

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 24, 2024

Findings Date: January 24, 2024

Project Analyst: Crystal Kearney

Co-Signer: Mike McKillip

Project ID #: E-12441-23

Facility: UNC Health Blue Ridge

FID #: 943191

County: Burke

Applicant: Blue Ridge Healthcare Systems, Inc.

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

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

Blue Ridge Healthcare Systems, Inc. (hereinafter referred to as to the “applicant”) propose to develop no more than one unit of shared fixed cardiac catheterization (cardiac cath) equipment at the UNC Health Blue Ridge – Morganton campus pursuant to the 2023 State Medical Facilities Plan (SMFP) need determination.

Need Determination

Chapter 17 of the 2023 State Medical Facilities Plan (SMFP) includes a need determination for one unit of shared fixed cardiac catheterization equipment in the Burke County cardiac catheterization service area.

The applicant does not propose to develop more units of shared fixed cardiac catheterization equipment than are determined to be needed in the 2023 SMFP for the Burke County cardiac catheterization service area. Therefore, the application is consistent with the need determination.

Policies

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

Policy GEN-3, on page 30 of the 2023 SMFP states:

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

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, pages 98-99; Section O, pages 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, pages 28 -29; Section C, pages 53-54; Section L, page 91-92; Section N, page 100 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 29–30; Section K, pages 85-86, 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 2023 SMFP. Therefore, the application is consistent with policy GEN-3.

Policy GEN-4, on page 30, of the 2023 SMFP states:

“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

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

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

The proposed capital expenditure for this project is greater than \$5 million. In Section B, pages 31-32, the applicant describes the project’s plan to improve energy efficiency and conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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 shared fixed cardiac catheterization units than are determined to be needed in the 2023 SMFP in the service area.
- The applicant adequately demonstrates that the proposal is consistent with Policy Gen-3 and Policy GEN-4 based on the following:

- The applicant adequately documents how the project will promote safety and quality in the delivery of cardiac catheterization services in Burke County.
 - The applicant adequately documents how the project will promote equitable access to cardiac catheterization services in Burke County; and
 - The applicant adequately documents how the project will maximize healthcare value for the resources expended.
 - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to acquire no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination. In Section C.1, pages 33-35, the applicant describes the project as follows:

“UNC Health Blue Ridge is a comprehensive healthcare system, providing advanced healthcare and wellness services from nearly 50 locations across Burke, Caldwell, and McDowell counties. The system includes one hospital with two campuses (in Morganton and Valdese, both in Burke County), and employs over 120 primary care and specialty physicians and physician extenders in the UNC Health Blue Ridge medical group.... However, UNC Health Blue Ridge is not able to provide emergent cardiac catheterization procedures at this time. In the case of a patient presenting with an emergent cardiac episode requiring a cardiac catheterization, the patient is typically transferred to Frye Regional Medical Center in Catawba County, a nearly 30-minute drive from UNC Health Blue Ridge’s campus in Morganton....As the proposed project is for a shared unit of fixed cardiac catheterization equipment, pursuant to the adjusted need determination as allocated for Burke County in the 2023 SMFP, the proposed unit of equipment will also be able to perform angiography procedures, as noted above, maximizing the effective utilization of the proposed equipment. In short, the proposed project will enable UNC Health Blue Ridge to ensure permanent availability of equipment at the hospital, maintaining this much-needed service in Burke County, while also supporting the planned expansion of emergent cardiac catheterization services, providing this service to patients in a more timely manner and closer to home....The proposed unit of shared cardiac catheterization equipment will be located on the second floor of UNC Health Blue Ridge – Morganton’s existing facility, in 2,755 square feet of existing space near the lab that currently houses the vendor-owned cardiac catheterization equipment.”

Patient Origin

On page 300, the 2023 SMFP defines the cardiac catheterization equipment service areas as “...the Acute Care Bed Service Areas defined in Chapter 5 and shown in Figure 5.1.” Figure 5.1, on page 36, shows Burke County as a single county service area. Morganton is in Burke County. Thus, the service area for this proposal is Burke County. Facilities may also serve residents of counties not included in their service area.

In Section C, page 44, the applicant states, it provides fixed cardiac catheterization services at its hospital campus in Morganton through a contract with DLP Cardiac Partners.

In Section C, page 36, the applicant provides historical patient (CY2022) origin for UNC Health Blue Ridge – Morganton cardiac catheterization services, as illustrated in the following table:

Cardiac Catheterization Lab	UNC Health Blue Ridge – Morganton	
	Last Full FY 07/01/2022 to 06/30/2023	
County or other geographic area such as ZIP code	Number of Patients	% of Total
Burke	466	55.4%
McDowell	172	20.4%
Caldwell	114	13.6%
Catawba	25	2.9%
Rutherford	18	2.2%
Other ^	46	5.5%
Total	842	100.0%

Source: Section C, page 36

^ NOTE: applicant lists counties in the “other” category on page 36.

In Section C, page 38, the applicant provides projected patient origin for the shared fixed cardiac cath lab at UNC Health Blue Ridge – Morganton for the first full three years of full operation (CY 2026-2028), as shown in the following table:

Shared Fixed Cardiac Cath Lab	UNC Health Blue Ridge - Morganton					
	1 st Full FY CY 2026		2 nd Full FY CY 2027		3 rd Full FY CY 2028	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Burke	488	55.4%	496	55.4%	503	55.4%
McDowell	180	20.4%	183	20.4%	186	20.4%
Caldwell	119	13.6%	121	13.6%	123	13.6%
Catawba	26	2.9%	26	2.9%	27	2.9%
Rutherford	19	2.2%	19	2.2%	20	2.2%
Other^	48	5.5%	49	5.5%	50	5.5%
Total	881	100.0%	894	100.0%	908	100.0%

In Section C, pages 36-40, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported

because it is based on historical utilization of cardiac catheterization services at UNC Health Blue Ridge – Morganton by residents of the proposed service area.

Analysis of Need

In Section C, pages 40-45, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states the proposed project is in response to an adjusted need determination in the 2023 SMFP for one unit of fixed cardiac catheterization equipment in Burke County.
- The applicant states the overall population growth in Burke County is expected to remain flat, but the 65 and older population in Burke County is projected to increase a total of 7.8 percent from 2023 to 2028, representing a compound annual growth rate (CAGR) of 1.5 percent that results in an additional 1,520 residents in this age group by 2028. Future demand for hospital-based cardiovascular services in Burke County is expected to increase based on the projected aging of the service area population.
- The applicant states the county’s population continues to age, the demand for cardiovascular services will continue to increase over time, and it is critical that UNC Health Blue Ridge has capacity at the Morganton campus to maintain and expand the inpatient and outpatient cardiac catheterization and angiography services it offers. As such, UNC Health Blue Ridge believes that the proposed project will enable it to meet the expanding need for cardiovascular services in Burke County.
- The applicant states the age-adjusted death rate in Burke County for the five years from 2016 to 2020 was 174.4 per 100,000 population, compared to 156.1 for all of North Carolina. This disparity increases when viewing the most recently available data for 2020; Burke County’s rate of 285.3 was 48 percent higher than the statewide death rate. These disproportionate statistics are indicative of the demand in Burke County for clinical services that support the diagnosis and treatment of heart and vascular disease, for the screening and prevention of advanced cardiovascular ailments as well as for emergent treatment of patients experiencing acute onset of heart-related conditions such as myocardial infarctions.
- The cardiac catheterization unit at UNC Health Blue Ridge can “toggle” between fixed and mobile status atwill. Although UNC Health Blue Ridge has provided cardiac catheterization services using the equipment owned by DLP Cardiac Partners for many years, the availability of the equipment is subject to a time-limited-service agreement contract with the vendor, which must be renewed periodically. While UNC Health Blue Ridge has successfully renewed its agreement with the vendor several times over the years, UNC Health Blue Ridge believes that the risk of a change in the status of its contract has increased, for several reasons.

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

- The applicant’s projected utilization is supported by its historical experience providing cardiac catheterization services utilizing the leased DLP mobile cardiac catheterization unit.
- The applicant provides information regarding current and projected population for Burke County.

Projected Utilization

In Section Q, the applicant provides projected utilization of the proposed shared fixed cardiac catheterization equipment, as illustrated in the following table.

Shared Fixed Cardiac Catheterization Utilization Projections	Partial FY 7/1/24 to 6/30/25	1st Full FY 7/1/25 to 6/30/26	2nd Full FY 7/1/26 to 6/30/27	3rd Full FY 7/1/27 to 6/30/28
# Units	1	1	1	1
# Diagnostic Procedures	451	458	465	472
# Therapeutic Procedures	154	156	158	161
# Diagnostic Equivalent Procedures	720	731	742	754

Source: Section Q, Form C.2b, page 108

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

- The applicant reviewed the utilization trend of cardiac catheterization and other procedures at the UNC Health Blue Ridge – Morganton campus. Because the proposed equipment is specifically allocated as a “shared” fixed unit in the 2023 SMFP, it will be able to provide both cardiac and non-cardiac (angiography) catheterization procedures. UNC Health Blue Ridge has experienced rapid growth in these procedures, with an overall compound annual growth rate (CAGR) of 39.7 percent between fiscal years 2019 and 2023.
- The applicant examined population growth projections by age category in Burke County, the defined service area according to the 2023 SMFP. Currently, 89 percent of cardiac catheterization patients at UNC Health Blue Ridge originate from Burke, Caldwell, or McDowell counties, with the majority coming from Burke County.
- Diagnostic-equivalent procedures are calculated by multiplying the total number of diagnostic procedures by a weight factor of 1.00 and the total number of interventional procedures by 1.75 then summing the result. UNC Health Blue Ridge projects that it will perform 731 diagnostic-equivalent procedures in FY 2026, the first project year, with volume increasing to 754 diagnostic-equivalent procedures in project year three (FY 2028).
- The applicant also projects that other angiography procedures performed on the proposed shared fixed cardiac catheterization equipment will increase at an annual rate of 1.5 percent, mirroring the population growth for the 65 and older population. Adding these procedures to the diagnostic-equivalent procedure volume results in total utilization of 998 cardiac catheterization procedures in the first project year, increasing to 1,029 total procedures in project year three, as shown in the table below:

Cardiac Catheterization and Other Procedure Volume Projections

Procedure Category	FY 2024	FY 2025	FY 2026	FY 2027	FY 2028	FY 23-28 CAGR[^]
Diagnostic	445	451	458	465	472	1.5%
Interventional	151	154	156	158	161	1.5%
Diagnostic Equivalent *	709	720	731	742	754	
Angiography	259	263	267	271	275	1.5%
Total**	968	983	998	1,013	1,029	1.5%

Source: Section Q, page 110

[^] Compound Annual Growth Rate

*Multiply diagnostic procedures by 1.00 and interventional procedure by 1.75

** Includes diagnostic -equivalent cardiac catheterization and angiography procedures per the performance standard

Projected utilization is reasonable and adequately supported because it is based on data on historical utilization of cardiac catheterization services at UNC Health Blue Ridge and by projected population growth for the age segment 65 and older in the proposed service area.

Access to Medically Underserved Groups

In Section C.6, page 53, the applicant states,

“UNC Health Blue Ridge provides access to care for all patients regardless of race, color, religion, natural origin, sex, age, disability, or source of payment.”

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

Medically Underserved Groups	Percentage of Total Patients
Low income persons	NA
Racial and ethnic minorities	8.8%
Women	44.5%
Persons with Disabilities	NA
The elderly	30.0%
Medicare beneficiaries	32.0%
Medicaid recipients	14.8%

Source: Section C, page 53

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 information provided on pages 53-54 of the application.

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

- (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 shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

In Section E, page 65, the applicant describes the alternative it considered and explains why this alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The applicant states to ensure availability of cardiac catheterization capacity at UNC Health Blue Ridge- Morganton, the only hospital campus in Burke County that provides inpatient services. The applicant states by locating the proposed shared fixed cardiac cath unit at the Morganton campus enables UNC Blue Ridge to have a permanent unit, owned by the hospital, and available for treatment of ST-elevated myocardial infarction (STEMI) treatment and emergent interventional catheterization cases that are not currently available. While the Valdese campus does include an Emergency Department, it does not have inpatient services and would be unable to provide care to emergent cases, many of which require inpatient admission following treatment. The Morganton campus will have existing space created by the ED relocation that can be renovated to minimize project capital costs, while locating the unit at the Valdese campus would require the development of additional support space, such as a control room, which already exists on the Morganton campus.

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

- The application is conforming to all statutory and regulatory review criteria.

- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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. Blue Ridge HealthCare Systems, Inc. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall acquire one unit of shared fixed cardiac catheterization equipment at UNC Health Blue Ridge- Morganton pursuant to the need determination in the 2023 SMFP.**
- 3. Upon completion of the project, UNC Health Blue Ridge- Morganton shall be licensed for no more than one unit of shared fixed cardiac catheterization equipment.**
- 4. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. 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 June 1, 2024.**

6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to insurance 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 shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

Capital and Working Capital Costs

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

Construction Costs	\$3,459,729
Architect/Engineering Fees	\$355,745
Medical Equipment	\$2,634,431
Non Medical Equipment	\$385,700
Furniture	\$46,863
Other	\$233,703
Total Capital Cost	\$7,116,169

In Section Q, Form F.1a, 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 letter from Patricia Moll, CFO of UNC Health Blue Ridge, in Exhibit F-2.1.

In Section F, page 69, the applicant states there will be no start-up costs or initial operating expenses because they currently perform cardiac catheterization and angiography procedures at the Morganton campus.

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 of the project, as shown in the table below.

Projected Revenues and Net Income UNC Health Blue Ridge Cardiac Catheterization	1st Full FY 07/01/25 to 06/30/26	2nd Full FY 07/01/26 to 06/30/27	3rd Full FY 07/01/27 to 06/30/28
Total Procedures	731	742	754
Total Gross Revenues (Charges)	\$22,793,229	\$23,834,023	\$24,922,342
Total Net Revenue	\$5,982,806	\$6,255,995	\$6,541,659
Average Net Revenue per Procedure	\$8,184	\$8,431	\$8,676
Total Operating Expenses (Costs)	\$3,338,275	\$3,466,427	\$3,584,795
Average Operating Expense per Procedure	\$4,567	\$4,672	\$4,754
Net Income	\$2,644,531	\$2,789,568	\$2,956,864

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q of the application.

The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- 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 costs and charges.

- (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 shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

On page 300, the 2023 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 36 of the 2023 SMFP shows Burke County as a single county acute care bed service area. Thus, the service area for this proposal is Burke County. Facilities may also serve residents of counties not included in their service area.

In Section G, page 77, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved cardiac catheterization services in Burke County. On page 77, the applicant states,

“As detailed in Section C.4, UNC Health Blue Ridge is the only provider of cardiac catheterization services in Burke County. While the 2023 SMFP shows the existing equipment as “fixed,” it is actually a legacy mobile unit that has been stationary at the hospital for some time. As described previously, because UNC Health Blue Ridge does not own the equipment that provides the service, it is at risk of losing its ability to provide this life-saving service to its patients if the vendor chooses to end the contract.... Moreover, the ability to own its own equipment and secure the service permanently in Burke County will enable UNC Health Blue Ridge to initiate emergent interventional cardiac catheterizations, including the introduction of a STEMI program that is available on a regular weekday (Monday-Friday) schedule. Further, the proposed shared fixed cardiac catheterization unit and introduction of the STEMI program will also serve as a recruiting tool for UNC Health Blue Ridge, enabling it to attract additional cardiovascular clinical professional staff and physicians specializing in cardiovascular care. For these reasons, UNC Health Blue Ridge believes the proposed project will not result in any unnecessary duplication of the existing or approved health service facilities in Burke County.”

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

- There is a need determination in the 2023 SMFP for the proposed shared fixed cardiac catheterization equipment.
- The applicant adequately demonstrates the need for the proposed unit of shared fixed cardiac catheterization unit, see discussion in Criteria (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 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 shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

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

Positions	1st Full FY FTE	2nd Full FY FTE	3rd Full FY FTE
Registered Nurses – Manager	1	1	1
Registered Nurse – Navigator	1	1	1
Registered Nurse	5	5	5
Tech	1	1	1
TOTAL FTEs	8	8	8

Source: Section Q, Form H, page 120

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b. In Sections H.2.1, and H.3, pages 79-80, the applicant describes the methods to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the information provided in Section H, pages 79 - 80 and Section Q, Form H as described above.

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 shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

Ancillary and Support Services

In Section I.1, 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.

In Exhibit I.1, a letter from the CEO of UNC Health Blue Ridge states:

“As an existing full-service acute care hospital that already offers diagnostic and interventional cardiac catheterization services, UNC Health Blue Ridge has all necessary ancillary and support service infrastructure in place to support services provided by UNC Health Blue Ridge including laboratory, radiology, pharmacy, housekeeping, maintenance, and administrative support, among others.

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

Coordination

In Section I.2, 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 information provided in Section I.2, page 82, and Exhibit I.2, as described above.

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.

- (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

- (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

In Section K.2, page 85, the applicant states the project involves developing a new cardiac catheterization lab that will occupy vacated emergency department (ED) space at UNC Health Blue Ridge – Morganton. The existing ED will move to a previously approved new tower in late Spring 2024. The proposed additional lab will be adjacent to the existing cardiac cath lab and will share an existing control room. The project involves renovating 2,755 square feet of space. Line drawings are provided in Exhibit C.1-1.

On pages 85-86, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal. The applicant states,

“The proposed project will provide a shared fixed cardiac catheterization unit in the most effective manner possible. Namely, by installing the proposed equipment in existing vacant space that was previously occupied by the emergency department, the cost of the project is significantly lower than if the hospital were to develop new construction to house the proposed equipment. UNC Health Blue Ridge has reduced expenses by utilizing existing space and avoiding new construction and thus has proposed the most value-conscious alternative for the installation of the proposed equipment. Additionally, the proposed location is adjacent to the existing control room (currently utilized for the DLP-owned equipment), which will be used for the proposed project, and will not need to be renovated, further reducing the need for new construction or renovation. As such, the proposed project will minimize duplication of clinical space as well as staff and support areas, further enhancing the cost effectiveness and reasonableness of the proposed renovations.”

On page 86, 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,

“UNC Health Blue Ridge has reduced expenses by utilizing existing space and minimizing new construction, therefore representing the most value-conscious alternative for the installation of the proposed equipment. Moreover, the proposed project includes the use of existing space, such as the equipment control room, and includes the reconfiguration of staff and support areas to create maximum efficiency and better movement for patients and staff.

Further, UNC Health Blue Ridge, through its relationship with the larger UNC Health system, benefits from significant cost saving measures through the consolidation of multiple services and large economies of scale. The proposed project will enable UNC Health Blue Ridge to continue to provide its patient population with the best care possible, while also being responsive in a healthcare environment that emphasizes cost containment, and efficient utilization of existing resources.

Finally, as noted in Section F.2, the proposed project will be funded through the accumulated reserves that UNC Health Blue Ridge maintains through its prudent financial stewardship. As such, the healthcare system will not incur the cost of debt to develop the project, which will ultimately result in lower costs to the public for the proposed service.”

On page 86, 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 89, the applicant provides the historical payor mix during from 7/1/22 to 6/30/23 for UNC Health Blue Ridge - Morganton, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	7.8%
Charity Care	0.0%
Medicare*	51.2%
Medicaid*	14.1%
Insurance*	26.9%
Total	100.00%

Source: Table on page 89 of the application

*Including any managed care plans.

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

UNC Health Blue Ridge – Morganton	Percentage of Total Patients Served by the Facility during the Last Full FY	Percentage of the Population of the Service Area
Female	44.5%	49.8%
Male	55.5%	50.2%
Unknown	0.0%	0.0%
64 and Younger	70.0%	78.0%
65 and Older	30.0%	22.0%
American Indian	0.7%	1.0%
Asian	0.7%	3.8%
Black or African American	5.4%	6.5%
Native Hawaiian or Pacific Islander	0.3%	0.7%
White or Caucasian	91.2%	85.9%
Other Race	1.0%	2.1%
Declined / Unavailable	0.7%	0.0%

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

Regarding any obligation to provide uncompensated care, community service, or access by minorities and persons with disabilities, in Section L.2, pages 91-92, the applicant states that UNC Health Blue Ridge has no obligations under any federal regulations.

In Section L, page 92, the applicant states that during the 18 months immediately preceding the application deadline, no complaints have been filed against UNC Health Blue Ridge – Morganton or UNC Health Blue Ridge-Valdese.

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 UNC Health Blue Ridge- Morganton overall and for cardiac cath services during the third full fiscal year of operation following completion of the project, as shown in the tables below.

UNC Health Blue Ridge – Morganton 3rd Full FY 7/1/2027 to 6/30/2028

Payor Category	Percent of Total Patients Served
Self-Pay	7.8%
Medicare*	51.2%
Medicaid*	14.1%
Insurance*	26.9%
Total	100.00%

Source: Table on page 92 of the application.

*Including any managed care plans.

UNC Health Blue Ridge- Morganton: Cardiac Catheterization

Payor Category	Percent of Total Patients Served
Self-Pay	9.5%
Medicare*	32.0%
Medicaid*	14.8%
Insurance*	43.5%
Other	0.2%
Total	100.00%

Source: Table on page 92 of the application.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 9.5% of total cardiac cath services will be provided to self-pay patients, 0.0% to charity care patients, 32.0% to Medicare patients and 14.8% to Medicaid patients.

On page 92, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the historical payor mix data from FY2022 for cardiac cath services at UNC Health Blue Ridge – Morganton.

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, pages 93-94, 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 acquire no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

In Section M.1, page 95, 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 application. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes.

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 shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

On page 300, the 2023 SMFP defines the service area for cardiac catheterization equipment as “...the Acute Care Bed Service Areas defined in Chapter 5, Acute Care Beds, and shown in Figure 5.1.” Figure 5-1 on page 36 of the 2023 SMFP shows Burke County as a single county acute care bed service area. Thus, the service area for this proposal is Burke County. Facilities may also serve residents of counties not included in their service area.

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 enhanced access to healthcare services, including the emergent interventional cardiac catheterization procedures and STEMI treatment services described in this application.

Regarding the impact of the proposal on cost effectiveness, in Section N, page 98, the applicant states the following:

- The proposed project will provide permanent cardiac catheterization equipment, owned by the hospital, enabling it to initiate emergent cardiac catheterization services.
- The applicant’s proposed project can be developed in renovated space and use existing support space as well, lowering the capital cost of the proposed project.
- The applicant’s management agreement with UNC Health will allow it to benefit from the enhanced economies of scale that come from having access to the resources of a large health system.
- The applicant will continue to provide its patient population with the best care possible, while also being responsive to a healthcare environment that emphasizes cost containment and efficient utilization of existing resources.

- The applicant will support the proposed shared fixed cardiac catheterization equipment at the Morganton campus and help ensure that UNC Health Blue Ridge's cardiac catheterization resources are appropriately utilized and well positioned to accommodate future growth.

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

Regarding the impact of the proposal on quality, in Section N, page 98, the applicant states the following:

- The applicant is committed to providing the utmost in high-quality healthcare services to the communities it serves, particularly in Burke County and the surrounding area.
- The applicant is associated with UNC Health's enduring reputation for excellence and innovation in providing high quality healthcare services.
- The applicant is committed to providing high safe, effective, high-quality care is further demonstrated by its Performance Improvement Plan, Risk Management Plan, Utilization Management, Patient Safety Plan, and Infection Protection Plan, included as Exhibits N.2-1 through N.2-5, respectively.

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 100, the applicant states the following:

- The proposed project will enhance their ability to access the high-quality cardiovascular services at UNC Health Blue Ridge – Morganton by ensuring that the service can be provided permanently, through equipment owned by the hospital.
- The applicant has historically provided access to care for all patients regardless of race, color, religion, natural origin, sex, age, disability, or source of payment.
- The Burke Health Network will include services provided at UNC Health Blue Ridge – Morganton and is indicative of UNC Health Blue Ridge's commitment to providing access to medically underserved groups.

See also Section 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

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.

NA

The applicant proposes to acquire no more than one unit of shared fixed cardiac catheterization equipment pursuant to the 2023 SMFP need determination.

In Section O, page 102, the applicant states UNC Health Blue Ridge does not own, operate, or manage any facilities that provide fixed catheterization services. Therefore, Criteria (20) is not applicable to this application.

- (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 application is conforming with all applicable Criteria and Standards for Cardiac Catheterization Equipment and Cardiac Angioplasty Equipment promulgated in 10 NCAC 14C.1600. 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;
- (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;
- (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;
- (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 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.

-NA- The applicant does not propose to acquire fixed cardiac catheterization equipment pursuant to a need determination in the 2023 State Medical Facilities Plan.

(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;

-C- In Section Q, Form C.2b, the applicant provides 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 proposed project.

- (2) provide the assumptions and methodology used to project the utilization required by Subparagraph (1) of this Paragraph; and

-C- In Section Q, pages 114-120, the applicant provides the assumptions and methodology used to project utilization of the proposed shared fixed cardiac catheterization

equipment during each of the first three full fiscal years of operation following completion of the proposed project.

- (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.

-C- Upon completion of the proposed project, UNC Health Blue Ridge will have one unit of shared fixed cardiac catheterization equipment. In Section Q, the applicant projects that the one unit of shared fixed cardiac catheterization equipment will perform 754 diagnostic-equivalent cardiac catheterization and angiography procedures during the third full fiscal year of operation following completion of this proposed project which exceeds the 225 procedures required by this Rule.

(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.