

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: April 2, 2019

Findings Date: April 2, 2019

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: F-11628-18

Facility: Rowan Endoscopy Center

FID #: 090849

County: Rowan

Applicant(s): Rowan Endoscopy Center, PLLC
Brenner Avenue, LLC

Project: Develop a new ambulatory surgical center with two gastrointestinal endoscopy (GI endoscopy) rooms

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.

C

The applicants, Rowan Endoscopy Center, PLLC and Brenner Avenue, LLC (Brenner LLC), propose to develop a new Ambulatory Surgical Center (ASC), Rowan Endoscopy Center, with two gastrointestinal endoscopy (GI endoscopy) rooms.

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 2018 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There are no policies in the 2018 SMFP which are applicable to this review.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 following reasons:

- The applicants do not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2018 SMFP.
 - The applicants adequately demonstrate that there are no policies in the 2018 SMFP which are 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- (2) Repealed effective July 1, 1987.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 applicants propose to develop a new ASC with two GI endoscopy rooms.

Patient Origin

The 2018 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) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicants projects to serve patients. In supplemental information the applicants define the primary service area as Rowan County. Thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates current and projected patient origin.

County	Current (CY2017)		Second Full FY of Operation following Project Completion (CY2020)	
	Patients	% of Total	Patients	% of Total
Rowan	2,575	88.92%	2,605	88.99%
Davidson	111	3.83%	112	3.81%
Davie	57	1.97%	57	1.96%
Stanly	52	1.80%	52	1.78%
Cabarrus	32	1.17%	35	1.18%
Iredell	24	0.83%	24	0.82%
Mecklenburg	10	0.35%	10	0.34%
Forsyth	6	0.21%	6	0.20%
Guilford	3	0.10%	3	0.10%
Randolph	2	0.07%	2	0.07%
Yadkin	2	0.07%	2	0.07%
Alamance	1	0.03%	1	0.03%
Allegheny	1	0.03%	1	0.03%
Anson	1	0.03%	1	0.03%
Catawba	1	0.03%	1	0.03%
Craven	1	0.03%	1	0.03%
Cumberland	1	0.03%	1	0.03%
Gaston	1	0.03%	1	0.03%
Granville	1	0.03%	1	0.03%
Lincoln	1	0.03%	1	0.03%
Orange	1	0.03%	1	0.03%
Pitt	1	0.03%	1	0.03%
Union	1	0.03%	1	0.03%
Watauga	1	0.03%	1	0.03%
Wilkes	1	0.03%	1	0.03%
Out of State	6	0.21%	6	0.20%
Total	2,896	100.00%	2,927	100.00%

Source: Section C., pages 9-10 and supplemental information.

In Section C, page 10, the applicants provide the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, page 11 and supplemental information the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. In supplemental information the applicants state:

Currently, the endoscopy center performs office based GI endoscopy procedures in 2 rooms however, the endoscopy center is not a licensed ambulatory service facility. The proposed project would convert the existing endoscopy center to a free standing, licensed ambulatory surgical facility with two GI endoscopy rooms, at the same location.

The proposed project is needed because it would allow the Rowan Endoscopy Center to secure the full range of fees for endoscopy procedures thus allowing the facility to:

“

- *protect the economic viability of the organization,*
- *Increase our outpatient services to Medicare and Medicaid patients and,*
- *Provide more services to indigent patients and those without insurance with a goal of 30 per year.”*

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

- Increased ability to provide GI Endoscopy services to Medicare, Medicaid and Indigent patients.
- Improved quality
- Improves economic viability of the only non-hospital based GI endoscopy services in Rowan County

Projected Utilization

In supplemental information the applicants provide historical and projected utilization as illustrated in the following tables.

	Prior Year CY2015	Prior Year CY2016	Prior Year CY2017	Interim Year CY2018	OY1 CY2019	OY2 CY2020	OY3 CY2023
# of GI Rooms	2	2	2	2	2	2	2
# of GI Procedures	2,521	2,936	3,442	3,873*	4,067	4,270	4,483
% change per year	na	16.5%	17.2%	12.50%	5.0%	5.0%	5.0%
Average # of GI Procedures Per GI Room	1,260.5	1,468	1,721.0	1,936.5	2,033.5	2,135	2,241.5

*In Section Q this was listed as 3,588 however, in supplemental information the applicants confirmed that the correct number of GI endoscopy procedures for CY2018 was 3,873. The “% change per year” and “the average # of GI procedures per GI Room for CY 2018” were adjusted based on the supplemental information.

In Section Q and supplemental information the applicants provide the assumptions and methodology used to project utilization, which is summarized below.

- The number of GI Endoscopy procedures performed from 2015 through 2018 has increased at least 12% per year.
- The applicants project a conservative growth rate of 5.0% per year for the first three operating years.
- The population ages 45-65+ is the age group that will most use GI endoscopy services and in Rowan County 44.3% of the population is within the 45-65+ age group which increase by 2.4% for the years 2010 to 2017.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected number of GI Endoscopy procedures to be performed by the two gastroenterologists are reasonable based on the historical number of GI Endoscopy procedures currently performed at the Endoscopy Center.
- Projected utilization is based on a 5.0% growth rate which is conservative compared to a minimum 12.0% actual growth rate from 2015 through 2018.

Access

In Section C, page 11, the applicants state “*Our policy states that the center shall provide the highest quality care, and serve as a resource for referring physicians in the community for treatment, diagnosis and management of patients for gastroenterology services without regard to race, color, religion, sex, age, national origin, disability, or socioeconomic class.*” In Section L, page 25, the applicants project the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	GI Endo Room Services as Percent of Total
Medicaid*	0.24%
Medicare*	34.64%
TRICARE	0.41%
Self-Pay	1.76%
Insurance*	62.95%
Total	100.00%

Source: Table on page 24 of the application.

*Including any managed care.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 the following reasons:

- The applicants adequately identified the population to be served.
- The applicants adequately explain why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicants project the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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 applicants do not propose to reduce, eliminate or relocate GI endoscopy rooms or services; 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 applicants propose to develop a new ASC with two GI endoscopy rooms.

In Section E, page 14, and supplemental information, the applicants describes the alternatives they 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 applicants could continue to perform GI endoscopy procedures in an office based setting not licensed as an ASF however, this would negatively impact the applicants ability to provide service to Indigent patients and patients reliant on Medicaid and Medicare. Therefore, the applicants determined that this was not the least costly or most effective alternative.

On page 14 and in supplemental information, the applicants state that its proposal is the most effective alternative because the existing facility becoming licenses as an ASF would allow the securing of the full range of fees for endoscopy procedures which would permit the facility to:

- Provide more services to indigent patients and those without insurance with a goal of 30 per year.
- Protect the economic viability of the organization
- Increase patient services to Medicaid and Medicare patients.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicants provide credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 stated above. Therefore, the application is approved subject to the following conditions:

- 1. Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall materially comply with the last made representation.**
- 2. Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall develop a new ambulatory surgical facility with two gastrointestinal endoscopy procedure rooms.**
- 3. Upon completion of the project Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall be licensed for no more than two gastrointestinal endoscopy procedure rooms.**
- 4. Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.**
- 5. Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 6. For the first three years of operation following completion of the project, Rowan Endoscopy Center, PLLC and Brenner Ave, LLC shall not increase charges more than 5% of the charges projected in Sections F and Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, & 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.**

11. Rowan Endoscopy Center, PLLC and Brenner Ave, LLC 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 applicants propose to develop a new ASC with two GI endoscopy rooms.

Capital and Working Capital Costs

In Section Q, page 32 and Exhibit 6, the applicants project the total capital cost of the project as shown in the table below.

Construction/Renovation Costs	\$135,750
Architect/Engineering Fees	\$17,520
Financing Costs	\$100
Other: CON Application Fee	\$5,000
Other: Contingency	\$41,630
Total	\$200,000

In Section Q and Exhibit 6, the applicants provide the assumptions used to project the capital cost.

In Section F, page 16, the applicants projects that there will be no start-up costs or initial operating expenses as the facility is already providing the procedures in an office based setting and the facility would continue to provide services during renovations.

Availability of Funds

In Section F, page 15, and supplemental information, the applicants state that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Brenner Avenue, LLC	Total
Loans	na	na
Accumulated reserves or OE *	\$100,000	\$100,00
Bonds	na	na
Other: Line of Credit	\$100,00	\$100,00
Total Financing	\$200,000	\$200,000

* OE = Owner's Equity

Exhibit 7 contains a letter dated October 9, 2018 from the Senior Commercial Banking Manager of F & M Bank committing to provide a line of credit in the amount of \$100,000 for the capital costs of the project. Exhibit 8 contains a letter from the owners of Brenner Avenue, LLC committing accumulated reserves and owners equity for the capital costs of the project. In supplemental information, the applicants provide a letter dated February 20, 2019 from their accountant, Manish Majithia, CPA, which states that the applicants have accumulated reserves and owner's equity of \$100,000 for the proposed project.

Financial Feasibility

The applicants provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.3, page 35, the applicants project that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Procedures	4,067	4,270	4,483
Total Gross Revenues (Charges)	\$2,673,861	\$2,808,429	\$2,948,026
Total Net Revenue	\$2,644,557	\$2,777,349	\$2,915,614
Average Net Revenue per Procedure	\$650.25	\$650.43	\$650.37
Total Operating Expenses (Costs)	\$871,154	\$896,108	\$921,807
Average Operating Expense per Procedure	\$214.20	\$209.86	\$205.62
Net Income	\$1,773,403	\$1,881,241	\$1,993,807

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application

- Exhibits to the application
- Supplemental information requested by the Agency
- 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 following reasons:

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

C

The applicants propose to develop a new ASC with two GI endoscopy rooms.

The 2018 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) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicants projects to serve patients. In supplemental information the applicants define the primary service area as Rowan County. Thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

Pursuant to the 2019 State Medical Facilities Plan, Table 6F: Endoscopy Room Inventory, page 95, currently only one facility has licensed GI Endoscopy Rooms in the applicants service area of Rowan County as illustrated in the table below.

Existing Facilities	# of Endoscopy Rooms	# of Patients	# of GI Procedures
Novant Health Rowan Regional Medical Center	4	1,876	2,025

In Section G, page 18, the applicants explain why they believe the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Rowan County. The applicant states: *“We are currently completing these procedures in the proposed service area and have been since 2013.”* In supplemental information the applicants state

“There are no other licensed ambulatory surgery centers or office based units that do endoscopy procedures in Rowan County. Rowan Endoscopy Center is the only free-standing non-hospital endoscopy center in Rowan County. Rowan Endoscopy Center is

currently completing endoscopy procedures in the proposed service area and has been since 201. Dr. Korrapati and Dr. Jagarlamudi are the only gastroenterologists in Rowan County. They provide endoscopy services in the office-based endoscopy center and at the single hospital in the county, Novant Health Rowan Regional Medical Center. We do not anticipate any shift in cases from the hospital or reduction in GI procedures done at the hospital.”

The applicants adequately demonstrate that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would not result in an increase in GI endoscopy facilities
- The applicant adequately demonstrates that the proposed GI endoscopy ASF is needed in addition to the existing or approved GI Endoscopy ASF facilities.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 stated 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

In Section H.1, page 19, and Exhibit 10, the applicants 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
	10/30/18	2nd Full Fiscal Year (CY2020)
Physicians	2	2
RN	1	1
LPN	1	1
Technicians	2	2
Receptionist	1	1
TOTAL	7	7

The assumptions and methodology used to project staffing are provided in Section H and Exhibit 10. Adequate costs for the health manpower and management positions proposed by

the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, page 19, the applicants describe the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4 page 19, and supplemental information, the applicants identify the proposed medical director. In Exhibit 12, the applicants provide a letter from the medical director indicating an interest in continuing to serve as medical director for the proposed services. In Exhibits 10, 11 and 12, the applicants provide supporting documentation.

The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 stated 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

In Section I, page 20, and supplemental information the applicants state that the following ancillary and support services are necessary for the proposed services:

- Anesthesia
- Pathology Services
- Medications and Medical Supplies
- Endoscopy Equipment and Endoscopy Supplies
- Human Resources
- Patient Billing and Scheduling
- Risk Management
- Financial Planning and Reporting
- Insurance and Medicare Claims Submissions

On page 20 and in supplemental information the applicants adequately explain how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 13.

In Section I, page 20, and supplemental information the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 13.

The applicants adequately demonstrate that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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.

- (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 applicants do 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 applicants do 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

Neither of the applicants is 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

In Section K, page 22, the applicants state that the project involves renovating 2,500 square feet of existing space. Line drawings are provided in Exhibit 14.

On page 22, and in supplemental information, the applicants adequately explain how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 14.

On page 22, and in supplemental information, the applicants adequately explain 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.

On page 22, the applicants state that *“the proposed renovations are not related to any energy saving features. No energy saving options have been determined to be feasible at this time.”*

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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.

- (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

Currently the applicants provide office-based GI endoscopy services. In supplemental information, the applicants provide the historical payor mix for the office-based GI endoscopy services during CY2017 for the proposed services, as shown in the table below.

Historical Payor Mix: CY2017

Payor Category	GI Endo Room Services as Percent of Total**
Medicaid*	0.24%
Medicare*	34.64%
Charity/ Indigent Care	0.00%
TRICARE	0.41%
Self-Pay	1.76%
Insurance*	62.95%
Total	100.0%

Source: Table on page 24 of the application.

*Including any managed care.

**The GI Endo Rooms were office based and not part of an ASC.

In Section L, page 24, the applicants provide the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY 2017	Percentage of the Population of the Service Area (Rowan County 2016)
Female	56.23	50.6
Male	43.77	49.4
64 and Younger	65.77	83.7
65 and Older	34.23	16.3
American Indian	Unable to measure	0.2
Asian	Unable to measure	0.9
Black or African-American	Unable to measure	16.1
Native Hawaiian or Pacific Islander	Unable to measure	0.0
White or Caucasian	77.42	78.1
Other Race	2.58	8.1
Declined / Unavailable	20.0	0.0

The Agency reviewed the:

- Application

- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately document 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 25, the applicants state that the facility is under no obligation under any applicable federal regulations.

In Section L, page 25, the applicants state that during the last five years 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
- Supplemental information requested by the Agency
- 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.

- (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 supplemental information the applicants project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

Projected Payor Mix: OY2 (CY2020)

Payor Category	GI Endo Room Services as Percent of Total
Medicaid*	0.74%
Medicare*	35.14%
Charity Care/ Indigent	0.76%
TRICARE	0.41%
Self-Pay	1.00%
Insurance*	61.95%
Total	100.0%

Source: Table on page 25 of the application.

*Including any managed care.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 0.76% of total services will be provided to charity care/indigent patients, 35.14% to Medicare patients and 0.74% to Medicaid patients.

In supplemental information, the applicants provide 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 as shown in the applicants statement in supplemental information.

“The foregoing tabulation is based on the following assumptions: the percentages in years 2019-2020 will include a goal of 30 indigent/charity care patients per year (0.76%) and an increase of 0.5% for Medicare and 0.5% for Medicaid, which would be an increase of 20 patients per year for each one. Historically, charity/indigent care was 0% because it was included in the self-pay category and we did not track it separately. We have implemented a plan to track charity/indigent care separately in 2019. Our strategy to reach the goal of 30 indigent care patients per year is to work with the physician provider of the Community Care Clinic in Rowan County, which is a free medical care clinic. To increase the number of Medicare/ Medicaid patients, we will provide presentations and/or materials to Rowan County Senior Services and to Rowan County Public Health Department staff.”

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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.

- (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.5, page 25, the applicants adequately describe the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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.

- (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 26, and supplemental information, the applicants describe 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 17.

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicants adequately demonstrate 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 applicants propose to develop a new ASC with two GI endoscopy rooms.

The 2018 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) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicants projects to serve patients. In supplemental information the applicants define the primary service area as Rowan County. Thus, the service area for this facility consists of Rowan County. Facilities may also serve residents of counties not included in their service area.

Pursuant to the 2018 State Medical Facilities Plan, Table 6F: Endoscopy Room Inventory, page 90, currently only one facility has licensed GI Endoscopy Rooms in the applicants service area of Rowan County as illustrated in the table below.

Existing Facilities	# of Endoscopy Rooms	# of Patients	# of GI Procedures
Novant Health Rowan Regional Medical Center	4	1,876	2,025

In Section N, page 27, the applicants describe 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. On page 27, the applicants state

“The endoscopy facility will provide increased access to physician office-based procedures and will offer lower cost, more easily accessible, and high quality, safe patient care. Physician office based procedures are clearly the least expensive facility setting for both the patient and insurance payers [sic].”

The applicants adequately describe the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application, any exhibits and supplemental information)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application, any exhibits and supplemental information)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Supplemental information requested by the Agency
- 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 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.

NA

In Section O, page 28, the applicants state that neither it nor any related entities own or manage any other licensed health care facilities in North Carolina.

The applicants are ultimately controlled by two gastroenterology physicians, Dr. Vineet Korrapti and Dr. Kiran Jagaralamudi, who have been operating an office-based endoscopy center since 2013. The application states that “*Quality of healthcare services is evident with the successful completion of the AAAHC [Accreditation Association for Ambulatory Healthcare] survey in 2017.*” The accreditation is good for three years. (See pages 5-7)

Therefore, Criterion (20) is not applicable to this review.

- (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

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

.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 applicants do 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- In supplemental information, the applicants state that they project to perform an average of 2,135 GI-Endo procedures in the proposed facility during the second year of operation following completion of the project. Neither the applicants nor any related entities own any other licensed facilities in the proposed service area.
- (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 C, page 12, Exhibit 5 and supplemental information, the applicants state that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at the proposed Rowan Endoscopy Center.
- (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- In Section C, page 12, and supplemental information, the applicants state that neither they nor any related entities own any inpatient operating rooms, outpatient operating rooms or shared operating rooms either currently or within the last 12 months.

(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- In Section Q, page 31, Exhibit 4 and supplemental information, the applicants provide 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.