

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: September 27, 2024

Findings Date: September 27, 2024

Project Analyst: Chalice L. Moore

Co-Signer: Micheala Mitchell

Project ID #: E-12527-24

Facility: UNC Health Caldwell

FID #: 933051

County: Caldwell

Applicant(s): Caldwell Memorial Hospital Inc.

Project: Acquire no more than one additional unit of fixed cardiac catheterization equipment pursuant to the 2024 SMFP need determination for a total of no more than two 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

Caldwell Memorial Hospital Inc. (hereinafter referred to as Caldwell Memorial Hospital or “the applicant”) proposes to acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

#### **Need Determination**

Chapter 15 of the 2024 State Medical Facilities Plan (SMFP) includes a need determination for one unit of fixed cardiac catheterization equipment in the Caldwell County service area. The applicant does not propose to develop more units of fixed cardiac catheterization equipment

than are determined to be needed in the 2024 SMFP within the Caldwell County service area. Therefore, the application is consistent with need determination.

### **Policies**

There is one policy in the 2024 SMFP which is applicable to this review. *Policy GEN-3: Basic Principles*, on page 29 of the 2024 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, pages 25-26, 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, through compliance with all applicable local, state, and federal standards established regarding cardiac catheterization services. 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 fixed cardiac catheterization 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 catheterization services in Caldwell County.

- The applicant adequately documents how the project will promote equitable access to fixed cardiac catheterization services in Caldwell 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 acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

**Patient Origin**

On page 304, the 2024 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 Caldwell County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Caldwell County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	Caldwell Memorial Hospital Cardiac Cath Historical Patient Origin	
	Last Full FY 01/01/2023-12/31/2023	
	Patients	% of Total
Caldwell	845	88.0%
Burke	43	4.5%
Watauga	17	1.8%
Catawba	14	1.5%
Wilkes	12	1.3%
Other NC Counties**	25	2.6%
Other States	4	0.4%
<b>Total</b>	<b>960</b>	<b>100.0%</b>

Source: Section C, page 31

<b>Caldwell Memorial Hospital Cardiac Cath Projected Patient Origin</b>						
<b>County</b>	<b>1<sup>st</sup> Full FY</b>		<b>2<sup>nd</sup> Full FY</b>		<b>3<sup>rd</sup> Full FY</b>	
	<b>01/01/26-12/31/26</b>		<b>01/01/27-12/31/27</b>		<b>01/01/28-12/31/28</b>	
	<b>FY2025</b>		<b>FY2026</b>		<b>FY2027</b>	
	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>	<b>Patients</b>	<b>% of Total</b>
Caldwell	983	88.0%	995	88.0%	1006	88.0%
Burke	50	4.5%	51	4.5%	51	4.5%
Watauga	20	1.8%	20	1.8%	21	1.8%
Catawba	17	1.5%	17	1.5%	17	1.5%
Wilkes	15	1.3%	15	1.3%	15	1.3%
Other NC Counties**	29	2.6%	29	2.6%	30	2.6%
Other States	3	0.4%	3	0.4%	3	0.4%
<b>Total</b>	<b>1,117</b>	<b>100.0%</b>	<b>1,130</b>	<b>100.0%</b>	<b>1,143</b>	<b>100.0%</b>

Source: Section C, page 33

In Section C, pages 36-37, the applicant provides the assumptions and methodology used to project its patient origin. The applicant, on page 36, states that the Two-Year (CY2021-CY2023) compound annual growth rate of diagnostic-equivalent procedures at CMH was 14.9%. The applicant further states that the annualized CY2024 year-to-date utilization at CMH, (the Three-Year (CY2021-CY2024) CAGR) is 16.1%. Based on annualized CY2024 year to date utilization, CMH’s fixed cardiac catheterization equipment is operating at 118% of equipment capacity as defined in the 2024 SMFP.

The applicant’s assumptions are reasonable and adequately supported based on the facility’s historical experience and the projected population growth in the service area.

**Analysis of Need**

In Section C, pages 35-42, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- There is a need determination in the 2024 SMFP for one unit of fixed cardiac catheterization equipment in Caldwell County. (page 39)
- There is a need for additional cardiac catheterization services in the service area based on the aging and growth of the population and the rise in cardiovascular disease in Caldwell County. (pages 37-42)
- Caldwell Memorial Hospital’s current workload and the projected growth in utilization is not sustainable on one unit of cardiac catheterization equipment. An additional unit is needed based on the historical Compound Annual Growth Rate (CAGR) in diagnostic and interventional procedures and the significant Caldwell County use rate, particularly among the 65+ population. (pages 36-37)

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

- The applicant cites publicly available data to support its conclusions about the growth and aging population in the service area.
- The applicant provides documentation of growth of cardiac catheterization procedures at Caldwell Health.
- The applicant justifies the need based on high utilization rates and capacity constraints.

**Projected Utilization**

In Section Q, Forms C.2a and C.2b, pages 103-104, the applicant provides historical and projected utilization, as illustrated in the following tables.

<b>Caldwell Memorial Hospital Historical and Interim Utilization</b>			
<b>Cardiac Catheterization Equipment</b>	<b>Last Full FY2023</b>	<b>Interim Full FY2024</b>	<b>Interim Full FY2025</b>
# of Units	1	1	1
# of Diagnostic Procedures	668	666	673
# of Therapeutic (Interventional) Procedures	472	632	638
# of Diagnostic Equivalent Procedures*	1,494	1,770	1,790

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

<b>Caldwell Memorial Hospital Projected Utilization</b>			
<b>Cardiac Catheterization Equipment</b>	<b>1<sup>st</sup> Full FY FY2025</b>	<b>2<sup>nd</sup> Full FY FY2026</b>	<b>3<sup>rd</sup> Full FY FY2027</b>
# of Units	2	2	2
# of Diagnostic Procedures	681	689	697
# of Therapeutic (Interventional) Procedures	646	653	661
# of Diagnostic Equivalent Procedures*	1,811	1,832	1,853

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

In Section Q, Form C-*Methodology and Assumptions*, pages 105-108, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant is the only provider offering cardiac catheterization services in Caldwell County. The applicant begins with the facility’s cardiac catheterization historical utilization to calculate an annualized CY2024 Three Year (CY2021-CY2024) compound annual growth rate (CAGR) of 14.6%. The table below, summarizes the most recent historical utilization of this cardiac catheterization equipment.

<b>Caldwell Memorial Hospital Historical Cardiac Catheterization Utilization CY2021-CY2024</b>						
	<b>FY2021</b>	<b>FY2022</b>	<b>FY20223</b>	<b>FY2024* Annualized</b>	<b>2-YR CAGR**</b>	<b>3-YR CAGR**</b>
Diagnostic Procedures	499	571	668	666	15.7%	10.1%
Interventional Procedures	362	433	472	631	14.2%	20.4%
<b>Total Procedures</b>	<b>861</b>	<b>1,004</b>	<b>1,140</b>	<b>1,297</b>	<b>15.1%</b>	<b>14.6%</b>

Source: Section Q, Form C, page 176; Caldwell Memorial Hospital Internal Data.

During CY2023, CMH operated at essentially 100% of the SMFP defined 1,500 procedure weighted capacity of its single unit of fixed cardiac catheterization equipment. Based on annualized CY2024 year-to-date utilization, CMH’s cardiac catheterization equipment is operating at 118% of equipment capacity as defined in the 2024 SMFP. The historical cardiac catheterization at CMH, calculated as diagnostic-equipment (or weighted) cardiac catheterization procedures is shown in the table below.

<b>Caldwell Memorial Hospital Historical Cardiac Catheterization Utilization CY2021-CY2024</b>						
	<b>FY2021</b>	<b>FY2022</b>	<b>FY20223</b>	<b>FY2024* Annualized</b>	<b>2-YR CAGR**</b>	<b>3-YR CAGR**</b>
Diagnostic Procedures	499	571	668	666	15.7%	10.1%
Interventional Procedures	362	433	472	631	14.2%	20.4%
<b>Total Procedures</b>	<b>861</b>	<b>1,004</b>	<b>1,140</b>	<b>1,297</b>	<b>15.1%</b>	<b>14.6%</b>
Diagnostic-Equivalent Procedures ***	1,132	1,329	1,494	1,770	14.9%	16.1%
Cardiac Catheterization Units	1	1	1	1		
Total Existing Capacity ****	1,500	1,500	1,500	1,500		
% Utilization	75.5%	88.6%	99.6%	118.0%		

To project future utilization, CMH assumes increasing cardiac catheterization utilization from CY2025 through CY2028 based on the projected growth rate of 1.16% CAGR for the Caldwell County age 65+ population. The projected future utilization is shown in the table below.

<b>Caldwell Memorial Hospital Projected Cardiac Catheterization Utilization CY2025-CY2028</b>					
	<b>FY2025</b>	<b>FY2026</b>	<b>FY2027</b>	<b>FY2028</b>	<b>3-YR CAGR**</b>
Diagnostic Procedures	673	681	689	697	1.16%
Interventional Procedures	638	646	653	661	1.16%
<b>Total Procedures</b>	<b>1,312</b>	<b>1,327</b>	<b>1,342</b>	<b>1,358</b>	<b>1.16%</b>
Diagnostic-Equivalent Procedures ***	1,790	1,811	1,832	1,853	
Cardiac Catheterization Units	1	2	2	2	
Performance Standard	900	1,800	1,800	1,800	
% of Performance Standard	198.9%	100.6%	101.8%	103.0%	

The table below projects the cardiac catheterization patients at CMH for CY2025-CY2028. To project the cardiac catheterization patients for CY2025-CY2028, CMH applied its procedure/patient ratio of 1.19 (1,140/960) and it held constant through CY 2028.

	Caldwell Memorial Hospital Projected Cardiac Catheterization Patients CY2025-CY2028				
	FY2025	FY2026	FY2027	FY2028	3-YR CAGR**
Total Procedures	1,312	1,327	1,342	1,358	1.16%
CY2023 Proc/Patient Ratio	1.19	1.19	1.19	1.19	
Cardiac Catheterization Patients	1,104	1,117	1,130	1,143	

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

- The applicant uses historical utilization to project utilization.
- The applicant’s utilization projections are supported by an increase in cardiac catheterization cases at Caldwell Memorial Hospital over a three-year period.
- The applicant projects a total of 1,853 diagnostic-equivalent (or weighted) procedures of the two CMH units of fixed cardiac catheterization equipment which exceeds the fixed catheterization performance standard of 1,800 in the .1603(a)(5) Criteria and Standards for Cardiac Catheterization Equipment.

**Access to Medically Underserved Groups**

In Section C, page 48, the applicant states:

*“UNC Health and its affiliated Network Entities comply with applicable Federal civil rights laws and do not discriminate, exclude people, or treat them differently on the basis of, race, ethnicity, color, culture, religion, language, national origin, age, physical or mental disability, or socioeconomic status, sex, sexual orientation, and gender identity or expression.”*

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

Caldwell Memorial Hospital 3 <sup>rd</sup> Full FY, FY2027	
Medically Underserved Groups	Percentage of Total Patients
Low-income persons*	16.2%
Racial and ethnic minorities	14.5%
Women	56.2%
Persons with Disabilities*	13.9%
Persons 65 and older	31.6%
Medicare beneficiaries	70.3%
Medicaid recipients	7.0%

Source: Section C, page 49

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:

- The applicant's proposal to acquire one unit of cardiac catheterization will not affect the needs of medically underserved groups currently served by Caldwell Memorial Hospital.
- Caldwell Memorial Hospital is an established facility in the service area currently serving patients defined as medically underserved.
- The applicant projects the percentage of total underserved patients to be served based on the number of patients served at Caldwell Memorial Hospital during CY2023.

### **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.

CA

The applicant proposes to acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.



In Section E, pages 59-60, 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 considered not developing additional cardiac catheterization equipment at the hospital. However, the applicant decided that this was not the most effective alternative, First, there is a need in the SMFP 2024 for an additional unit of fixed cardiac catheterization equipment in Caldwell County. Second, the utilization of fixed cardiac catheterization equipment at CMH has grown steadily, including both diagnostic and interventional procedures. Lastly, both cardiologists and referring providers desire to ensure ready patient access to cardiac catheterization services.

**Contract Supplemental Access on a Leased Mobile Cardiac Catheterization System-** The applicant states that contracting for supplemental mobile cardiac catheterization could be a short-term solution to address the need to enhance access to cardiac catheterization services in Caldwell County. However, mobile service typically has limited access due to statewide demand. The applicant also states that mobile cardiac catheterization equipment is operationally inefficient and more costly, compared to having permanent fixed cardiac catheterization equipment.

**Develop the Project as Proposed-** Caldwell Memorial Hospital maintains that the most effective alternative is to acquire a second unit of fixed cardiac catheterization equipment installed at its Lenoir hospital facility. The proposal is the most effective alternative because the additional fixed cardiac catheterization equipment will help ensure that Caldwell County residents receive timely, convenient, high-quality and cost-effective cardiac catheterization services, and will be available to serve hospital inpatients, outpatients, and emergency patients. The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant's proposal to add an additional unit of fixed cardiac catheterization equipment will enhance access to services for Caldwell Memorial Hospital patients.
- The applicant's proposal is more cost-efficient than leasing a mobile cardiac catheterization system.
- 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. Caldwell Memorial Hospital 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 pursuant to the need determination in the 2024 SMFP.**
  - 3. Upon completion of the project, the Caldwell Memorial Hospital shall be licensed for no more than two units of fixed cardiac catheterization equipment.**
  - 4. Progress Reports:**
    - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. The certificate holder shall complete all sections of the Progress Report form.**
    - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. The first progress report shall be due on February 1, 2025.**
  - 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  - 6. The certificate holder shall 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 acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 109, the applicant projects the total capital cost of the project, as shown in the table below.

<b>Capital Costs</b>	
Medical Equipment	\$889,777
Other (contingencies)	\$52,250
<b>Total</b>	<b>\$992,027</b>

Source: Section Q, page 109

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 applicant is proposing to develop the project in an existing space already equipped to function as a cardiac catheterization lab without incurring any capital costs.
- Contingency costs are based on the applicant’s experience with similar projects.

In Section F, page 63, the applicant states there will be no start-up costs or initial operating expenses because Caldwell Memorial Hospital currently provides fixed cardiac catheterization services.

**Availability of Funds**

In Section F, page 70, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
<b>Type</b>	<b>Caldwell Memorial Hospital</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$992,027	\$992,027
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$100,000</b>	<b>\$100,000</b>

\*OE = Owner’s Equity

In Exhibit F.2.1, the applicant provides a letter, dated May 22, 2023, from the chief financial officers for Caldwell Memorial Hospital, stating that contingency costs will be funded through accumulated cash reserves. Exhibit F.2.2 contains a letter from the vice president of First Citizens Bank advising that the hospital has sufficient funds to cover the estimated projected capital costs of \$992,027.

**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.

<b>Caldwell Memorial Hospital</b>	<b>1<sup>st</sup> Full FY FY2026</b>	<b>2<sup>nd</sup> Full FY FY2027</b>	<b>3<sup>rd</sup> Full FY FY2028</b>
Total Procedures	1,327	1,342	1,358
Total Gross Revenues (Charges)	\$35,306,969	\$36,787,812	\$38,330,765
Total Net Revenue	\$7,196,085	\$7,497,903	\$7,812,380
Average Net Revenue per Procedure	\$5423	\$5587	\$5753
Total Operating Expenses (Costs)	\$6,329,026	\$6,605,191	\$6,826,028
Average Operating Expense per Procedure	\$26,611	\$27,410	\$28,232
Net Income	\$867,059	\$892,712	\$986,352

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’s projections are based on FY2023 historical payor mix and charges per procedures performed on the existing unit of cardiac catheterization equipment.
- 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 and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

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

The applicant proposes to acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

On page 304, the 2024 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 Caldwell County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Caldwell County. Facilities may also serve residents of counties not included in their service area.

According to Table 15A-3 in Chapter 15 of the 2024 SMFP, there is a need for one unit of fixed cardiac catheterization equipment in Caldwell County, as illustrated in the table below.

Fixed Cardiac Catheterization Equipment Inventory –Caldwell County			
Facility	# Units	2023 Procedures	Machines Required (80% Utilization)
Caldwell Memorial Hospital	1	1,713	1.43

Source: SMFP 2024, 15A-3, page 309

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 Caldwell County. The applicant states:

*“...Caldwell Memorial Hospital does not propose to acquire and operate more fixed cardiac catheterization equipment than is determined to be needed in the 2024 SMFP. As evidenced by the need determination in the 2024 SMFP, the State Health Coordination Council (SHCC) considers the sole existing fixed cardiac catheterization equipment inadequate to meet the need in the cardiac catheterization service area.*

*...the proposed equipment will add capacity at Caldwell Memorial Hospital, enabling its providers to treat more cardiovascular patients and accommodate those requiring emergent care.”*

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:

- The 2024 SMFP has identified a need determination for one unit of cardiac catheterization equipment in Caldwell County.
- The applicant adequately demonstrates that the proposed equipment is needed in addition to the existing cardiac 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 acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

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

<b>Caldwell Memorial Hospital</b>				
	<b>Current FY2024</b>	<b>1st Full FY2025</b>	<b>2<sup>nd</sup> Full FY2026</b>	<b>3<sup>rd</sup> Full FY2027</b>
Registered Nurses	3.1	5.1	5.1	5.1
Other (Coordinator, Invasive Diagnostics)	1	1.0	1.0	1.0
Other (Manager, Invasive Heart & Vascular)	1	1.0	1.0	1.0
Other (Cardiovascular Specialist)	<b>2.50</b>	<b>4.50</b>	<b>4.5</b>	<b>4.5</b>
<b>TOTAL</b>	<b>7.60</b>	<b>11.60</b>	<b>11.60</b>	<b>11.60</b>

Source: Section Q, Form H, page 115

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 71-74, 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 catheterization services which already employs staff necessary to offer fixed cardiac catheterization services.
- The applicant is part of an established healthcare system in Caldwell 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 acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

#### **Ancillary and Support Services**

In Section I, page 75, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 75-76, 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 Caldwell Memorial Hospital currently provides the ancillary and support services that will be necessary for the additional unit of fixed cardiac catheterization equipment.

#### **Coordination**

In Section I, pages 76-77, 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.1.2, the applicant provides letters of support from Caldwell Memorial Hospital physicians supporting the addition of an additional unit of fixed cardiac catheterization 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.

C



The applicant proposes to acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

In Section K, page 79, the applicant states that the project involves constructing 11,015 square feet of new space. Line drawings are provided in Exhibit C.1-1.

On page 79, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states:

*“Caldwell Memorial Hospital’s project to accommodate the additional fixed cardiac catheterization equipment is being planned and directed by experienced architect and construction professionals. This project represents the most reasonable alternative for the proposed additional unit of fixed cardiac catheterization equipment because the equipment will be located in new space to be part of the updated cardiac catheterization lab suite, and thus leverages the existing infrastructure and support spaces.”*

On page 80, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services. The applicant states:

- The second fixed cardiac catheterization equipment will not unduly increase the costs of providing medical services at Caldwell Memorial Hospital.
- The proposed additional cardiac catheterization equipment can achieve higher productivity and cost savings with advanced technology and improved scheduling.
- The project will not increase cardiac catheterization charges to the public.

On page 80, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

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

C

In Section L, page 83, the applicant provides the historical payor mix during FY2023 for the proposed services, as shown in the table below.

<b>Caldwell Memorial Hospital Historical Payor Mix 01/01/2023-12/31/2023</b>	
<b>Payor Category</b>	<b>Percent of Total</b>
Medicare*	70.31%
Medicaid*	6.98%
Insurance*	22.4%
TRICARE	0.31%
<b>Total</b>	<b>100.0%</b>

\* Including any managed care plans

In Section L, page 84, the applicant provides the following comparison.

Caldwell Memorial Hospital	Last Full FY Submission of the Application	
	Percentage of Total Patients	Percentage of the Population of the Service Area
Female	56.2%	50.2%
Male	43.8%	49.8%
Unknown	0.0%	0.0%
64 and Younger	68.4%	78.7%
65 and Older	31.6%	21.3%
American Indian	0.1%	0.7%
Asian	0.4%	0.9%
Black or African American	6.9%	5.4%
Native Hawaiian or Pacific Islander	0.02%	0.1%
White or Caucasian	85.5%	86.4%
Other Race	5.4%	6.5%
Declined / Unavailable	1.7%	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 85, the applicant states it has no such obligation.

In Section L, page 86, 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.

**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

In Section L, page 86, 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.

Payor Category	% of Total – Entire Facility
Self-Pay	1.6%
Charity Care^	3.8%
Medicare*	63.1%
Medicaid*	13.3%
Insurance*	14.8%
Workers Compensation^^	%
TRICARE^^	%
Other Gov't/Institutional	3.5%
<b>Total</b>	<b>100.0%</b>

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.6% of cardiac catheterization services will be provided to self-pay patients, 63.1% of cardiac catheterization services to Medicare patients, and 13.3% of cardiac catheterization services to Medicaid patients.

On page 86, 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.

**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 87, 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 acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

In Section M, page 89, 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 Caldwell County
- The applicant states all educational programs that have clinical agreements with Caldwell Community College and Technical Institute and Catawba Valley Community College will have the same access upon completion of the proposed project.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

On page 304, the 2024 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 Caldwell County as a single county service area. Therefore, the service area for the fixed cardiac catheterization equipment is Caldwell County. Facilities may also serve residents of counties not included in their service area.

According to Table 15A-3 in Chapter 15 of the 2024 SMFP, there is a need for one unit of fixed cardiac catheterization equipment in Caldwell County, as illustrated in the table below.

<b>Fixed Cardiac Catheterization Equipment Inventory –Caldwell County</b>			
<b>Facility</b>	<b># Units</b>	<b>2023 Procedures</b>	<b>Machines Required (80% Utilization)</b>
Caldwell Memorial Hospital	1	1,713	1.43

Source: SMFP 2024, 15A-3, page 309

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 90, the applicant states:

*“Caldwell Memorial Hospital, as an experienced provider, is expecting to enhance competition in the service area by augmenting the cardiac catheterization services it currently offers in Caldwell County and promoting improved and more timely patient access to quality, cost-effective, and accessible cardiac catheterization services.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 91, the applicant states:

*“The addition of a second unit of fixed cardiac catheterization equipment at CMH represents an opportunity to contain healthcare costs and maximize healthcare benefit, while also ensuring that CMH increases its health service capacity to meet the needs of the population it serves, which includes rural and medically underserved residents. Caldwell Memorial Hospital will develop the fixed cardiac catheterization project in a cost-effective manner. This cardiac catheterization equipment acquisition project will not increase the charges or projected reimbursement for these services which are established by Medicare, Medicaid, and/or existing private payor contracts.”*

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 92, the applicant states:

*“The proposed project will promote safety and quality in the delivery of healthcare services. Caldwell Memorial Hospital is an experienced local provider of healthcare services, including cardiac catheterization, and is dedicated to ensuring quality and patient safety through compliance with all applicable regulatory standards established regarding cardiac catheterization. Patient safety and quality will be incorporated into all aspects of the project, including equipment selection and installation, facility construction, staff credentialing and education, patient selection and scheduling, and continuous quality measure and patient satisfaction surveys.”*

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 94, the applicant states:

*“This Caldwell Memorial Hospital project is aligned with this principle: CMH will continue to provide high quality, care to all patients, including medically underserved groups, regardless of ability to pay. The proposed fixed cardiac catheterization equipment acquisition project is designed to expand and improve access to all patients (inpatient, outpatient, and emergency patients), including the medically underserved, particularly timely access to the cardiac catheterization services proposed in the application.”*

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 acquire no more than one unit of fixed cardiac catheterization equipment at UNC Health Caldwell pursuant to the 2024 SMFP need determination for a total of no more than two units of fixed cardiac catheterization equipment upon project completion.

In Section Q, form O, page 116, the applicant identifies existing and approved facilities with fixed cardiac catheterization equipment located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of twelve (12) hospitals with fixed cardiac catheterization equipment located in North Carolina.



In Section O, page 99, the applicant states that none of the facilities in Form O were determined by the Division of Health Service Regulation to have had any situations resulting in a finding of immediate jeopardy during the 18-month look-back period. After reviewing and considering the information provided by the applicant and the Acute Care and Home Care License and Certification Section and considering the quality of care provided at all facilities, the applicant has 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

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 Q, Form C.2a, page 108, the applicant identifies one (1) existing unit of fixed cardiac catheterization equipment at Caldwell Memorial Hospital. The 2024 SMFP

lists the existing and approved cardiac catheterization inventory for Caldwell Memorial Hospital in the table below.

Fixed Cardiac Catheterization Equipment Inventory –Caldwell County			
Facility	# Units	2023 Procedures	Machines Required (80% Utilization)
Caldwell Memorial Hospital	1	1,713	1.43

^ Caldwell Memorial Hospital has 1 Cardiac Cath units and one CON approved Cardiac Cath unit in development.

- (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 51, the applicant states there are no approved fixed cardiac catheterization equipment owned or operated by the applicant or a related entity in the proposed fixed cardiac catheterization equipment service area (Caldwell 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- In Section Q, Form C.2b, pages 107-108, the applicant provides projected utilization of the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in Caldwell 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 catheterization equipment owned or operated by the applicant or a related entity and located in Caldwell 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- In Section Q, Form C.2b, pages 106-108, the applicant projects that the existing, approved, and proposed fixed cardiac catheterization equipment owned or operated by the applicant or a related entity and located in Caldwell County will perform 900 or more diagnostic-equivalent procedures per unit of cardiac catheterization 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 catheterization 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 catheterization equipment.