

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: October 27, 2023
Findings Date: November 1, 2023

Project Analyst: Ena Lightbourne
Co-Signer: Micheala Mitchell

Project ID #: B-12388-23
Facility: Digestive Health Partners
FID #: 943487
County: Buncombe
Applicant(s): Endoscopy Center of North Carolina, LLC
Entero-Med, LLC

Project: Relocate the facility and develop three new GI endoscopy rooms for a total of no more than eight GI endoscopy rooms upon project completion

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

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Endoscopy Center of North Carolina, LLC and Entero-Med, LLC (“applicant”) propose to develop a GI endoscopy ambulatory surgical facility (ASF) by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building on Sweeten Creek Road in Asheville, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

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 2023 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

One Policy in Chapter 4 of the 2023 SMFP, Policy *GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* is applicable to this review.

Policy *GEN-4*

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 are required to submit a plan of 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, page 34, the applicant describes the project’s plan for energy efficiency and to conserve water. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to ensure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy *GEN-4*.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4; 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.

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The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

Patient Origin

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 2023 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 facility will be developed in Buncombe County. In Section C, page 41, the applicant projects that 70.55% of its patients will originate from Buncombe County. Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	The Endoscopy Center (Existing) Historical Patient Origin	
	Last Full FY 10/01/2021-09/30/2022 (FY2022)	
	Patients	% of Total
Avery	31	0.20%
Buncombe	11,097	70.55%
Burke	89	0.57%
Haywood	812	5.20%
Henderson	1,224	7.80%
Jackson	146	1.00%
Macon	115	0.73%
Madison	782	5.10%
McDowell	431	3.00%
Mitchell	173	1.10%
Rutherford	128	1.00%
Swain	50	0.32%
Transylvania	198	1.30%
Yancey	454	3.10%
Total	15,730	100.0%

Source: Section C, page 39

Digestive Health Partners (Proposed) Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	10/01/24-09/30/25		10/01/25-09/30/26		10/01/26-09/30/27	
	FY2025		FY2026		FY2027	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Avery	44	0.20%	46.91	0.20%	49.85	0.20%
Buncombe	15,568	70.55%	16,546.79	70.55%	17,587.40	70.55%
Burke	126	0.57%	133.69	0.57%	142.09	0.57%
Haywood	1,147	5.20%	1,219.61	5.20%	1,296.31	5.20%
Henderson	1,721	7.80%	1,829.41	7.80%	1,944.46	7.80%
Jackson	221	1.00%	234.54	1.00%	249.29	1.00%
Macon	161	0.73%	171.21	0.73%	181.98	0.73%
Madison	1,125	5.10%	1,196.15	5.10%	1,272.40	5.10%
McDowell	661	3.00%	703.62	3.00%	747.87	3.00%
Mitchell	243	1.10%	257.99	1.10%	274.29	1.10%
Rutherford	221	1.00%	234.54	1.00%	249.29	1.00%
Swain	71	0.32%	75.05	0.32%	79.77	0.32%
Transylvania	287	1.30%	304.90	1.30%	324.07	1.30%
Yancey	684	3.10%	727.07	3.10%	772.80	3.10%
Total	22,066 [22,280]	100.00%	23,454 [23,681]	100.00%	24,929 [25,172]	100.00%

Source: Section C, page 41

Project Analyst's calculations in brackets.

In Section C, pages 41-42, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states:

“The proposed Center will be just over four (4) miles from the existing Center and the relocation of GI Endoscopy rooms to the new location is not expected to impact the relative number of patients served from Buncombe County and surrounding areas.”

The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant’s projected patient origin is based on the historical patient origin of the existing facility which is not expected to significantly change because the proposed facility will serve the same patient population.
- The applicant projects a slight increase in the number of patients based on the increase in the number of GI endoscopy rooms.

Analysis of Need

In Section C, pages 44-55, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

Facility Issues-The existing endoscopy center operates five endoscopy rooms that have historically experienced high utilization. Expanding the existing center to accommodate three more GI endoscopy rooms would not be suitable because it will cause operational issues and interrupt patient services. (pages 45-46)

High Historical Utilization and Reasonable Assumptions for Growth-In the most recent three years, the five existing GI endoscopy rooms have demonstrated a steady growth in the number of procedures performed. The applicant reasonably projects growth with the addition of the three proposed GI endoscopy rooms. The applicant is also proposing to add two physician practices in October 2024 and two more by 2025.(Pages 46-48)

Growth and Aging of the Population-The applicant demonstrates that the projected growth and aging of the state and county population is an indicator of the projected growth in demand for GI endoscopy services. (pages 48-51)

New American Cancer Society Guideline-The American Cancer Society recommends colonoscopy screening beginning at the age of 45 for those at average risk for colorectal cancer. This is five years earlier than its previous recommendations. This demonstrates the need to expand access to preventive care such as endoscopic procedures for cancer screening. (pages 51-52)

Patient Preference-The applicant assumes that physicians and patients prefer endoscopy services to be performed in a freestanding setting because of the cost savings and the convenient location. In Exhibit I.2, the applicant provides letters of support from a referring physician and other health care providers in the area. (page 52)

Cost Savings and ASC preference-The applicant cites reports and articles related to the gastrointestinal endoscopy industry to demonstrate the cost saving benefits of performing procedures in an ambulatory surgical facility. The existing Endoscopy Center performed more procedures than the acute care hospital located in the service area. The applicant states that this demonstrates the preference for a non-hospital setting. Patients can easily park and access the facility as opposed to navigating a hospital setting. (pages 52-55)

Physician Growth-As stated above, the applicant proposes to expand the number of physicians over the next three project years. The applicant expects that the growth in the number of physicians practicing at the facility will “bolster the group’s physician talent and expand the number of physicians available to provide services to patients within the Center over the coming years.” (page 55)

Future Utilization-The historical utilization of the existing GI endoscopy rooms and the applicant’s projected utilization demonstrates the need for the proposal. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. (page 55)

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

- The facility is currently operating at full capacity and the high utilization of the existing GI endoscopy rooms supports the need to expand access to GI endoscopy services.
- Patients in the service area have historically demonstrated their preference to have their GI endoscopy procedure performed in an ambulatory surgical facility because of the cost-saving benefits and convenience of a freestanding setting.

Projected Utilization

In Section Q, Form C.3a and C.3b, the applicant provides historical and projected utilization, as illustrated in the following tables.

The Endoscopy Center (Existing) Historical and Interim Utilization			
	Last Full Fiscal Year	Interim Full Fiscal Year	Interim Full Fiscal Year
	FY2022	FY2023	FY2024
# of Rooms	5	5	5
# Inpatient GI Endoscopy Procedures	0	0	0
# Outpatient GI Endoscopy Procedures	18,375	18,375	18,375
Total GI Endoscopy Procedures	18,375	18,375	18,375
Average # of Procedures per Room	3,675	3,675	3,675

Digestive Health Partners (Proposed) Projected Utilization			
	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	FY2025	FY2026	FY2027
# of Rooms	8	8	8
# Inpatient GI Endoscopy Procedures	0	0	0
# Outpatient GI Endoscopy Procedures	22,066	23,454	24,929
Total GI Endoscopy Procedures	22,066	23,454	24,929
Average # of Procedures per Room	2,758	2,932	3,116

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

Step 1: Examine Historical Utilization

The Endoscopy Center (Existing) Projected Utilization				
SMFP*	2021 10/1/18-9/30/19	2022** 10/1/19-9/30/20	2023 10/1/20-9/30/21	2024 10/1/21-9/30/22
Procedures	15,300	14,779	17,757	18,375
Procedures per Room	3,060	2,956	3,551	3,675

*By way of example, data in the 2021 SMFP is for 10/01/2018-09/30/2019 as reported on the 2019 License Renewal Application. Volumes reported for 10/01/2021-9/30/2022 on the 2023 License Renewal Application (filed with DHSR in late 2022) will appear in the 2024 SMFP.

**COVID-19-impacted data.

Step 2: Determine Facility Growth

The Endoscopy Center (Existing) Projected Utilization					
SMFP*	2021 10/1/18- 9/30/19	2022** 10/1/19- 9/30/20	2023 10/1/20- 9/30/21	2024 10/1/21- 9/30/22	CAGR***
Procedures	15,300	14,779	17,757	18,375	6.29%
Procedures per Room	3,060	2,956	3,551	3,675	6.29%

*By way of example, data in the 2021 SMFP is for 10/01/2018-09/30/2019 as reported on the 2019 License Renewal Application. Volumes reported for 10/01/2021-9/30/2022 on the 2023 License Renewal Application (filed with DHSR in late 2022) will appear in the 2024 SMFP.

**COVID-19-impacted data.

***Compound Annual Growth Rate

Step 3: Consider Area Population Growth & Aging/New American Cancer Society Guidelines/New Physicians

- Population Growth and Aging

Citing data from the North Carolina Office of State Budget and Management (NCOSBM), the applicant examines the historical population growth and aging in the proposed service area. The applicant projects that as the population grows and ages, the demand of GI endoscopy services will increase. The following tables illustrate the historical Buncombe County population growth from April 2010 to July 2020 and the projected population growth through 2030. According to NCOSBM, Buncombe County had the 9th largest population increase between 2010 and 2020.

County Population Growth	April 1, 2010 Population Estimate	July 1, 2020 Population Estimate	Numeric Change	Percent Change
Buncombe	238,315	269,797	31,482	13.2%

Source: NCOSBM, Standard Population Estimates, Vintage 2021 and Population Projections, Vintage 2022.

County Population Growth	July 1, 2020 Population Estimate	July 1, 2030 Population Estimate	Numeric Change	Percent Change
Buncombe	269,797	297,608	27,811	10.3%

Source: NCOSBM, Standard Population Estimates, Vintage 2021 and Population Projections, Vintage 2022.

Regarding the aging population, the Buncombe County Strategic Plan¹ states that the 65+ age group of Buncombe County residents are projected to grow 5% to 24% by 2037.

- American Cancer Society Guideline Change

The American Cancer Society recommends colonoscopy screening beginning at the age of 45 for those at average risk for colorectal cancer. This is five years earlier than its previous recommendations. The applicant states that colorectal cancer screening is essential for early detection and treatment.

- Plan for Physician Recruitment

The applicant proposes to expand the number of physicians over the next three project years. The applicant assumes that the proposed increase in the number of physicians supports the need to expand capacity, thereby increasing the demand for services.

Step 4: Calculate Expected Procedure Volumes Based on Historical Growth

The applicant projects the number of procedures based on the historical CAGR of 6.29% experienced at the existing facility. The applicant states that its projections are reasonable

¹ <https://www.buncombecounty.org/common/commissioners/strategic-plan/strategic-plan-2025.pdf>

because of the projected growth and aging of the service area population, cancer screening recommendations, and the proposed physician recruitment. As illustrated in *Step 3*, the Buncombe County population is projected to grow by 10.3% by July 1, 2030, and the age recommended for colorectal cancer screening was reduced by five years. Furthermore, the applicant is proposing to expand the number of physicians during the first three project years to support the growing need.

	Historical Year	Interim* Year	Interim* Year	Year 1 (Projected)	Year 2 (Projected)	Year 3 (Projected)	CAGR
	10/1/21-9/30/22	10/1/21-9/30/22	10/1/21-9/30/22	10/1/24-9/30/25	10/1/25-9/30/26	10/1/26-9/30/27	
Procedures	18,375	19,531	20,760	22,066	23,454	24,929	6.29%

*Although the facility has historically demonstrated a 6.29% annual growth, to be conservative, the applicant projects that the number of procedures will remain constant at 18,375 during the interim years. This is based on the current capacity constraints of the existing five GI endoscopy rooms. See *Step 5* below.

Step 5: Determine to Hold Interim Years “Constant” due to Facility Constraints

The applicant does not project an increase in the number of procedures during the interim years due to the current facility constraints. The applicant projects that volumes will remain constant prior to the first three years of operation.

Step 6: Combine Interim Year (Held Constant) with Projected Years (Grown by Historical CAGR)

The applicant applies the historical CAGR of 6.29% to project the number of procedures performed during the first three years of the project while projecting the interim years to remain constant at the historical number through the end of FY2024. The applicant proposes to begin operation of the three additional GI endoscopy rooms in October 2024.

	Historical (2023 LRA)*	Interim Projected	Interim Projected	Year 1 (Projected)	Year 2 (Projected)	Year 3 (Projected)
	10/1/21-9/30/22	10/1/22-9/30/23	10/1/23-9/30/24	10/1/24-9/30/25	10/1/25-9/30/26	10/1/26-9/30/27
Rooms	5	5	5	5 +3 = 8	5 +3 = 8	5 +3 = 8
Procedures	18,375	18,375	18,375	22,066	23,454	24,929
Procedures Per Room	3,675	3,675	3,675	2,758	2,932	3,116

*License Renewal Application

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

- The applicant cites data from the NCOSBM to illustrate the projected growth and aging of the population in the service area to support its projections.
- The applicant’s projections are supported by the growing need to perform GI endoscopy procedures for early detection and treatment of colorectal cancer.

- The applicant’s projected growth rate of GI endoscopy procedures is conservative and based on the historical average annual growth rate of the number of procedures performed in the five existing GI endoscopy rooms.
- The applicant demonstrates that the projected utilization exceeds the performance standards of 1,500 procedures per GI endoscopy room.

Access to Medically Underserved Groups

In Section C, page 62, the applicant states:

“Access to the services offered in the new Center will be the same as current access for all groups, including medically underserved groups. The Applicants provide care to all individuals regardless of race, color, national origin, religion, sex, age, disability, or payor source and will continue to do so. In addition, the Applicants maintain an Indigent/Charity Care Policy for individuals who do not have insurance, do not otherwise qualify for medical assistance, or are unable to pay for services due to severe financial hardship.

“”

The Center has partnered with the Western Carolina Medical Society Foundation and The Western North Carolina Colorectal Cancer Screening Initiative (“WNC-CRCSI”). WNC-CRCSI is a program managed by Digestive Health Partners to provide screening to average risk, uninsured, low-income patients between the ages of 50-75.”

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	Unable to track
Racial and ethnic minorities	8.1%, 16%
Women	59.2%
Persons with Disabilities	Unable to track
Persons 65 and older	43%
Medicare beneficiaries	29.5%
Medicaid recipients	1.6%

Source: Section C, page 63

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.

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The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

In Section D, page 68, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 68, the applicant states:

“The GI Endoscopy rooms relocated to the new Center will be available to patients who have historically utilized the existing Center and the new Center will be expanded to afford additional access. The Applicants plan for the existing Center to operate until the new Center is built so that the transition is as close to seamless as possible.”

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

- The applicant is proposing to expand services at a new endoscopy center that is near the existing location.
- The two locations are approximately 3.9 miles apart from each other, according to Google Maps. Thus, the GI endoscopy services will still be accessible to the same population at the new location.

Access to Medically Underserved Groups

In Section D, pages 68-69, the applicant states:

“The proposed Center will follow the same open access policies as the existing Center and will afford care to patients represented...The new Center will enhance access for patients in each group above by adding endoscopy capacity in Buncombe County. The Center will be relocated within Buncombe County to a location with good roadway

access and ample parking. The Center's physical location and its operating policies will be designed to optimized access for patients in and around Buncombe County."

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use GI endoscopy services will be adequately met following completion of the project because services will continue to be accessible to the same population at the new location.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

- (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.

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The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

In Section D, pages 73-74, 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 maintaining the status quo is not an effective alternative because of the growth and aging of the service area population and the high demand for endoscopy services. Maintaining the status can cause delays in preventive care or result in patients seeking care outside of the service area.

Shifting Procedures to a Hospital Setting-The applicant states that this is not an effective or less costly alternative because patients have historically demonstrated their preference for services delivered in an ASF because of the convenience, safety, and cost-effectiveness.

Adding a Different Number of GI Endoscopy Rooms-The applicant states that adding three endoscopy rooms has proven to be the most effective amount based on historical and projected utilization.

Locating to an Alternative Site-Based on area research, the applicant determined that the proposed location proven to be the most effective alternative. Other sites were either more costly, inaccessible to patients or not suitable to accommodate a medical office building and the endoscopy rooms.

Delaying Development of the Project-The applicant states that delaying the project is not an effective alternative because the existing facility is operating at full capacity and will not be able accommodate the growing demand for GI endoscopy services.

On page 73, the applicant states that its proposal is the most effective alternative because of the need to expand endoscopy services at the existing facility based on its historical utilization.

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

- Relocating the ASF to a larger space and adding three endoscopy rooms will meet the growing demand for GI endoscopy services and allow the applicant to provide quality care in larger space in a convenient location.
- 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. Endoscopy Center of North Carolina, LLC and Entero-Med, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a GI endoscopy ambulatory surgical facility (ASF) by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building on Sweeten Creek Road in Asheville, and adding three GI**

endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

- 3. Upon completion of the project, Digestive Health Partners on Sweeten Creek Road shall be licensed for no more than eight 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 March 1, 2024.**
 - 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
 - 6. 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. 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.**
 - 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.

The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

Capital and Working Capital Costs

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

Digestive Health Partners (Proposed)	
Capital Costs	Entero-Med, LLC
Construction/Renovation Contract(s) (Includes site preparation)	\$4,909,374
Landscaping	\$5,550
Architecture/Engineering Fees	\$646,444
Medical Equipment	\$1,900,000
Non-Medical Equipment	\$110,000
Furniture	\$89,000
Consultant Fees	\$45,000
Financing Costs	\$52,000
Interest during Construction	\$490,338
Other	\$646,444
Total	\$8,894,150

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 that are based on the following:

- Most of the capital costs are based on the cost of upfitting the new location and developing the medical office space within the building.
- Relocation costs are included in the cost to relocate medical and non-medical equipment.
- Other costs are based on the applicant's experience with similar projects and input from the builder and lender.

In Section F, page 79, the applicant states there will be no start-up costs or initial operating expenses because the proposal includes the relocation of an existing facility.

Availability of Funds

In Section F, page 76, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Entero-Med, LLC	Total
Loans	\$8,894,150	\$8,894,150
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (\$100 per square foot up-fit allowance within the lease)	\$0	\$0
Total Financing	\$8,894,150	\$8,894,150

* OE = Owner's Equity

Exhibit F.2.b contains a letter dated May 11, 2023, from the Senior Vice President of Truist Bank, stating their consideration in funding the project through a loan based on their long banking relationship with the applicant and their financial status. The letter includes the proposed terms of the loan and an amortization schedule. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of 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.

The Digestive Health Partners	1 st FFY FY2025	2 nd FFY FY2026	3 rd FFY FY2027
Total Procedures	22,066	23,454	24,929
Total Gross Revenues (Charges)	\$36,408,539	\$38,609,205	\$40,734,390
Total Net Revenue	\$12,378,903	\$13,127,130	\$13,849,693
Average Net Revenue per Treatment	\$561	\$560	\$556
Total Operating Expenses (Costs)	\$9,419,939	\$10,101,842	\$10,709,427
Average Operating Expense per Treatment	\$427	\$431	\$430
Net Income	\$2,958,964	\$3,025,288	\$3,140,266

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant projects gross revenue by multiplying the average charges by the projected number of procedures. The applicant projections are based on the existing facility's historical utilization.
- The applicant assumes that revenue will increase as the number of procedures performed increases.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

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 2023 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 facility will be developed in Buncombe County. In Section C, page 41, the applicant projects that 70.55% of its patients will originate from Buncombe County. Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

The 2023 SMFP shows there are eleven existing GI endoscopy rooms in two facilities in Buncombe County, as illustrated in the table below.

Buncombe County GI Endoscopy Services – FY2022 Data				
Existing Facilities	Endoscopy Rooms	Cases	Procedures	Procedures per Room
Mission Hospital	6	5,579	7,251	1,209
The Endoscopy Center	5	15,359	17,757	3,551
Total	11	20,938	\$25,008	4,760

Source: Table 6F: Endoscopy Room Inventory (page 83 of the 2023 SMFP)

In Section G, page 86, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Buncombe County. The applicant states:

“The inventory of GI endoscopy rooms will increase in response to growth in the population, growth among residents aged 45 and older, and the need for non-hospital endoscopy services...Based on the performance standard of 1,500 procedure per year, the Applicants performed more than twice the performance standard procedures-per-room during 10/01/2020-9/30/2021 as reported on the 2022 license renewal application.”

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 applicant’s proposal would not result in unnecessary duplication based on the high utilization of the existing GI endoscopy rooms.
- Adding GI endoscopy rooms to the service area is in response to the growth and aging of the population.
- The applicant adequately demonstrates that the proposed GI endoscopy rooms are needed in addition to the existing 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.

The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

In Section Q, Form H, 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		
	Last Full Fiscal Year	1 st Full Fiscal Year (FY2025)	2 nd Full Fiscal Year (FY2026)	3 rd Full Fiscal Year (FY2027)
Registered Nurses	17.2	20.64	22.7	24.08
Licensed Practical Nurses	2	2.5	2.5	3
Registered Nurse Manager	1	1	1	1
Endo/Scope Reprocessing Tech	17.6	20.3	21.8	22.8
Schedulers	4	6	6	7
TOTAL	41.8	50.44	54.00	57.88

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 88-89, the applicant describes the methods to be 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:

- As an established provider in the service area, the applicant will be able to recruit staff through the local community college and its established partners in the community.
- The applicant will recruit staff through online advertisements and job postings within the existing endoscopy center.
- New staff are subject to an orientation process and a tour of the facility.
- All staff are required to maintain competency in their respective fields annually.

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 an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

Ancillary and Support Services

In Section I, page 90, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 90-91, 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. The applicant is relocating to an existing facility. Ancillary and support services will be provided by the facility staff.

Coordination

In Section I, page 91, 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 applicant's established relationships with local health care providers in the service area, such as a transfer agreement with Mission Hospital. Additionally, the applicant demonstrates the support of the project by referring physicians and other providers.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

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

NA

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

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

C

The applicant proposes to develop an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

In Section K, page 94, the applicant states that the project involves renovating 16,453 square feet of existing space. Line drawings are provided in Exhibit K.1.

On pages 97-98, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits

K.4.b and K.4.c. The site appears to be suitable for the proposed GI endoscopy rooms based on the applicant's representations and supporting documentation.

On pages 95-96, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant is expanding GI endoscopy services by relocating the existing facility to a larger space to accommodate the growing demand.
- The new facility will be designed to be cost-effective and modern, which will allow the provider to provide quality services to its patients.

On page 96, 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 based on the following:

- GI endoscopy services offered in a freestanding facility in a convenient location is a lower cost option for service area residents.
- This proposal is in response to the existing facility constraints and the growing demand for GI endoscopy services.

On page 96, 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;

In Section L, page 100, the applicant provides the historical payor mix during FY2022 for the proposed services, as shown in the table below.

The Endoscopy Center (Existing) Historical Payor Mix 10/01/2021-09/30/2022	
Payor Category	Percentage of Total Patients Served
Self-Pay	1.6%
Charity Care	Included in Self-Pay
Medicare*	29.5%
Medicaid*	1.6%
Insurance* (includes TRICARE)	67.3%
Total	100.0%

*Including any managed care plans.

In Section L, pages 101-102, the applicant provides the following comparison.

The Endoscopy Center (Existing)	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	59.2%	51.8%
Male	40.8%	48.2%
Unknown	Unknown	Unknown
64 and Younger	57.0%	79.0%
65 and Older	43.0%	21.0%
American Indian	Unknown	0.6%
Asian	Unknown	1.5%
Black or African American	Unknown	6.2%
Native Hawaiian or Pacific Islander	Unknown	0.2%
White or Caucasian	Unknown	89.3%
Other Race	Unknown	Unknown
Declined / Unavailable	Unknown	Unknown

*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 102, the applicant states that the facility is not obligated to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 103, 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 103, 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.

Digestive Health Partners (Proposed)^	
Projected Payor Mix	
3rd Full FY, FY 2027	
Payor Category	Percentage of Total Patients Served
Self-Pay	1.6%
Charity Care	Included in Self-Pay
Medicare*	29.5%
Medicaid*	1.6%
Insurance* (includes TRICARE)	67.3%
Other	4.5%
Total	100.0%

*Including any managed care plans.

^In the Table on page 103 of the application, the applicant identified the name of facility as Digestive Health Partners, however, the Analyst assumes this was a typographical error because the applicant identifies the name of the facility in Section A.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.6% of total services will be provided to self-pay patients, 29.5% to Medicare patients and 1.6% to Medicaid patients.

On page 103, 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 applicant's assumption that payor mix will not change from the last full fiscal year because the facility will be serving the same patient population.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 105, 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 an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

In Section M, page 107, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The facility has a documented relationship with Mountain Area Health Education Center for clinical training and refresher courses.
- The facility has an agreement with Blue Ridge Community College to allow students to use the facility for clinical experience.

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 an ASF by relocating an existing ASF with five GI endoscopy rooms to a newly upfitted building, and adding three GI endoscopy rooms, for a total of no more than eight GI endoscopy rooms upon project completion.

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 2023 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 facility will be developed in Buncombe County. In Section C, page 41, the applicant projects that 70.55% of its patients will originate from Buncombe County. Thus, the service area for this facility consists of Buncombe County. Facilities may also serve residents of counties not included in their service area.

The 2023 SMFP shows there are eleven existing GI endoscopy rooms in two facilities in Buncombe County, as illustrated in the table below.

Buncombe County GI Endoscopy Services – FY2022 Data				
Existing Facilities	Endoscopy Rooms	Cases	Procedures	Procedures per Room
Mission Hospital	6	5,579	7,251	1,209
The Endoscopy Center	5	15,359	17,757	3,551
Total	11	20,938	\$25,008	4,760

Source: Table 6F: Endoscopy Room Inventory (page 83 of the 2023 SMFP)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 109, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 109, the applicant states:

“By relocating and enlarging the Center, patients will have a new larger site of service from which to access the more cost-effective option to receive GI Endoscopy services in

a non-hospital setting. Patient access to cost effective endoscopy care will be greatly enhanced by the development of the proposed Center with additional capacity.”

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 109, the applicant states:

“The Applicants have a strong record of providing quality services and will continue those traditions in the delivery of quality care in the larger Center. The new Center will operate under the same protocols and policies which have allowed for the provision of quality care for years. Patients will have a new option to receive quality services with enhanced ability to schedule services sooner which contributes to quality by avoiding delays in service.”

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 109, the applicant states:

“The Applicants will carry forward the historical payor mix from the existing Center and will continue to offer care without discrimination, allowing medically underserved groups more access to quality care at non-hospital prices.”

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

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

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

C

In Section Q, Form O, the applicant identifies the ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of two of these types of facilities located in North Carolina.

In Section O, page 112, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care had 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, incidents related to quality of care had not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at both 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 facility will be developed in Buncombe County. In Section C.3, page 41, the applicant projects that 70.55% of its patients will originate from Buncombe County. Thus, the service area for this facility consists of Buncombe 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 License Renewal Application and Table 6F in the 2023 SMFP, there are five existing and 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.3b, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project for the existing and proposed GI endoscopy rooms.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	FY2025	FY2026	FY2027
# of Rooms	8	8	8
# Inpatient GI Endoscopy Procedures	0	0	0
# Outpatient GI Endoscopy Procedures	22,066	23,454	24,929
Total GI Endoscopy Procedures	22,066	23,454	24,929
Average # of Procedures per Room	2,758	2,932	3,116

(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 C, Form C.3b, the applicant projects to perform an average of 3,116 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- Section Q, Form C-*Assumptions and Methodology*, the applicant provides the assumptions and methodology used to project utilization of the existing and proposed GI endoscopy rooms. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.