are forced to access care at another facility.

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

- The applicant cites appropriate data that correlates with the 65+ age cohort population growth in Cabarrus County.
- The applicant's proposal is in response to the need for one unit of fixed cardiac catheterization equipment, as published in the 2021 SMFP.
- The applicant relies on the high utilization and capacity constraints of its existing cardiac catheterization units to justify the need.

Projected Utilization

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

Atrium Health Cabarrus Historical Utilization – Cardiac Cath Lab		
	Last Full FY CY 2020	Interim Full FY CY 2021
# of Units	2	2
# Diagnostic Procedures	1,599	1,629
# Therapeutic (interventional) Procedures	962	980
# Diagnostic-Equivalent Procedures	3,283	3,345
Electrophysiology (EP) in Cath Labs & EP Labs		
# of Units	3	3
# Diagnostic Procedures	625	637

Atrium Health Cabarrus Projected Utilization – Cardiac Cath Lab				
	Interim Full FY CY 2022	1st Full FY CY 2023	2nd Full FY CY 2024	3rd Full FY CY 2025
# of Units	3	3	3	3
# Diagnostic Procedures	1,660	1,692	1,724	1,757
# Therapeutic Procedures	999	1,018	1,037	1,057
# Diagnostic Equivalent Procedures	3,408	3,473	3,539	3,607
Electrophysiology (EP) in Cath Labs & EP Labs				
# of Units	3	3	3	3
# Diagnostic Procedures	649	661	674	687

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

Cardiac Catheterization Historical Utilization

The applicant begins with the historical utilization of Atrium Health Cabarrus’ existing fixed Cardiac catheterization units. The facility experienced a 5.4% annual growth in total procedures and 5.7% in total diagnostic equivalent procedures. Diagnostic equivalent procedures are calculated by multiplying the number of interventional procedures by 1.75 and adding the result to the number of diagnostic procedures.

Atrium Health Cabarrus Historical Utilization – Cardiac Catheterization					
	CY 2017	CY 2018	CY 2019	CY 2020	CAGR
Diagnostic Procedures	1,390	1,604	1,860	1,599	4.8%
Interventional Procedures	796	856	968	962	6.5%
Total Procedures	2,186	2,460	2,828	2,561	5.4%
Diagnostic Equivalent Procedures	2,783	3,102	3,554	3,283	5.7%
# of Units	2	2	2	2	
Total Capacity*	3,000	3,000	3,000	3,000	
Units Required Based on 80% Utilization**	2.3	2.6	3.0	2.7	
% Utilization***	93%	103%	118%	109%	

Source: Section Q, Form C, page 1

*Total Capacity = # of Units x 1,500 procedure capacity

**Units Required = Diagnostic Equivalent Procedures/1,200 procedures (80% of 1,500 procedure capacity)

***% Utilization = Diagnostic Equivalent Procedures/Total Capacity

The applicant states that the growth in diagnostic equivalent procedures is driven by the rapid growth of interventional procedures in comparison to diagnostic procedures, which grew 6.5% and 4.8% annually, respectively. The applicant states that the units are operating at above 100% of their capacity and is insufficient to meet the needs of its growing number of patients.

Electrophysiology (EP) Historical Utilization

The applicant proposes to develop the additional cardiac catheterization unit in its existing EP lab. EP procedures will continue to be performed in the EP lab which will be used as the third cardiac catheterization lab. The applicant examines the historical growth in EP procedures performed in one of its two existing cardiac catheterization labs or its existing EP lab. The facility experienced 7.0% annual growth in the number of EP procedures performed, as shown in the table below.

Atrium Health Cabarrus Historical EP Utilization in Cardiac Catheterization Labs and EP Labs					
	CY 2017	CY 2018	CY 2019	CY 2020	CY 2017-2020 CAGR
EP Procedures	510	649	638	625	7.0%

Source: Section Q, Form C, page 2

Cardiac Catheterization Projected Utilization

As previously illustrated, the number of diagnostic equivalent procedures performed on the two existing cardiac catheterization units have consistently been higher than the cardiac

catheterization performance standard of 2,700 procedures and could meet that standard now with three cardiac catheterization units. The facility experienced 5.7% annual growth in total diagnostic equivalent procedures during CY 2017 - CY 2020. The applicant conservatively projects an annual growth rate of 1.9% in its cardiac catheterization utilization, consistent with the Cabarrus County projected annual growth rate in population from 2021 through 2025, as shown in the table below.

Atrium Health Cabarrus Projected Utilization – Cardiac Catheterization						
	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	CAGR
Diagnostic Procedures	1,629	1,660	1,692	1,724	1,757	1.9%
Interventional Procedures	980	999	1,018	1,037	1,057	1.9%
Total Procedures	2,610	2,659	2,710	2,761	2,814	1.9%
Diagnostic Equivalent Procedures	3,345	3,408	3,473	3,539	3,607	1.9%
# of Units Required Based on 80% Utilization*	2.8	2.8	2.9	2.9	3.0	
# of Units Required Based on 60% Utilization**	3.7	3.8	3.9	3.9	4.0	
Existing and proposed Units	2.0	2/3 [^]	3.0	3.0	3.0	

Source: Section Q, Form C, page 3

*Units Required = Diagnostic Equivalent Procedures/1,200 procedure (80% of 1,500 Procedure capacity)

**Units Required = Diagnostic Equivalent Procedures/900 procedures (60% of 1,500 procedure capacity)

[^]An additional unit of cardiac cath equipment scheduled to be operational July 1, 2022, six months after the start of CY 2022.

The applicant states that proposed project is scheduled for July 1, 2022 and in order to be in responsive to the performance standards for cardiac catheterization equipment, it converted its “Calendar Year” projected utilization to “Project Year” projected utilization, based on the following formula:

$$PY1 = CY22 \times 0.5 + CY 23 \times 0.5$$

$$PY2 = CY23 \times 0.5 + CY 24 \times 0.5$$

$$PY2 = CY24 \times 0.5 + CY 25 \times 0.5$$

The applicant’s Project Year projected utilization demonstrates that the three cardiac catheterization units following completion of the proposed project will operate above the 60% performance standard for cardiac catheterization equipment, as shown in the table below.

Atrium Health Cabarrus Projected Utilization – Cardiac Catheterization Project Years			
	PY1	PY2	PY3
Diagnostic Procedures	1,676	1,708	1,740
Interventional Procedures	1,008	1,028	1,047
Total Procedures	2,685	2,736	2,788
Diagnostic Equivalent Procedures			
	3,441	3,506	3,573
# of Units	3	3	3
# Total Capacity*	4,500	4,500	4,500
% Utilization**	76%	78%	79%

Source: Section Q, Form C, page 4

*Total Capacity = # of Units x 1,500 procedure capacity

**% Utilization = Diagnostic Equivalent Procedures/Total Capacity

Electrophysiology (EP) Projected Utilization

The applicant proposes to develop the additional cardiac catheterization unit in its existing EP lab. EP procedures will continue to be performed in the EP lab which will be used as the third cardiac catheterization lab. Historically, the number of EP procedures has grown 7.0% annually from CY 2017 to CY 2020. The applicant projects the number of EP procedures to be performed in its proposed three cardiac catheterization labs to grow at 1.9% annually, consistent with the Cabarrus County projected annual growth rate in population from 2021 through 2025, as shown in the table below.

Atrium Health Cabarrus Projected EP Utilization in Cardiac Catheterization Labs and EP Labs						
	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025	CAGR
EP Procedures	637	649	661	674	687	1.9%

Source: Section Q, Form C, page 6

The following table illustrates the total projected utilization of the three fixed cardiac catheterization labs, which includes diagnostic and interventional cardiac catheterization and EP procedures:

Atrium Health Cabarrus Projected Utilization – Cardiac Catheterization Labs					
	CY 2021	CY 2022	CY 2023	CY 2024	CY 2025
Total Cath Procedures	2,610	2,659	2,710	2,761	2,814
EP Procedures in Cath Labs	637	649	661	674	687
Total Cath + EP Procedures in Cath Labs	3,247	3,308	3,371	3,435	3,501
Diagnostic Equivalent Cardiac Cath Procedures*	3,345	3,408	3,473	3,539	3,607
EP Procedures in Cath Labs	637	649	661	674	687
Total Diagnostic Equivalent Cardiac Cath Procedures + EP Procedures in Cath Labs	3,982	4,057	4,135	4,213	4,293
% Utilization**	88%	90%	92%	94%	95%

Source: Section Q, Form C, page 6

*Diagnostic Equivalent Procedures-calculated by multiplying the number of interventional procedures by 1.75 and adding the result to the number of diagnostic procedures.

**% Utilization = Total Procedures/Total Capacity of 4,500 Procedures

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

- The applicant relies on the high utilization of its existing cardiac catheterization units and the historical growth in diagnostic, interventional and EP procedures.
- The applicant conservatively projects utilization using the Cabarrus County projected population growth rate.

Access to Medically Underserved Groups

In Section C, page 47, the applicant states:

“Atrium Health Cabarrus provides services to all persons in need of medical care, regardless of race, color, religion, nation origin, sex, age, disability, or source of payment.

...

Patients who do not qualify for financial assistance will be offered an installment payment plan. Patients will receive the appropriate medical screening examination

and any necessary stabilization treatment for emergency medical condition, regardless of ability to pay.”

The applicant provides the estimated percentage for each medically underserved group in the third year of the project, as shown in the table below.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	
Racial and ethnic minorities	18.7%
Women	62.3%
Persons with disabilities	
Persons 65 and older	34.7%
Medicare beneficiaries	41.8%
Medicaid recipients	14.0%

Source: Section C, page 48

On page 48, the applicant states that Atrium Health Cabarrus does not maintain data that includes the number of low-income persons or handicapped persons it serves. Therefore, the applicant cannot provide an estimated percentage for these groups. 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. Atrium Health Cabarrus is an existing facility in the service area and has established policies in place regarding non-discrimination and financial assistance.

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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

In Section D, pages 65-66, 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 Status Quo-The applicant states that not developing additional cardiac catheterization capacity will cause the facility to continue to face capacity constraints, resulting in a delay in patient care. Further, physicians practicing at the facility would have to refer their patients to other facilities located outside of Cabarrus County.

Upfit Vacant Space Within the Hospital's Existing Footprint and Purchase New Cardiac Catheterization Equipment-This alternative was considered but the proposed project proved to be a more cost effective and efficient alternative. The applicant states that this alternative would require significant structural construction in order to accommodate the equipment.

On page 66, the applicant states that its proposal is the most effective alternative because it represents an efficient use of existing space that can be accomplished in a "*timely and resource-responsible manner.*" The applicant states that because the EP lab is already in place, all that is required to utilize the equipment as fixed cardiac catheterization equipment is the addition of the applications platform and related hardware. Further, the proposed project will be developed in close proximity to the hospital's existing cardiac catheterization services in the Health and Vascular Tower.

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 proposed project is a cost-effective alternative because it involves developing the project in an existing EP lab.
- The third unit will alleviate its existing capacity constraints.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. The Charlotte-Mecklenburg Hospital Authority (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 Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three 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.

- (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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization 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, as shown in the table below.

Atrium Health Cabarrus Capital Costs	
Construction/Renovation Contract(s)	\$12,100
Architecture/Engineering Fees	\$32,000
Medical Equipment	\$186,700
Consultant Fees	\$100,000
Other	\$10,500
Total	\$341,300

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:

- Construction costs and architecture and engineering fees are based on the experience of the project architect and the possible event that any potential cabling and/or electrical wiring is needed.
- Medical equipment costs are based on the vendor’s estimated costs and the applicant’s experience with similar projects.
- Consultant fees consist of CON and legal fees associated with the planning and development of the proposed project.

In Section F, pages 69-70, the applicant states that there will be no start-up or initial operating costs associated with this project since it does not involve a new service or facility.

Availability of Funds

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

Sources of Capital Cost Financing

Type	The Charlotte-Mecklenburg Hospital Authority	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$341,300	\$341,300
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$341,300	\$341,300

* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated June 15, 2021, from the Chief Financial Officer of CMHA, stating its commitment to fund the project through its accumulated reserves. Exhibit F.2-2 contains the audited financial statements of the CMHA, which show that as of December 31, 2020, the applicant had over \$900 million in cash and cash equivalents, \$13.5 billion in total assets, and \$7.4 billion in net assets (total assets less total liabilities).

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.

Atrium Health Cabarrus Cardiac Catheterization	1 st FFY CY 2023	2 nd FFY CY 2024	3 rd FFY CY 2025
Total Procedures	3,473	3,539	3,607
Total Gross Revenues (Charges)	\$200,584,805	\$210,530,171	\$220,968,647
Total Net Revenue	\$45,852,508	\$48,125,961	\$50,512,135
Average Net Revenue per Procedure	\$13,203	\$13,599	\$14,004
Total Operating Expenses (Costs)	\$20,342,895	\$21,369,649	\$22,365,750
Average Operating Expense per Procedure	\$5,857	\$6,038	\$6,201
Net Income	\$25,509,613	\$26,756,312	\$28,146,385

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 2020 payor mix and average charge for each project year.
- Percent of total utilization is based on CY 2020 payor mix for the service.

- The applicant assumes that projected payor mix will be consistent with the 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.
- (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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

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 Cabarrus County as a single county Acute Care Bed Service Area. Therefore, the applicant’s service area is Cabarrus 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, Atrium Health Cabarrus is the only facility with cardiac catheterization equipment located in Cabarrus County. Information about the facility, is shown in the table below.

Cardiac Catheterization Equipment Cabarrus County			
Facility	# of Units	2019 Procedures (unweighted)	# of Machines Needed (80% util.)
Atrium Health Cabarrus	2	3,255	2.75

In Section G, page 78, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Cabarrus County. The applicant states:

“...the 2021 SMFP has determined that additional cardiac catheterization capacity is needed in Cabarrus County. As the only provider of acute care, open heart, and cardiac catheterization services in Cabarrus County, CMHA believes that Atrium Health Cabarrus is the best and most logical location for the additional cardiac catheterization lab.”

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 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.
- As the only provider of acute care, open heart, and cardiac catheterization services in Cabarrus County, the applicant’s proposal will meet the need for cardiac catheterization services.

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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization 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.

Position	Current FTE Staff	Projected FTE Staff		
	(As of 12/31/2020)	1 st Full Fiscal Year (CY 2023)	2 nd Full Fiscal Year (CY 2024)	3 rd Full Fiscal Year (CY 2025)
Registered Nurses	13.90	14.90	15.50	15.90
Administrative/Management	0.80	0.80	0.80	0.80
Supervisory	2.20	2.20	2.20	2.20
Registered Technician	6.02	6.02	6.02	6.02
Technician	0.62	0.62	0.62	0.62
TOTAL	23.54	24.54	25.14	25.54

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 F.3b. In Section H, pages 79-80, 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. The applicant is an existing provider of cardiac catheterization services in Cabarrus County and has established recruiting and training methods to recruit and maintain sufficient manpower. Cabarrus College of Health Sciences and Carolinas College of Health Sciences are two schools of nursing within CMHA's system.

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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

Ancillary and Support Services

In Section I, page 81, the applicant identifies the necessary ancillary and support services for the proposed services. On page 81, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available. Atrium Health Cabarrus has these services already in place that will support the proposed fixed cardiac catheterization equipment.

Coordination

In Section I, page 82, 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 several physicians stating their intention to refer patients to Atrium Health Cabarrus.

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 make more than minor 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, page 89, the applicant provides the historical payor mix during CY 2020 for the proposed services, as shown in the table below.

Atrium Health Cabarrus Historical Payor Mix CY 2020	
Payor Category	Percent of Total
Self-Pay	8.6%
Medicare*	41.8%
Medicaid*	14.0%
Insurance*	33.0%
Workers Compensation	0.4%
Other (Tricare)	2.1%
Total	100.0%

Source: Section C, page 89

*Including any managed care plans.

Note: The applicant states that Atrium Health Cabarrus's internal data does not include charity care as a payor source for patients. Patients in any payor category can and do receive charity care.

In Section L, page 90, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area*
Female	62.3%	51.2%
Male	37.6%	48.8%
Unknown	0.1%	0.0%
64 and Younger	65.2%	86.6%
65 and Older	34.7%	13.4%
American Indian	0.3%	0.7%
Asian	0.5%	4.7%
Black or African-American	16.6%	19.6%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	53.9%	72.4%
Other Race	0.0%	2.5%
Declined / Unavailable	28.6%	0.0%

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

The Agency reviewed the:

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

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's

service area which is medically underserved. Therefore, the application is conforming to this criterion.

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 91, the applicant states:

“Atrium Health Cabarrus has no obligation to provide a specific uncompensated care amount, community service, or access to care by medically underserved, minorities, or handicapped persons.”

In Section L, page 92, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 92, 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.

Atrium Health Cabarrus Projected Payor Mix 3rd FY, CY 2025	
Payor Category	Cardiac Cath Services as Percent of Total
Self-Pay	8.6%
Medicare*	41.8%
Medicaid*	14.0%
Insurance*	33.0%
Workers Compensation	0.4%
Other (Tricare)	2.1%
Total	100.0%

Source: Section C, page 92

*Including any managed care plans.

Note: The applicant states that Atrium Health Cabarrus's internal data does not include charity care as a payor source for patients. Patients in any payor category can and do receive charity care.

On page 92, the applicant states that the facility's internal data does not include charity care as a payor source and any payor category can and does receive charity care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 8.6% of total services will be provided to self-pay patients, 41.8% to Medicare patients and 14.0% to Medicaid patients.

On page 93, 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 its assumption that the projected payor mix will be consistent with the historical payor mix during CY 2020 despite the possible effects of healthcare reform, Medicaid expansion, and other policy initiatives.

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 94, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

In Section M, page 96, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- CMHA's established relationships with health professional training programs, including Central Piedmont Community College, Queens University of Charlotte, University of North Carolina at Charlotte, Gardner-Webb University, and Presbyterian School of Nursing.
- CMHA's contractual agreement with University of North Carolina at Chapel Hill to manage the Charlotte Area Health Education Center (AHEC), who coordinates various educational programs and produces continuing medical education programming for employees of Atrium Health.
- CMHA and the University of North Carolina at Charlotte offer a collaborative program for registered nurses to obtain a master's degree and professional nurse anesthetist training (CRNA program).

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 no more than one unit of fixed cardiac catheterization equipment at Atrium Health Cabarrus pursuant to the need determination in the 2021 SMFP for a total of no more than three units of fixed cardiac catheterization equipment upon project completion.

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 Cabarrus County as a single county Acute Care Bed Service Area. Therefore, the applicant’s service area is Cabarrus 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, Atrium Health Cabarrus is the only facility with cardiac catheterization equipment located in Cabarrus County. Information about the facility, is shown in the table below.

Cardiac Catheterization Equipment Cabarrus County			
Facility	# of Units	2019 Procedures (unweighted)	# of Machines Needed (80% util.)
Atrium Health Cabarrus	2	3,255	2.75

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 98, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to cardiac catheterization services.”

Regarding the impact of the proposal on cost effectiveness, in Section B, pages 28-29, the applicant states:

“...CMHA intends to develop the proposed third unit of fixed cardiac catheterization equipment simply by adding equipment to its EP lab. This represents an efficient use of existing space for development of the proposed project that can be accomplished in a timely and resource-responsible manner.”

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

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

“Each year, CMHA facilities are recognized by many of the top accrediting and ranking organizations in the industry.

...

CMHA’s commitment to providing quality care is further demonstrated by its Quality Assessment and Performance Improvement, Utilization Management, and Risk Management Plan...”

See also Sections 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. CMHA 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 as demonstrated in CMHA’s Non-Discrimination policies...”

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

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

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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

In Section Q, Form O, the applicant identifies the acute care hospitals located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 17 of this type of facility located in North Carolina.

In Section O, page 102, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy occurred in one of these facilities. The applicant states that Atrium Health Cleveland was subject to termination of its provider agreement, however all of the problems have been corrected. 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, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all 17 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 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- In Section C, page 52, 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 77% capacity, as shown in the table below.

	Project Year 3 4 th Quarter
	April-June 2025
Diagnostic	146
Interventional	81
Total Procedures	227
Diagnostic Equivalent Procedures	289
# of Units	1
Capacity	375
% Utilization	77%

(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- In Section Q, Form C, page 4, and Section C, page 53, the applicant projects to perform 1,047 interventional cardiac catheterization procedures during the third year of operation following completion of the project and utilize three teams. Therefore, each team will perform 349 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- In Section Q, Form C, page 4, and Section C, page 53, the applicant projects to perform 1,740 diagnostic cardiac catheterization procedures during the third year of operation following completion of the project which is equivalent to 580 procedures for each of three teams, 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- In Section C.3, page 35, the applicant projects that 87.3% of cardiac catheterization and EP procedures will be performed on patients residing within its defined primary service area: Cabarrus, Stanly, Mecklenburg and Rowan counties. The discussion regarding patient origin found in Criterion (3) is incorporated herein by reference.

(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- The applicant does not 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- According to the most recent Licensure Renewal Application (LRA) on file with the Division of Health Service Regulation, the facility demonstrated that its existing items of cardiac catheterization equipment operated at an average of at least 80% of capacity during the twelve-month period, as shown in the table below.

Atrium Health Cabarrus	FFY 2020
Diagnostic Procedures	1,711
Interventional Procedures	958
Total Procedures	2,669
Diagnostic-Equivalent Procedures	3,388
# of Units	2
Capacity*	3,000
% Utilization**	113%

Source: Section C, page 55; 2021 License Renewal Application

*Capacity = # of Units x 1,500 procedure capacity

**% Utilization = Diagnostic Equivalent Procedures/Capacity

- (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- In Section C, page 56, the applicant demonstrates that its two 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.

	Project Year 3 4 th Quarter
	April-June 2025
Diagnostic	292
Interventional	163
Total Procedures	455
Diagnostic Equivalent Procedures	577
# of Units	2
Capacity	750
% Utilization	77%

As shown in the table above, the existing units of cardiac catheterization equipment are projected to operate at 77% of capacity as measured during the fourth quarter of the third year following completion of the proposed project.

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

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

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

(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*

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

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

-NA- The applicant does not 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- The applicant does not propose to offer pediatric cardiac catheterization.