

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 29, 2022

Findings Date: August 29, 2022

Project Analyst: Donna Donihi

Co-Signer: Lisa Pittman

Project ID # B-12217-22

Facility: Carolina Mountain Gastroenterology Endoscopy Center

FID # 070560

County: Henderson

Applicant(s): Carolina Mountain Gastroenterology Endoscopy Center, LLC, SVR Properties, LLC

Project: Add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

REVIEW CRITERIA

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. 131E-183(a) The Agency 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

The applicant, Carolina Mountain Gastroenterology Endoscopy Center LLC, d/b/a Carolina Mountain Gastroenterology Endoscopy Center, (CMGEC) and SVR Properties LLC, collectively referred to as “the applicant” proposes to develop a new gastrointestinal endoscopy (GI-Endo) procedure room for a total of three upon completion of this project at CMGEC located at 1032 Fleming Street Hendersonville, NC 28791, in Henderson County.

Need Determination and Policies

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 determination is applicable to this review nor any policy. Thus, this criterion is not applicable to this review.

Conclusion

The applicant does not propose to:

- Develop any beds or services for which there is a need determination in the 2022 SMFP.
- Acquire any medical equipment for which there is a need determination in the 2022 SMFP.
- Offer a new institutional health service for which there are any policies in the 2022 SMFP.

Therefore, 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

Patient Origin

The 2022 SMFP does not define the service area for GI-Endo procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms promulgated in 10A NCAC 14C .3901(6) does define the service area. *“The county where the proposed GI endoscopy room will be developed.”*

The following illustrates historical and projected patient origin.

Carolina Mountain Gastroenterology Endoscopy Center				
Patient Origin				
County	Current		Third Full FY of Operation Following Project Completion	
	10/01/2020-09/30/2021		01/01/2026-12/31/2026	
	Patients	% of Total	Patients	% of Total
Henderson	3,602	61.83%	3802	62.0%
Transylvania	952	16.34%	981	16.0%
Buncombe	547	9.39%	613	10.0%
Polk	278	4.77%	307	5.0%
Rutherford	138	2.37%	154	2.5%
Jackson	21	0.36%	31	0.5%
Other	288	4.94%	245	4.0%
TOTAL	5,826	100.0%	6,133	100.0%

Source: Section C.3, pages 26 & 27.

In Section C.3, page 27, the applicant provides the assumptions and methodology used to project its patient origin.

- The projected patient origin is based on historical utilization by county
- Patient origin is not expected to change following the addition of the third endoscopy room.
- The number of procedures is higher than the number of patients because some patients require more than one procedure.
- The projected increase in the number of patients is consistent with the growth of the population.

The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, page 29-30, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 28-30, the applicant states:

- High Utilization – The proposed project is needed to accommodate projected utilization at the center. The two existing GI endoscopy rooms are operating at over twice the 1,500 procedures per room performance standard in 10A NCAC 14C.3903b.
- Per the 2022 SMFP, the GI endoscopy rooms at the center provided 72% of the procedures done in Henderson County in SFY20. The two Henderson County hospitals combined provided only 28 percent of the procedures done in Henderson county in FY2020, indicating a strong preference of the community for a non-hospital-based provider.
- The overall need for the proposed project is based on the need for the center to operate a third GI-endoscopy room to improve its ability to facilitate timely delivery of high-quality care.
- Some physicians have hospital privileges, however physician access to these hospital facilities is highly restricted. Not allowing all physicians to perform these procedures at a hospital, thus causing the need for independent facilities.

The information is reasonable and adequately supported for the following reasons:

- Need to accommodate growth in patients and procedures

Projected Utilization

In Section Q, Form C.3.a, the applicant provides projected utilization, which is summarized below.

Carolina Mountain Gastroenterology Endoscopy Center	Last Full FY2021	First Interim FY2022	Second Interim FY2023	First Full FY2024	Second Full FY2025	Third Full FY2026	CAGR FY2022-FY2026
# of Rooms	2	2	2	3	3	3	
# of Outpatient GI Endoscopy Procedures	6,985	7,044	7,103	7,163	7,223	7,284	0.84%
Average # of Procedures per Room*	3,492	3,522	3,552	2,388	2,408	2,428	
Number of Rooms Needed at 1,500 Procedures Per Room*	4.7	4.7	4.7	4.8	4.8	4.9	

- Calculated by project analyst

In Section Q, C3.a, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- CY2021 volume increased by 116 procedures over CY2019 for a CAGR of 0.84%, and is projected to increase 0.84% each year through 2026.
- The projected time per procedure is based historical time per procedure.
- The 2 GI endoscopy rooms will remain in operation during construction/renovation for the third GI endoscopy room.

Projected utilization is reasonable and adequately supported because it is based on the CAGR of 0.84% from 2019-2021 which is more conservative than growth from 2016 through 2021 (CAGR of 2.03%).

Access

In Section C.6, page 48, the applicant states, “they will 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 applicant maintains 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 applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	0.0%
Racial and ethnic minorities	4.5%
Women	59.0%
Persons with Disabilities	0.0%
The elderly	53.0%
Medicare beneficiaries	53.0%
Medicaid recipients	2.5%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services based on the following:

- The applicant provides a statement that it will provide access to the proposed services for underserved groups.
- The applicant provides a copy of the non-discrimination policy it will use at Carolina Mountain Gastroenterology Endoscopy Center in Exhibit C.6.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce, relocate or eliminate a 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 add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section E, pages 58-59, 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, “although it would be possible to continue providing services with only two GI-endoscopy rooms, the population of the service area would not be well served by this alternative. By not expanding services, it could not ensure adequate access to meet current and projected need, operate cost effectively or efficiently, and enhance patient, staff and physician satisfaction.
- *Extend Hours* – The applicant states that this is not the most cost-effective alternative. Expanding hours could increase number of procedures to be performed. The primary reason for rejecting this alternative is the need to attract and retain quality staff and maintain employee morale. Demanding facility staff to work extended hours or weekend hours is not conducive to employee retention.
- *Shift procedure to a hospital setting.* - The applicant states doctors who perform endoscopy procedures at the facility could perform the same procedures at regional hospitals. However, the time allotted to the doctor to perform procedures at these hospitals is limited, which can cause significant delays in scheduling procedures to be performed at the hospital. A delay in a patient receiving endoscopy procedures is an undesirable outcome, making reliance on hospital procedures a less effective alternative.
- *Add 2 GI Endo rooms.* This alternative was rejected because constructing 2 rooms in the current physician space would be more expensive and cause more disruptions to current operations

The applicant provides supporting documentation in Exhibit O.

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

- It will increase overall patient access
- It will ensure the level of care necessary for high-risk patients
- It will contain costs vs. the other alternatives
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. The applicant, Carolina Mountain Gastroenterology Endoscopy Center LLC, (hereafter the certificate holder), shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop one new gastrointestinal endoscopy procedure room for a total of three.**
- 3. Upon completion of the project, the certificate holder shall be licensed for no more than three gastrointestinal endoscopy procedure rooms.**
- 4. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. For the first three years of operation following completion of the project, Carolina Mountain Gastroenterology Endoscopy Center 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.**
- 6. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on January 1, 2023 and so forth.**
- 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 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 add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

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

Carolina Mountain Gastroenterology Endoscopy Center Projected Capital Cost	
Construction	\$333,960
Architect/Engineering	\$33,396
Medical Equipment	\$241,000
Non-Medical Equipment	\$1,775
Furniture	\$560
Consult Fees	\$45,000
Financing Costs	8,500
Interest During Construction	78,792
Project Contingency	75,000
Total	\$817,983

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 reasonably and adequately supported assumptions based on the experience of the project architect with similar projects and the recent experience of the applicant.

In Section F, page 62, the applicant projects no start-up costs and no initial operating expenses because the proposed project is not a new service or facility.

Availability of Funds

In Exhibit F.2, the applicant states that the capital cost will be funded as shown below in the table.

Type	Carolina Mountain Gastroenterology Endoscopy Center	Total
Loans	\$817,983.00	\$817,983.00
Total Financing	\$817,983.00	\$817,983.00

Financial Feasibility

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

GI-Endo Procedure Rooms			
	1st Full Fiscal 2024 Year	2nd Full Fiscal 2025 Year	3rd Full Fiscal 2026 Year
Total Procedures*	7,163	7,223	7,284
Total Gross Revenues	8,344,187	8,414,278	8,484,958
Total Net Revenue	3,831,650	3,863,867	3,896,356
Average Net Revenue per Procedure	534.92	534.94	539.44
Total Operating Expenses (Costs)	3,321,371	3,413,216	3,429,497
Average Operating Expense per Procedure	463.68	472.55	474.80
Net Income	510,228	459,652	466,859

*See Section Q, Form F.3

The assumptions used by the applicant in preparation of the pro forma financial statements adequately demonstrate that the feasibility of the proposal is reasonable and adequately supported based on the following:

- Assumptions are based on the experience of the applicant and architect.
- Gross revenue is based on historical experience and conservatively projected forward.
- 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. See Section Q of the application for the assumptions used regarding costs and charges.

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

C

The applicant plans to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

The 2022 SMFP does not define the service area for GI-Endo 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 applicant defines its service area as Henderson County. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 69, the applicant identifies the existing and approved GI-Endo services Henderson County and the number of GI-Endo procedures performed October 1, 2019 through September 30, 2020 as depicted in the following table.

County	Provider	Rooms	Cases	Procedures
Henderson	Carolina Mountain Gastroenterology Endoscopy Center	2	5,021	5,963
Henderson	Margaret Pardee Memorial Hospital	3	1,571	1,979
Henderson	Advent Health Hendersonville	1	360	360
Total		6	6,952	8,302

*Table 6F of the 2022 SMFP.

As illustrated in the table above two of the three GI-Endo facilities in Henderson County, exceeded 1,500 procedures per GI-Endo procedure room in FY2022.

In Section G, page 69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI Endo services in CMGEC's primary service area. The applicant states:

“... The addition of one GI endoscopy room at the existing facility will not result in unnecessary duplication in the proposed service area. The inventory of endoscopy rooms will increase from 6 to 7 in an area that is experiencing continuous growth in the population over 45 years old and need for endoscopy procedures. ... based on performance standards of 1,500 procedures per room per year, the applicants are performing enough procedures to justify nearly four (4) total rooms and the Applicants project exceeding 6,000 total procedures in the coming year.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area. The applicant adequately demonstrates that the proposed GI Endo procedure room is needed in addition to the existing or approved GI Endo services in the applicant's service area.

Conclusion

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 application is conforming to this criterion for 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 add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section Q, Form H, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

Current & Projected Staffing FTEs				
Position	Current	Projected		
	FFY 05/01/2022	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
RN	4.01	6.01	6.01	6.01
RN Team Lead	1.00	1.00	1.00	1.00
RN Manager	1.00	1.00	1.00	1.00
LPN	1.02	2.02	2.02	2.02
CNA	1.00	1.00	1.00	1.00
Surgical Tec	7.01	8.51	8.51	8.51
Total	15.04	19.54	*[19.54] 20.00	[19.54] 20.00

*Brackets reflect correct totals.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F, which is found in Section Q. In Section H, pages 71-72, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Exhibit I.2, the applicant provides supporting documentation from the medical director and all physician that perform service.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on its 2022 staffing.

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 above stated reasons.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise plan 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 add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

Ancillary and Support Services

In Section I, page 73, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Admin/Management
- Marketing
- Human Resources
- Staff Training
- Information Technology
- Building Maintenance
- Equipment Maintenance
- Purchasing
- Dietary
- Housekeeping
- Medical records
- Billing/Finance/Insurance claims filing

Since there are two rooms that already provide these services the ancillary services listed on page 73 are already being provided and made available.

Coordination

In Section I, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section K, page 76, the applicant states that the project involves renovating 360 square feet of existing space. Line drawings are provided in Exhibit K.2.

On page 78, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K.2, Site and Floor Plans. The applicant states,

“The existing facility can accommodate the physical space for an additional GI endoscopy room by relocating an existing wall and converting office space into a new procedure room.”

On page 78, 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. In Exhibit K.3 the applicant provides supporting documentation from the architect for the proposed GI-Endo procedure room in this project.

On page 78 the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

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.

- (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 handicapped persons, 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

The applicant proposes to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section L, page 81, the applicant provides the historical payor mix for the proposed services in the last calendar year, as shown below in the table.

GI Endoscopy Payor Mix 01/01/2021-12/31/2021	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	1.0%
Charity Care*	0.0%
Medicare	52.7%
Medicaid	2.5%
Insurance**	42.3%
Workers Compensation	0.0%
TRICARE	1.5%
Other	.0%
Total	100.0%

In Section L, page 82, the applicant provides the following comparison.

Medically Underserved Populations as Percentage of Total Population in the Service Area		
	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	58.6%	52.0%
Male	41.3%	48.0%
Unknown	0.1%	0.0%
64 and Younger	47.1%	73.6%
65 and Older	52.9%	26.4%
American Indian	<0.01%	0.7%
Asian (inc Hawaiian or Pacific Islander)	0.4%	1.3%
Black or African American	2.2%	3.4%
Native Hawaiian	<0.01%	0.2%
White or Caucasian	89.7%	92.5%
Other Race	1.4%	1.9%
Declined / Unavailable	5.9%	0.0%

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

The Agency reviewed the:

- Application
- Exhibits to the application

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

The applicant proposes to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 83, the applicant states, that it is under no applicable federal regulations to provide uncompensated care, community service or access to persons with disabilities.

In Section L, page 83, the applicant states, "*The Applicants have not had any patient civil rights equal access complaints filed in the last 18 months preceding the application deadline.*"

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

The applicant proposes to add no more than one GI endoscopy room for a total of no more than three endoscopy rooms upon project completion.

In Section L, page 84, 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 below in the table.

Projected Payor Mix 01/01/2026 to 12/31/2026	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	1.0%
Charity Care*	0.0%
Medicare	52.7%
Medicaid	2.5%
Insurance**	42.3%
Workers Compensation	0.0%
TRICARE	1.5%
Other	0.0%
Total	100.0%

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.0% of total services will be provided to self-pay patients, 52.7% to Medicare patients and 2.5% to Medicaid patients.

On page 85, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant assumes the proposed project will not have a significant impact on payor mix, thus the projected payor mix will closely resemble the existing 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.

- (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

The applicant proposes to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section L., page 85, 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

In Section M, page 87, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (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 add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

The 2022 SMFP does not define the service area for GI-Endo procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms promulgated in 10A NCAC 14c.39001(6) defines the service area as the “county where the proposed GI endoscopy room will be developed. “The applicant defines its primary service area Henderson County. Facilities may also serve residents of counties not included in their service area.

In Section G page 69, the applicant identifies the existing and approved GI-Endo services in Henderson County and the number of GI-Endo procedures performed October 1, 2019 through September 30, 2020 as depicted in the following table.

County	Provider	Rooms	Cases	Procedures
Henderson	Carolina Mountain Gastroenterology Endoscopy Center	2	5,021	5,963
Henderson	Margaret Pardee Memorial Hospital	3	1,571	1,979
Henderson	Advent health Hendersonville	1	360	360
Total		6	6,952	8,302

As illustrated in the table above, two of the 3 GI-Endo facilities in Henderson County, have exceeded 1,500 procedures per GI-Endo procedure rooms.

In Section G, page 69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI Endo services in CMGEC’s primary service area. The applicant states:

“... The addition of one GI endoscopy room at the existing facility will not result in unnecessary duplication in the proposed service area. The inventory of endoscopy rooms will increase from 6 to 7 in an area that is experiencing continuous growth in the population over 45 years old and need for endoscopy procedures. ... based on performance standards of 1,500 procedures per room per year, the applicants are performing enough procedures to justify nearly four (4) total rooms and the Applicants project exceeding 6,000 total procedures in the coming year.”

In Section N, page 88-89, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services.

- The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates: 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.
- 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.
- 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 which was publicly available during the review and used by the Agency (if applicable)

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

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

C

The applicant proposes to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section O, page 90, the applicant identifies the GI-Endo facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of thirty-eight of this type of facility located in North Carolina.

In Section O, page 91, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all seven 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.
- (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

Add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

The proposal is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900. The specific criteria are discussed below.

.3903 PERFORMANCE STANDARDS

- (a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*

-NA-

The applicant does not propose to develop operating rooms. Therefore, this rule is not applicable to this review.

- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI-Endo procedures only per GI-Endo room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*

-C-

The applicant plans to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section C, page 26, the applicant states that it projects to perform an average of 3,739 GI-Endo procedures in each licensed facility that the applicant or a related entity owns in the proposed service area during the second year of operation following completion of the project.

- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall demonstrate that at least the following types of GI-Endo procedures will be provided in the proposed facility or GI-Endo room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*

-C-

In Section Q, Form C, the applicant states that endoscopy procedures, esophagoscopy procedures, have historically and will continue to be provided at CMGEC.

(d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*

- (1) *if the applicant or a related entity performs GI-Endo procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI-Endo cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or*
- (2) *demonstrate that GI-Endo procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*

-C-

Add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section C, page 29, the applicant states that neither it nor any related entities perform GI Endo procedures in licensed operating rooms.

(e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop an additional GI-Endo room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*

-C-

The applicant proposed to add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms upon project completion.

In Section Q, the applicant provides the assumptions and methodology used to project GI Endo procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.