

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 28, 2023

Findings Date: February 28, 2023

Project Analyst: Ena Lightbourne

Co-Signer: Micheala Mitchell

Project ID #: E-12305-22

Facility: UNC Health Blue Ridge-Morganton

FID #: 943191

County: Burke

Applicant(s): Blue Ridge HealthCare Systems, Inc.

Project: Add no more than one GI endoscopy room at the Morganton campus for no more than two GI endoscopy rooms

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.

NA

Blue Ridge HealthCare Systems, Inc. (“applicant”) proposes to develop one GI endoscopy room for a total of two GI endoscopy rooms at UNC Health Blue Ridge-Morganton (“Morganton”). The applicant is the only provider of GI endoscopy services in Burke County.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There are no policies in the 2022 SMFP which are applicable to this project.

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 Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.*” The GI endoscopy room will be developed in Burke County. In Section C, page 29, the applicant projects that 48% of its GI endoscopy patients will originate from Burke County in the first project year. Thus, the service area for this facility consists of Burke County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	UNC Health Blue Ridge-Morganton GI Endoscopy Historical Patient Origin	
	Last Full FY 01/01/2021-12/31/2021	
	Patients	% of Total
Burke	1,266	48.0%
Caldwell	567	21.5%
McDowell	364	13.8%
Catawba	233	8.8%
Rutherford	34	1.3%
Other^	173	6.3%
Total	2,638	100.0%

Source: Section C, page 28

^Other includes Alexander, Avery, Buncombe, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Mitchell, Wilkes and Yancey counties and other states.

UNC Health Blue Ridge-Morganton GI Endoscopy Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	7/1/2023-6/30/2024		7/1/2024-6/30/2025		7/1/2025-6/30/2026	
	FY2024		FY2025		FY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Burke	1,376	48.0%	1,423	48.0%	1,471	48.0%
Caldwell	617	21.5%	638	21.5%	659	21.5%
McDowell	395	13.8%	409	13.8%	423	13.8%
Catawba	254	8.8%	262	8.8%	271	8.8%
Rutherford	37	1.3%	38	1.3%	40	1.3%
Other*	188	6.6%	195	6.6%	201	6.6%
Total	2,867	100.0%	2,965	100.0%	3,065	100.0%

Source: Section C, pages 29-30

*Other includes Alexander, Avery, Buncombe, Cleveland, Gaston, Iredell, Lincoln, Mecklenburg, Mitchell, Wilkes and Yancey counties and other states.

In Section C, page 29, the applicant provides the assumptions and methodology used to project its patient origin for GI endoscopy services.

“Projected patient origin for GI endoscopy services at UNC Health Blue Ridge-Morganton is based on historical patient origin of GI endoscopy cases at UNC Health Blue Ridge-Morganton. UNC Health Blue Ridge does not expect the proposed project to impact patient origin.”

The applicant's assumptions are reasonable and adequately supported based on the applicant's assumption that the CY2021 ratio of procedures to patients will remain constant and applies it to its projected procedures to project patients (cases).

Analysis of Need

In Section C, pages 32-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

Use of GI Endoscopy Services for Diagnosis, Treatment, and Prevention of GI Conditions (pages 32-34)

- The applicant cites data from Becker's Healthcare, a media firm that provides business information and healthcare analysis, to demonstrate the high number of endoscopy procedures performed in the United States.
- Patients with GI conditions are at a higher risk to develop colorectal cancer, demonstrating the need to use GI endoscopy procedures for regular screening.
- The high incidence of new colorectal cancer cases and deaths in Burke County when compared to other counties within the state.
- The historical GI endoscopy room use rate per 1,000 population in Burke County implies limited access to GI endoscopy services.

The Need for Additional Hospital-Based GI Endoscopy Capacity (pages 34-37)

The high utilization of the existing GI endoscopy rooms owned by UNC Health Blue Ridge in Burke County and the growth in the number of procedures performed from CY2019 to CY2021 demonstrates the need to expand GI endoscopy capacity.

The Aging Service Area Population

- The applicant cites data from the North Carolina Office of State Budget Management to illustrate the projected population growth in Burke County, particularly among the older age group, the group more likely to utilize healthcare services at a higher rate.
- The proposed project supports the need to have enough hospital-based GI endoscopy capacity at Morganton as the population in Burke County continues to age.

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

- The applicant adequately demonstrates the need for GI endoscopy services as a treatment GI conditions and early detection of colorectal cancer.
- The historical growth in GI endoscopy procedures performed in the applicant's existing GI endoscopy rooms in the service area.
- Projected population growth in Burke County, particularly among the 45+ age cohort.

Projected Utilization

In Section Q, Form C.3, pages 1-2, the applicant provides historical and projected utilization, as illustrated in the following tables.

UNC Health Blue Ridge-Morganton GI Endoscopy Historical and Interim Utilization		
	Last Full FY	Interim Full FY
	FY2022	FY2023
# of Rooms	1	1
# Inpatient GI Endoscopy Procedures	598	618
# Outpatient GI Endoscopy Procedures	3,053	3,157
Total GI Endoscopy Procedures	3,651	3,774
Average # of Procedures per Room	2.4	2.5

UNC Health Blue Ridge-Morganton GI Endoscopy Projected Utilization			
	1st Full FY	2nd Full FY	3rd Full FY
	FY2024	FY2025	FY2026
# of Rooms	2	2	2
# Inpatient GI Endoscopy Procedures	639	660	683
# Outpatient GI Endoscopy Procedures	3,264	3,374	3,488
Total GI Endoscopy Procedures	3,902	4,034	4,171
Average # of Procedures per Room	1.3	1.3	1.4

In Section Q, Form C Utilization-*Assumptions and Methodology*, pages 1-4, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant examines the historical utilization of the existing GI endoscopy rooms owned and operated by UNC Health Blue Ridge in Burke County. There is one operational GI endoscopy room at Morganton and two at Carolina Digestive Care. During CY2019 - CY2021, Morganton experienced a 14% annual growth in hospital-based GI endoscopy services despite the impact of the pandemic in 2020. From CY2020 to CY2021, the total number of procedures performed at Morganton and Carolina Digestive Care increased by 2,222, well above the 1,500 procedures per room performance standard. The following table illustrates historical utilization.

Table 1: Burke County Historical GI Endoscopy Utilization				
Facility	CY2019	CY2020	CY2021	CY19 – CY21 CAGR*
UNC Health Blue Ridge[^]	2,762	2,695	3,590	14.0%
Carolina Digestive Care	6,514	4,998	6,325	-1.5%
Total Procedures	9,276	7,693	9,915	3.4%
GI Endoscopy Rooms	5	5	5	
Procedures Per Room**	1,855	1,539	1,983	

Source: Section Q, Form C Utilization-*Assumptions and Methodology*, page 1; UNC Health Blue Ridge Internal data

[^]UNC Health Blue Ridge includes one hospital-based GI endoscopy room at UNC Health Blue Ridge-Morganton and two non-operational GI endoscopy rooms at UNC Health Blue Ridge-Valdese, which will be separately licensed to Blue Ridge Surgery Center upon completion of the of the previously approved Project ID# E-11287-17. As such, from CY2019 to CY2021, UNC Health Blue Ridge’s historical utilization is comprised solely of GI Endoscopy procedures performed at UNC Health Blue Ridge-Morganton.

*Compound Annual Grow Rate

**Procedures Per Room = Total Procedures / Number of Rooms

As illustrated in the table above, utilization of all the operating GI endoscopy rooms in Burke County grew 3.4% annually. The applicant applies this growth rate to project utilization. The applicant states that using a 3.4% annual growth rate is reasonable and conservative considering the high historical utilization of all the existing GI endoscopy rooms in Burke County. The applicant states that the historical utilization already supports the proposed GI endoscopy room. Therefore, even if the proposed GI endoscopy room existed, the number of procedures would still meet the 1,500 procedures per room performance standard. (9,915 total procedures (CY2021) / 6 GI endoscopy rooms = 1,652 procedures per GI endoscopy room).

The following table illustrates the applicant’s projected utilization for the existing and proposed GI endoscopy rooms in Burke County.

Table 2: Projected Calendar Year GI Endoscopy Utilization for UNC Health Blue Ridge							
	CY 2021	CY 2022	CY 2023*	CY 2024	CY 2025	CY 2026	Assumption CY21 – CY26
Number of Procedures	9,915	10,251	10,598	10,957	11,328	11,712	3.4%
GI Endoscopy Rooms	5	5	6	6	6	6	
Procedures Per Room**	1,983	2,050	1,766	1,826	1,888	1,952	

Source: Section Q, Form C Utilization-*Assumptions and Methodology*, page 3

*The proposed additional GI endoscopy room will become operational mid-way through CY2023 on July 1, 2023, the first day of FY2024.

**Procedures per room = Number of Procedures / Number of Rooms

The proposed project is scheduled to become operational July 1, 2023. The applicant states that to further integrate with UNC Health, UNC Health Blue Ridge changed its fiscal year from Calendar Year (CY) to correspond with the State Fiscal Year (SFY). The applicant divided the sum of the CYs that comprise each respective SFY by two (e.g. (CY2023 procedures +

CY2024 procedures) / 2 = SFY2024 procedures). The applicant projects that each GI endoscopy room will exceed the 1,500 procedures per room performance standard, as illustrated below.

Table 3: Projected Fiscal Year GI Endoscopy Utilization for UNC Health Blue Ridge			
	SFY24 1st Full FY	SFY25 2nd Full FY	SFY26 3rd Full FY
Number of Procedures	10,777	11,143	11,520
GI Endoscopy Rooms	6	6	6
Procedures Per Room*	1,796	1,857	1,920

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 3

*Procedures per room = Number of Procedures / Number of Rooms

The applicant projects calendar year GI endoscopy utilization for Morganton.

Table 4: Projected Calendar Year GI Endoscopy Utilization for UNC Health Blue Ridge-Morganton								
	CY 2020	CY 2021	CY 2022	CY 2023*	CY 2024	CY 2025	CY 2026	Assumption CY21 – CY26
Number of Procedures	2,695	3,590	3,712	3,837	3,967	4,102	4,241	3.4%
GI Endoscopy Rooms	1	1	1	2	2	2	2	
Procedures Per Room**	2,695	3,590	3,712	1,919	1,984	2,051	2,121	

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 4

*The proposed additional GI endoscopy room will become operational mid-way through CY2023 on July 1, 2023, the first day of FY2024.

**Procedures per room = Number of Procedures / Number of Rooms

The applicant adjusted its projections for the SFY using the same calculation illustrated in Table 3. To project the number of inpatient and outpatient procedures performed at Morganton from SFY2021 through SFY2026, the applicant applies the percentage of inpatient (16%) and outpatient (84%) procedures performed at Morganton, as stated in the 2022 License Renewal Application.

Table 5: Projected GI Endoscopy Utilization at UNC Health Blue Ridge-Morganton						
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	FY 2026
Total Procedures	3,143	3,651	3,774	3,902	4,034	4,171
GI Endoscopy Rooms*	1	1	1	2	2	2
Procedures Per Room	3,143	3,651	3,774	1,951	2,017	2,086
Inpatient Procedures^	514	598	618	639	660	683
Outpatient Procedures^^	2,628	3,053	3,157	3,264	3,374	3,488

Source: Section Q, Form C Utilization-Assumptions and Methodology, page 4

*The proposed additional GI endoscopy room will become operational mid-way through CY2023 on July 1, 2023, the first day of FY2024.

^Assumes inpatient procedures account for 16 percent of total procedures each year (IP = TP x 0.16)

^^Assumes outpatient procedures account for 84 percent of total procedures each year (OP = TP x 0.84)

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

- Projected utilization is based on the most recent GI endoscopy procedure data of UNC Health Blue Ridge’s GI endoscopy rooms in Burke County.
- The applicant’s projected growth rate in GI endoscopy procedures is supported by the historical annual growth rate of the total procedures performed in all of UNC Health Blue Ridge’s GI endoscopy rooms in Burke County.
- The applicant adequately demonstrates that the projected utilization exceeds the required 1,500 procedures per GI endoscopy room performance standard.

In Section C, page 44, 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 UNC Health Blue Ridge programs are designed to ensure assistance is provided to patients demonstrating a financial need and to ensure UNC Health Blue Ridge complies with any required Federal or State regulations related to financial assistance.”

The applicant provides the estimated percentage for each medically underserved group proposed to be served during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	
Racial and ethnic minorities	8.1%
Women	60.0%
Persons with Disabilities	
Persons 65 and older	34.8%
Medicare beneficiaries	45.0%
Medicaid recipients	15.3%

Source: Section C, page 45

On page 45, the applicant states that UNC Health Blue Ridge does not maintain data on low income and disabled persons.

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.

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 develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

In Section E, pages 54-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Maintain the Status Quo-The applicant states that UNC Health Blue Ridge and its related entities have operated well above the GI endoscopy room performance standard from CY2019 through CY2021, including during the peak of the pandemic. The applicant projects that the demand for hospital-based GI endoscopy services will continue to grow due to the partnership with UNC Health and the development of the CON-exempt patient tower on the Morganton campus. Maintaining the status quo would not meet the need to expand capacity for future demand of hospital-based GI endoscopy services.

Develop a Different Number of GI Endoscopy Rooms-The applicant states that developing more than one GI endoscopy room would result in unnecessary duplication due to the two approved GI endoscopy rooms that will be developed at the Blue Ridge Surgery Center in Burke County. Additionally, developing more than one GI Endoscopy room may require construction or renovations that can disrupt patient care.

Develop the Proposed GI Endoscopy at a Different Location-The applicant states that the proposed GI endoscopy room is needed at Morganton to support the existing hospital-based GI endoscopy services.

Relocate an Existing GI Endoscopy Room from a Related Entity-The applicant has two GI endoscopy rooms located at Carolina Digestive Care and two approved GI endoscopy rooms that will be located at Blue Ridge Surgery Center. The applicant states that removing one from Carolina Digestive Care would result in capacity constraints and the two approved rooms are designated to meet the future need of freestanding GI endoscopy services in the service area.

On page 54, the applicant states that its proposal is the most effective alternative because it will meet the demand for hospital-based GI endoscopy services that is projected to grow based on the recent partnership with UNC Health and the development of the CON-exempt patient tower 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:

- The applicant adequately demonstrates that there is a future demand for hospital-based GI endoscopy services on the Morganton campus.
- 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. 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 develop one GI endoscopy room for a total of two GI endoscopy rooms at UNC Health Blue Ridge-Morganton.**
- 3. Upon completion of the project, UNC Health Blue Ridge-Morganton, shall be licensed for no more than two GI endoscopy rooms.**
- 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 August 1, 2023.**
- 5. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.**
- 6. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need,**

the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:

- a. Payor mix for the services authorized in this certificate of need.**
- b. Utilization of the services authorized in this certificate of need.**
- c. Revenues and operating costs for the services authorized in this certificate of need.**
- d. Average gross revenue per unit of service.**
- e. Average net revenue per unit of service.**
- f. Average operating cost per unit of service.**

8. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

Capital and Working Capital Costs

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

UNC Health Blue Ridge-Morganton Capital Costs	
Other (Contingency)	\$50,000
Total	\$50,000

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 convert an existing procedure room to a GI endoscopy room which does not require construction or renovations to the space.
- The applicant projects that the only cost required will be contingency, which is based on the applicant's experience with similar projects.

On page 58, the applicant states that there will be no start-up or initial operating costs.

Availability of Funds

In Section F, page 56, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	UNC Health Blue Ridge	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$50,000	\$50,000
Bonds	\$0	\$0
Other	\$0	\$0
Total Financing	\$50,000	\$50,000

* OE = Owner's Equity

Exhibit F.2.1 contains a letter dated November 14, 2022, from the Chief Executive Officer of UNC Health Blue Ridge stating that UNC Health Blue Ridge will fund the project using funds from accumulated reserves. Exhibit F.2.1 contains the most recent audited financial statements for Blue Ridge HealthCare system, Inc., verifying sufficient funds available for the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

UNC Health Blue Ridge-Morganton	1 st Full FY FY2024	2 nd Full FY FY2025	3 rd Full FY FY2026
Total Procedures	3,902	4,034	4,171
Total Gross Revenues (Charges)	\$20,262,212	\$21,576,951	\$22,976,998
Total Net Revenue	\$4,293,068	\$4,571,629	\$4,868,265
Average Net Revenue per Treatment	\$1,100	\$1,133	\$1,167
Total Operating Expenses (Costs)	\$3,873,536	\$4,086,817	\$4,312,799
Average Operating Expense per Treatment	\$993	\$1,013	\$1,034
Net Income	\$419,532	\$484,412	\$555,466

- The applicant projects gross revenue based on the projected payor mix, which is based on historical payor mix and the average charge per procedure with 3% inflation.
- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which is incorporated herein by reference.

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

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “...the county where the proposed GI endoscopy room will be developed.” The GI endoscopy room will be developed in Burke County. In Section C, page 29, the applicant projects that 48% of its GI endoscopy patients will originate from Burke County in the first project year. Thus, the service area for this facility consists of Burke County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP shows there are five existing GI endoscopy rooms and two con-approved but not developed in Burke County, as shown below. UNC Health Blue Ridge is the only provider of GI endoscopy services in Burke County.

Burke County GI Endoscopy Services – FY2021 Data				
Existing Facilities	Endoscopy Rooms	Approved Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Blue Ridge Surgery Center		2	0	0
Carolina Digestive Care	2		3,411	4,353
UNC Health Blue Ridge	3		2,221	2,844
Total	5	2	5,632	7,197

Source: Table 6F: Endoscopy Room Inventory (pages 88-89 of the 2022 SMFP)

In Section G, pages 66-67, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Burke County. On page 66, the applicant states:

Currently, UNC Health Blue Ridge has only one operational hospital-based GI endoscopy room. The proposed project represents the opportunity to develop additional capacity to meet the demand for GI endoscopy services in Burke County and will enable UNC Health Blue Ridge to ensure sufficient capacity to care for higher acuity inpatients and outpatients that require GI endoscopy services but are not appropriate for an ASF.”

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 proposed project will ensure sufficient capacity as the demand for hospital-based GI endoscopy services grow.
- The existing GI endoscopy rooms owned and operated by UNC Health Blue Ridge has consistently performed above the performance standard for GI endoscopy services, demonstrating the need to expand capacity.
- The applicant adequately demonstrates that the proposed GI endoscopy room is needed in addition to the existing and approved GI endoscopy rooms.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

In Section Q, Form H, page 10, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	As of 07/01/2022	2nd Full Fiscal Year (CY2025)
Registered Nurses	1.0	2.0
Endoscopy Technicians	1.0	2.0
Certified Registered Nurse Anesthetists	1.0	2.0
Surgical Technicians	1.0	2.0
TOTAL	4.0	8.0

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 68-69, 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's methods to recruit staff include strategies that are tailored to the position requirements.
- The applicant recruits staff through job postings on the HealthCare Source website and through other traditional means such as internet postings, job fairs and recruitment from relevant training programs.
- All future staff are required to meet appropriate licensing standards and competency levels and ongoing training needs are assessed on a regular basis.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

Ancillary and Support Services

In Section I, page 70, the applicant identifies the necessary ancillary and support services for the proposed services. On page 70, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- Morganton is an existing acute care hospital with the necessary ancillary and support services already in place.
- In Exhibit I.1, the applicant provides a letter from the CEO of UNC Health Blue Ridge, stating the availability of the necessary ancillary and support services.

Coordination

In Section I, page 71, 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:

- UNC Health Blue Ridge has a transportation agreement with Caldwell Memorial Hospital and Appalachian Regional Healthcare System to transfer patients to Morganton for endoscopic retrograde cholangiopancreatography (ERCP) procedures. ERCP is a procedure that includes GI endoscopy and x-rays to treat problems related to the liver, gall bladder and pancreas.
- In Exhibit I.2, the applicant provides letters from providers expressing their support for the development of an additional GI endoscopy room.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

NA

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and ... persons [with disabilities], which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 78, the applicant provides the historical payor mix during CY2021 for the entire facility, as shown in the table below.

UNC Health Blue Ridge-Morganton Historical Payor Mix 01/01/2021-12/31/2021	
Payor Category	As Percent of Total
Self-Pay	8.2%
Charity Care^	
Medicare*	45.0%
Medicaid*	15.3%
Insurance*^^	29.2%
Workers Compensation^^	
TRICARE^^	
Other ^^	2.3%
Total	100.0%

*Including any managed care plans.

^UNC Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^^Workers Compensation, TRICARE, Department of Corrections, and other payors are included in the Other payor category.

In Section L, page 79, the applicant provides the following comparison.

UNC Health Blue Ridge-Morganton	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	60.0%	50.0%
Male	40.0%	50.0%
Unknown	0.0%	0.0%
64 and Younger	65.2%	79.3%
65 and Older	34.8%	20.7%
American Indian	0.1%	0.9%
Asian	0.9%	3.6%
Black or African-American	7.0%	6.9%
Native Hawaiian or Pacific Islander	0.1%	0.7%
White or Caucasian	90.7%	86.1%
Other Race	0.0%	1.8%
Declined / Unavailable	1.2%	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>. Just enter in the name of the county.

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 80, the applicant states:

“While UNC Health Blue Ridge is not obligated under any federal regulations such as the Hill-Burton Act, as a tax exempt hospital, UNC Health Blue Ridge has a responsibility for community benefit.”

In Section L, page 80, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 81, 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.

UNC Health Blue Ridge-Morganton Projected Payor Mix FY2026	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	2.1%
Charity Care [^]	
Medicare*	57.2%
Medicaid*	8.7%
Insurance* ^{^^}	32.0%
Workers Compensation ^{^^}	
TRICARE ^{^^}	
Other ^{^^}	
Total	100.0%

*Including any managed care plans.

[^]UNC Health internal data does not include Charity Care as a payor source for patients. Patients in any payor category can and do receive charity care.

^{^^}Workers Compensation, TRICARE, Department of Corrections, and other payors are included in the Other payor category.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.1% of total services will be provided to self-pay patients, 57.2% to Medicare patients and 8.7% to Medicaid patients.

On page 80, 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. The applicant based the projected payor mix on the historical payor mix of GI endoscopy services. The applicant does not project that the proposed project will have an impact on payor mix.

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.

In Section L, page 82, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

In Section M, pages 84-85, 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:

- Morganton is an established facility in the service area and serves as a clinical training site for health training programs.
- UNC Health Blue Ridge has agreements for physician assistant and nurse practitioner programs at several colleges and universities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

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

C

The applicant proposes to develop one GI endoscopy room for or a total of two GI endoscopy rooms at Morganton.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.*” The GI endoscopy room will be developed in Burke County. In Section C, page 29, the applicant projects that 48% of its GI endoscopy patients will originate from Burke County in the first project year. Thus, the service area for this facility consists of Burke County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP shows there are five existing GI endoscopy rooms and two con-approved but not developed in Burke County, as shown below. UNC Health Blue Ridge is the only provider of GI endoscopy services in Burke County.

Burke County GI Endoscopy Services – FY2021 Data				
Existing Facilities	Endoscopy Rooms	Approved Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Blue Ridge Surgery Center		2	0	0
Carolina Digestive Care	2		3,411	4,353
UNC Health Blue Ridge	3		2,221	2,844
Total	5	2	5,632	7,197

Source: Table 6F: Endoscopy Room Inventory (pages 88-89 of the 2022 SMFP)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 87, the applicant states:

“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to healthcare services, including the hospital-based GI endoscopy services proposed in this application.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 87, the applicant states:

“As previously discussed, the proposed project requires only minimal capital expenditures to be developed at UNC Health Blue Ridge-Morganton. As an acute care hospital with existing GI endoscopy services, UNC Health Blue Ridge-Morganton already has all necessary clinical, ancillary, and support services necessary to operate the proposed additional GI endoscopy room.”

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

Regarding the impact of the proposal on quality, in Section N, pages 88-89, the applicant states:

“...as part of the UNC Health System, UNC Health Blue Ridge is now associated with UNC Health’s enduring reputation for excellence and innovation in providing high quality healthcare services. By way of example, UNC Health has earned various rankings and awards that demonstrate its ability to provide ongoing quality care across the health system.

...

UNC Health Blue Ridge’s commitment 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...”

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 89, the applicant states:

“In fact, the proposed project will enhance their ability to access the high quality inpatient and outpatient GI endoscopy services at UNC Health Blue Ridge-Morganton.

...

...UNC Health Blue Ridge is such an applicant; it has historically demonstrated a commitment to ensuring equitable access and will continue to provide such access upon completion of the proposed project...in FY 2019, UNC Health Blue Ridge provided more than \$82 million in charity care and bad debt.”

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

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.

- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section Q, Form O, page 12, the applicant identifies one acute care hospital and two ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of these types of facilities located in North Carolina. However, one of the ambulatory surgical facilities is not operational.

In Section O, page 92, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy has not occurred in any of these facilities. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, UNC Health Blue Ridge was surveyed in 2022 and is currently under Emergency Medical Treatment and Labor Act (EMTALA) review. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at all of the facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and

may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The application is conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities. The specific criteria are discussed below.

SECTION .3900 – CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

.3903 PERFORMANCE STANDARDS

An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:

(1) *identify the proposed service area;*

-C- The GI endoscopy room will be developed in Burke County. In Section C.3, page 29, the applicant projects that 48.0% of its patients will originate from Burke County. Thus, the service area for this facility consists of Burke County.

(2) *identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;*

-C- According to the 2022 SMFP, there are five existing endoscopy rooms and two approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area.

(3) *provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;*

-C- In Section Q, Form C Utilization-*Assumptions and Methodology*, page 3, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project for all operating GI endoscopy rooms owned by the applicant or related entity.

Table 3: Projected Fiscal Year GI Endoscopy Utilization for UNC Health Blue Ridge			
	SFY24 1st Full FY	SFY25 2nd Full FY	SFY26 3rd Full FY
Number of Procedures	10,777	11,143	11,520
GI Endoscopy Rooms	6	6	6
Procedures Per Room*	1,796	1,857	1,920

- (4) *project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and*
- C- In Section Q, Form C Utilization-*Assumptions and Methodology*, page 3, the applicant projects to perform an average of 1,920 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project.
- (5) *provide the assumptions and methodology used to project the utilization required by this Rule.*
- C- In Section Q, Form C Utilization-*Assumptions and Methodology*, pages 1-4, the applicant provides the assumptions and methodology used to project GI endoscopy procedures in its existing GI endoscopy rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.