

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 28, 2017

Findings Date: July 28, 2017

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: E-11347-17

Facility: Gastroenterology Associates

FID #: 061239

County: Catawba

Applicants: Gastroenterology Associates, P.A.

Gastrocorp, LLC

Project: Develop two additional GI endoscopy procedure rooms in an existing facility for a total of five GI endoscopy procedure rooms upon project completion

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Gastroenterology Associates is an existing ambulatory surgical facility with three licensed gastrointestinal (GI) endoscopy procedure rooms located in Hickory, in Catawba County. The applicants, Gastroenterology Associates P.A. (GAPA) and Gastrocorp, LLC (Gastrocorp) propose to develop two additional licensed GI endoscopy procedure rooms for a total of five licensed GI endoscopy procedure rooms upon project completion. The total cost for the proposed project is \$1,593,734.

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 2017 State Medical Facilities Plan (SMFP). In addition, no policies in the 2017 SMFP are applicable to this review. Therefore, this criterion is not applicable in 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- (2) Repealed effective July 1, 1987.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

Gastroenterology Associates is an existing ambulatory surgical facility located in Hickory, Catawba County, which operates three licensed GI endoscopy procedure rooms. The applicants propose to develop two additional licensed GI endoscopy procedure rooms for a total of five licensed GI endoscopy procedure rooms upon project completion.

Patient Origin

The 2017 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) defines the service area as the geographical area, as defined by the applicants using county lines, from which the applicants project to serve patients. Therefore, the primary service area for this review, as defined by the applicants on page 37, is Caldwell and Catawba counties. On page 38, the applicants define the secondary service area as Alexander, Ashe, Avery, Burke, Cleveland, Gaston, Iredell, Lincoln, McDowell, Mecklenburg, Rutherford, Watauga, and Wilkes counties. The applicants may also serve residents of counties not included in their service areas.

In Sections III.6 and III.7, pages 54-55, the applicants provide the current and projected patient origin for GI endoscopy services provided at Gastroenterology Associates, as illustrated in the following table:

Gastroenterology Associates Current & Projected Patient Origin by County				
County	Historical Patient Origin (FFY 2016)		Projected Patient Origin (FFY 2020)	
	# of Patients	% of Patients	# of Patients	% of Patients
Catawba	4,653	58.76%	5,244	60.31%
Caldwell	1,098	13.87%	1,184	13.61%
Lincoln	695	8.78%	725	8.33%
Alexander	592	7.48%	699	8.04%
Burke	588	7.43%	553	6.36%
Iredell	44	0.56%	49	0.56%
Gaston	64	0.81%	48	0.55%
Cleveland	34	0.43%	47	0.54%
Watauga	53	0.67%	37	0.43%
Wilkes	22	0.28%	25	0.29%
McDowell	12	0.15%	16	0.19%
Mecklenburg	13	0.16%	14	0.16%
Rutherford	4	0.05%	7	0.08%
Ashe	9	0.11%	6	0.07%
Avery	7	0.09%	5	0.06%
Other	40	0.51%	37	0.43%
Total	7,919	100.00%	8,695	100.00%

On page 54, the applicants state that since patient origin fluctuates from year to year, the projections are based on the six-year history of patient origin. The applicants adequately identify the population proposed to be served.

Analysis of Need

In Section III.1, pages 33-44, the applicants describe the factors which they state support the need for the proposed project, including:

- As of March 2017, the waiting time for non-emergency GI endoscopy services at Gastroenterology Associates was three months, which the applicants state translates to approximately 1,880 patients waiting at any given time. The applicants also state that for the last six years they have exceeded the regulatory performance standard promulgated in 10A NCAC 14C .3903 of 1,500 procedures annually per procedure room, and in supplemental information received July 18, 2017, the applicants state that the six year compound annual growth rates (CAGRs) for cases and procedures was 3.02 percent and 2.72 percent, respectively.
- While the incidence of colorectal cancer has been slightly declining in recent years, according to the North Carolina Center for Health Statistics (NCCHS), including in the applicants' primary and secondary service areas, the number of survivors of colorectal cancer is increasing, which means more screenings. Additionally, the use rates for GI endoscopy rooms statewide, per the 2013-2017 SMFPs, has been steadily increasing over time (pages 37-40).

- The area population is growing. According to the North Carolina Office of State Budget and Management (NC OSBM), both counties in the applicants' primary service area and all but two counties in the applicants' secondary service area are forecasted to have increases in the population ages 50-74 years, the years during which annual screening for colorectal cancer is suggested (pages 40-42).
- Risk factors for colorectal cancer in the population of both the primary and secondary service areas are at or above the statewide average in four critical categories (pages 42-44).

In summary, the applicants adequately demonstrate the need for two additional licensed GI endoscopy procedure rooms at Gastroenterology Associates.

Projected Utilization

In Section IV.1, page 60, the applicants provide projected utilization as shown in the following table.

Gastroenterology Associates – Projected Utilization Operating Years 1-3						
	CY 2016 (Historical)	CY 2017 (Interim)	CY 2018 (Interim)	CY 2019 (OY1)	CY 2020 (OY2)	CY 2021 (OY3)
# of Rooms	3	3	3	5	5	5
# of Procedures	9,218	9,218	9,218	10,090	10,121	10,151
# of Cases	7,906	7,906	7,906	8,699	8,725	8,751

As shown in the table above, the applicants project to be performing 10,121 GI endoscopy procedures in five GI endoscopy rooms during the second year following project completion, or 2,024 procedures per room. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

In Section III.1(b), page 46, and supplemental information received July 12, 2017 and July 18, 2017, the applicants provide the methodology they used to make the above projections, summarized below:

- Convert fiscal year numbers to calendar year numbers by assuming procedures were distributed evenly throughout the year, then taking 75 percent of the current fiscal year's procedures and adding to that 25 percent of the following fiscal year's procedures.
- Keep procedures and cases constant in CYs 2016-2018.
- Convert cases to procedures by multiplying the number of cases by 1.16, which is the procedure per case ratio for FY 2016.
- Increase procedures for CY 2019 by 0.30 percent, which the applicants state is more conservative than the compound annual growth rate (CAGR) for ages 50-74 in the primary service area.

- Add 40 percent of the existing waiting list to the CY 2019 projections and assume that due to patient choice, this eliminates the waiting list.
- Increase procedures in CYs 2020 and 2021 by 0.30 percent as above.

Additionally, in FY 2015, the most recent year for which the applicants could provide data, the applicants performed enough procedures to support five licensed GI endoscopy procedure rooms and still exceed the performance threshold required (8,812 procedures / 5 GI endoscopy procedure rooms = 1,762 procedures per room).

Projected utilization of GI endoscopy procedures is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section VI.2, page 69, the applicants state that Gastroenterology Associates has an unwritten policy not to discriminate against medically underserved patients, which includes medically indigent, uninsured, and underinsured patients. The applicants state that Gastroenterology Associates is certified for and accepts both Medicare and Medicaid patients. In Section VI.12, page 76, the applicants state that 37.64 percent of the patients who received services at Gastroenterology Associates had some or all of their services paid for by Medicare or Medicaid in CY 2016. In Section VI.14, page 77, the applicants project that 40.14 percent of the patients who will receive treatments at Gastroenterology Associates in the second operating year (CY 2020) will have some or all of their services paid for by Medicare or Medicaid. The applicants state that the projected payor mix is based on the historical payor mix and the only projected change is an increase in Medicare replacement plans (with a corresponding decrease in Blue Cross Blue Shield plans) because of the aging population.

The applicants adequately demonstrate the extent to which all residents of the service area, including underserved groups, are likely to have access to the services proposed.

Conclusion

In summary, the applicants adequately identify the population to be served, demonstrate the need the population has for two additional licensed GI endoscopy procedure rooms, and demonstrate the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, the application is conforming to this criterion.

- (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.

- (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

In Section III.8, pages 56-58, the applicants discuss the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicants state that the current space is over-utilized by the state's definition of capacity and that there is a three-month waiting list that maintaining the status quo would not resolve. Therefore, this is not an effective alternative.
- Increase Hours of Operation/Days Per Week – the applicants state that earlier hours would require patients to begin preparing earlier in the day for their procedures, which may be difficult for patients who have to work, or may result in longer periods of fasting for patients, which decreases patient comfort and satisfaction. Additionally, physician schedules may not allow for extended hours, and there would be an increase in operating costs due to payment differentials for different shifts. Therefore, this is not an effective alternative.
- Build a New Facility with Additional Rooms – the applicants state that this option would be considerably more expensive as well as requiring it to move to a location away from where patients have been coming for the last 20 years. It is also across the street from a hospital in its current location. Therefore, this is not an effective alternative.
- Expand by More/Less GI Endoscopy Procedure Rooms – the applicants state that the current volume at Gastroenterology Associates could support three additional GI endoscopy procedure rooms, but that there would be higher costs and there are space restraints in the current facility. The applicants state that adding only one GI endoscopy procedure room would not be helpful to meeting the patient needs and still limit flexibility. Therefore, this is not an effective alternative.
- Direct Patients to Hospital-Based GI Endoscopy Procedure Rooms – the applicants state that this option would result in an inconvenience to patients and physicians as well as increase the costs that patients are responsible for. Therefore, this is not an effective alternative.

The applicants state that adding two additional rooms can be done in a way that maximizes efficient patient and staffing flow, can be done without disrupting current operations, is cost-effective, and provides sufficient space to accommodate growth; thus, according to the applicants, the proposed alternative is the most effective alternative.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

- 1. Gastroenterology Associates, P.A. and Gastrocorp, LLC shall materially comply with all representations made in the certificate of need application and supplemental information received July 12, 2017 and July 18, 2017. In those instances where representations conflict, Gastroenterology Associates, P.A. and Gastrocorp, LLC shall materially comply with the last made representation.**
 - 2. Gastroenterology Associates, P.A. and Gastrocorp, LLC shall develop no more than two additional licensed gastrointestinal endoscopy procedure rooms and shall be licensed for a total of no more than five gastrointestinal endoscopy procedure rooms at Gastroenterology Associates following project completion.**
 - 3. Gastroenterology Associates, P.A. and Gastrocorp, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
 - 4. For the first two years of operation following completion of the project, Gastroenterology Associates, P.A. and Gastrocorp, LLC shall not increase actual private pay charges more than 5% of the projected private pay charges provided in Section X 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.**
 - 5. Gastroenterology Associates, P.A. and Gastrocorp, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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 two additional licensed GI endoscopy procedure rooms for a total of five licensed GI endoscopy procedure rooms upon project completion.

Capital and Working Capital Costs

In Section VIII.2, pages 88-91, the applicants state that the projected capital cost is \$1,593,734. GAPA's proposed capital expenditure will include \$970,861 for equipment and \$24,272 for

contingency funding, while Gastrocorp's proposed capital expenditure will include \$420,450 for construction, \$10,000 for IT wiring, \$79,932 in consultant fees, and \$88,220 in financing, interest, and contingency funding. In Section IX, page 96, the applicants state that because Gastroenterology Associates is currently open and operating three licensed GI endoscopy procedure rooms, they do not anticipate any additional working capital requirements for the proposed project.

Availability of Funds

In Section VIII.3, page 92, the applicants state that bank loans are being used to finance the proposed project. Exhibit 13 contains two letters from the same Senior Vice President of First Citizens Bank, both dated May 8, 2017, which offer to provide up to \$1,000,000 in loans to GAPA and up to \$600,000 in loans to Gastrocorp. Exhibit 14 contains amortization schedules for the proposed loans. The applicants adequately demonstrate the availability of funds for the capital needs of the project.

Financial Feasibility

The applicants provide pro forma financial statements for the first three full fiscal years of operation following completion of the project. In the pro forma financial statement (Form B), the applicants project that operating expenses will exceed revenues in the first two operating years of the project, but revenues will exceed operating expenses in the third operating year of the project. In supplemental information received July 18, 2017, the applicants projected utilization and provided corresponding pro forma financial statements for two additional full fiscal years of operation following completion of the project to demonstrate a continued trend of revenues exceeding expenses. Information from both sets of pro formas is shown in the table below.

Projected Revenues and Operating Expenses – Operation Years 1-5 (CYs 2019 – 2023)					
Gastroenterology Associates	OY 1 CY 2019	OY 2 CY 2020	OY 3 CY 2021	OY 4 CY 2022	OY 5 CY 2023
Total Number of Cases	8,699	8,725	8,751	8,777	8,803
Gross Patient Revenue	\$7,708,559	\$7,886,477	\$8,068,503	\$8,254,229	\$8,444,571
Deductions from Gross Patient Revenue	\$3,958,518	\$4,055,775	\$4,149,386	\$4,244,899	\$4,337,875
Net Patient Revenue	\$3,750,041	\$3,830,702	\$3,919,117	\$4,009,330	\$4,101,785
Average Net Revenue per Case	\$431.09	\$439.05	\$447.85	\$456.80	\$465.95
Total Operating Expenses	\$3,804,471	\$3,837,890	\$3,871,587	\$3,905,529	\$3,939,766
Average Operating Expenses per Case	\$437.35	\$439.87	\$442.42	\$444.97	\$447.55
Net (Loss)/Profit	(\$54,430)	(\$7,188)	\$47,530	\$103,800	\$162,019

The applicants' projections of cases and revenues are reasonable based on the number of cases projected for the first five operating years. See the pro formas section 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. 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.

Conclusion

In summary, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable and adequately supported assumptions regarding projected utilization, revenues (charges), and operating costs. Therefore, the application is conforming to this criterion.

- (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

Gastroenterology Associates is an existing ambulatory surgical facility located in Hickory, Catawba County, which operates three licensed GI endoscopy procedure rooms. The applicants propose to develop two additional licensed GI endoscopy procedure rooms for a total of five licensed GI endoscopy procedure rooms upon project completion.

The 2017 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) defines the service area as the geographical area, as defined by the applicants using county lines, from which the applicants project to serve patients. Therefore, the primary service area for this review, as defined by the applicants on page 37, is Caldwell and Catawba counties. On page 38, the applicants define the secondary service area as Alexander, Ashe, Avery, Burke, Cleveland, Gaston, Iredell, Lincoln, McDowell, Mecklenburg, Rutherford, Watauga, and Wilkes counties. The applicants may also serve residents of counties not included in their service areas.

Gastroenterology Associates is one of four providers of GI endoscopy services in hospitals or ambulatory surgical facilities in its defined service area. The table below lists information about all providers of GI endoscopy services in the applicants' identified service area (taken from Table 6E, pages 84-85, of the 2017 SMFP).

GI Endoscopy Service Providers in Caldwell & Catawba Counties				
FY 2015 Data				
Provider	County	Type of Facility	# of Endoscopy Rooms	# of Procedures
Caldwell Memorial Hospital	Caldwell	Hospital	2	1,383
Catawba Valley Medical Center	Catawba	Hospital	2	2,308
Frye Regional Medical Center	Catawba	Hospital	2	2,413
Gastroenterology Associates	Catawba	Freestanding	3	8,812
Total			9	14,916

Gastroenterology Associates is the only freestanding GI endoscopy provider in its service area. Its procedure volume is higher than all three hospital-based providers of GI endoscopy procedures combined. In Section III.9, page 59, the applicants state that hospital-based providers of GI endoscopy services bill at hospital outpatient rates and that private GI endoscopy centers are more efficient and cost-effective for outpatient procedures.

The applicants state that the need for two additional licensed GI endoscopy procedure rooms is based on increasing utilization. In FY 2015, the applicants performed enough procedures to support five licensed GI endoscopy procedure rooms and still exceed the performance threshold required (8,812 procedures / 5 GI endoscopy procedure rooms = 1,762 procedures per room). The applicants project to be performing 10,121 GI endoscopy procedures in five GI endoscopy rooms during the second year following project completion, or 2,024 procedures per room. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

The applicants adequately demonstrate the need to develop two additional licensed GI endoscopy procedure rooms based on the number of patients they currently serves and propose to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicants adequately demonstrate that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the defined service area. Consequently, the application is conforming to this criterion.

- (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 Sections VII.1 and VII.2, pages 78-79, the applicants provide the current and proposed staffing for its GI endoscopy services for the second full project year, CY 2020, as illustrated in the table below:

Gastroenterology Associates Staffing Current & Projected (Second Project Year)			
Position	Current Staff (FTEs)	Projected Staff Additions (FTEs)	Total Projected Staff (FTEs) Project Year 2 CY 2020
Administrator	1	0	1
Registered Nurses (RNs)	5	3	8
Nursing Aides/Orderlies/Attendants	8	2	10
Surgical Technicians	2	5	7
Non-health/technical personnel	3	3	6
Totals	19	13	32

Gastroenterology Associates will add three registered nurses, two nursing aides/orderlies/attendants, five surgical technicians, and three non-health/technical personnel members to its staff to accommodate the proposed project. In Section VII.3, page 80, the applicants discuss the reasons they believes they will be able to recruit all necessary staff. In Section VII.8, page 83, the applicants state that there are currently eight board certified gastroenterologists on their staff and that they are beginning the recruitment process for one

additional physician. In Section VII.9, page 84, the applicants identify Dr. Siddharth Sura, MD, MPH, as the medical director of the facility. Exhibit 4 contains a letter dated May 15, 2017 from Dr. Sura, indicating willingness to continue to serve as the role of medical director and expressing support for the proposed project. Exhibit 9 contains letters of support from local physicians.

The applicants adequately document the availability of sufficient health manpower and management personnel to staff the proposed GI endoscopy procedure rooms at Gastroenterology Associates. Therefore, the application is conforming to this criterion.

- (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 II.2, pages 23-24, the applicants discuss all of the ancillary and support services they provide and will continue to provide for the proposed GI endoscopy services. A table is provided on page 23 that lists all of the services needed and indicates the in-house staff and contracted providers who will provide each of the services. Exhibit 5 contains a letter dated May 15, 2017 from the Chief Executive Officer of Gastroenterology Associates, detailing a list of ancillary and support services currently available at Gastroenterology Associates, and committing to continue provision of these services following project completion. The applicants adequately demonstrate the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing healthcare system. Therefore, 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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;

- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

C

The applicants propose to renovate 4,310 square feet in existing leased space to accommodate the two new GI endoscopy procedure rooms. In Section XI.8, page 106, the applicants describe the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. In Exhibit 17, the applicants provide a letter from a construction company quoting the price for the project as \$420,450, as well as seven percent of that as the cost of consultant fees, which corresponds to the projected capital costs in Section VIII.2, page 91. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicants adequately demonstrate that the cost, design, and means of construction represent the most reasonable alternative, and that the construction cost will not unduly increase costs and charges for health services. Therefore, 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

In Section VI.12, page 76, the applicants report that 37.64 percent of the patients who received services at Gastroenterology Associates had some or all of their services paid for by Medicare or Medicaid in CY 2016. The historical payor mix for patients is shown in the table below.

Gastroenterology Associates Historical Payor Mix – CY 2016	
Payor	% of Procedures
Self-Pay	0.52%
Commercial Insurance	13.43%
Medicare	23.13%
Medicare Replacement	12.12%
Medicaid	2.39%
Blue Cross Blue Shield	37.71%
United Healthcare	10.60%
Charity	0.11%
Total	100.01%

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicants' primary service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Caldwell	18%	51%	12%	19%	14%	20%
Catawba	16%	51%	23%	16%	9%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicants' current payor mix would be of little value. The population data by age, race, or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicants demonstrate that they currently provides adequate access to medically underserved populations. 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service, and access by minorities and handicapped persons. In Section VI.11, page 75, the applicants state that they have no obligation to provide uncompensated care or community service under federal regulations. In Section VI.10, page 75, the

applicants state there have been no civil rights access complaints filed within the last five years. Therefore, the application is conforming to this criterion.

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

C

In Section VI.14, page 77, the applicants project that 40.14 percent of the patients who will receive treatments at Gastroenterology Associates in the second operating year (CY 2020) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility.

Gastroenterology Associates Historical Payor Mix – CY 2016	
Payor	% of Procedures
Self-Pay	0.52%
Commercial Insurance	13.43%
Medicare	23.13%
Medicare Replacement	14.62%
Medicaid	2.39%
Blue Cross Blue Shield	35.21%
United Healthcare	10.60%
Charity	0.11%
Total	100.01%

On page 77, the applicants state that they do not project any significant difference in the historical payor mix, with the exception of an increase in Medicare Replacement as the population in the service area ages, and a corresponding decrease in Blue Cross Blue Shield.

The applicants demonstrate that medically underserved groups will have adequate access to the services offered at Gastroenterology Associates. Therefore, 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 VI.9, pages 73-75, the applicants describe the range of means by which a person will have access to the GI endoscopy services at Gastroenterology Associates, including self-referral and referrals from physicians at several types of medical practices. The applicants adequately demonstrate that the facility will offer a range of means by which patients will have access to GI endoscopy services. Therefore, 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.

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In Section V.1, page 62, the applicants state that they have initiated development of new affiliations and relationships with area medical schools. The applicants state that there are few health training programs at local community colleges, and that thus far there has not been any interest from training programs, but that high schools and community colleges in the area will have the option to rotate students through the physician practice and GI endoscopy center for health training purposes if requested. Exhibit 8 contains letters from the CEO of Gastroenterology Associates to Wake Forest University, Duke University, and Lenoir Rhyne University, offering the facility for use by their health professional training programs. The information provided by the applicants is reasonable and credible and supports a finding of conformity 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.

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Gastroenterology Associates is an existing ambulatory surgical facility located in Hickory, Catawba County, which operates three licensed GI endoscopy procedure rooms. The applicants propose to develop two additional licensed GI endoscopy procedure rooms for a total of five licensed GI endoscopy procedure rooms upon project completion.

The 2017 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) defines the service area as the geographical area, as defined by the applicants using county lines, from which the applicants project to serve patients. Therefore, the primary service area for this review, as defined by the applicants on page 37, is Caldwell and Catawba counties. On page 38, the applicants define the secondary service area as Alexander, Ashe, Avery, Burke, Cleveland, Gaston, Iredell, Lincoln, McDowell, Mecklenburg, Rutherford, Watauga, and Wilkes counties. The applicants may also serve residents of counties not included in their service areas.

Gastroenterology Associates is one of four providers of GI endoscopy services in hospitals or ambulatory surgical facilities in its defined service area. The table below lists information about all providers of GI endoscopy services in the applicants' identified service area (taken from Table 6E, pages 84-85, of the 2017 SMFP).

GI Endoscopy Service Providers in Caldwell & Catawba Counties (FY 2015 data)				
Provider	County	Type of Facility	# of Endoscopy Rooms	# of Procedures
Caldwell Memorial Hospital	Caldwell	Hospital	2	1,383
Catawba Valley Medical Center	Catawba	Hospital	2	2,308
Frye Regional Medical Center	Catawba	Hospital	2	2,413
Gastroenterology Associates	Catawba	Freestanding	3	8,812
Total			9	14,916

Gastroenterology Associates is the only freestanding GI endoscopy provider in its service area. Its procedure volume is higher than all three hospital-based providers of GI endoscopy procedures combined. In Section III.9, page 59, the applicants state that hospital-based providers of GI endoscopy services bill at hospital outpatient rates and that private GI endoscopy centers are more efficient and cost-effective for outpatient procedures.

The applicants state that the need for two additional licensed GI endoscopy procedure rooms is based on increasing utilization. In FY 2015, the applicants performed enough procedures to support five licensed GI endoscopy procedure rooms and still exceed the performance threshold required (8,812 procedures / 5 GI endoscopy procedure rooms = 1,762 procedures per room). The applicants project to be performing 10,121 GI endoscopy procedures in five GI endoscopy rooms during the second year following project completion, or 2,024 procedures per room. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

In Section V.7, pages 66-67, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicants state that it will reduce patient wait times and have lower charges than hospital-based GI endoscopy procedures. On page 66, the applicants state: "..., the difference in payments using Medicare as an example can be approximately 66 percent more at the hospital, depending on the specific procedure."

See also Sections II, III, V, VI, and VII of the application where the applicants discuss the impact of the project on cost effectiveness, quality, and access.

The information provided by the applicants in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality, and access to GI endoscopy services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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.

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Gastroenterology Associates is certified for Medicare and Medicaid participation, is accredited by the American Association for Ambulatory Health Care, and has been recognized by the American Society for Gastrointestinal Endoscopy for outstanding measures of quality and safety. In Section I.13, page 16, the applicants state that they currently own, lease, or manage only one GI endoscopy center in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of the application through the date of the decision no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, all facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicants and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the existing facility, the applicants provide 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.

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The application is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities 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 applicants do not propose to operate any surgical operating rooms. In Section II, page 29, the applicants state that Gastroenterology Associates hours of operation are 6:30 a.m. to 4:00 p.m. Monday through Friday, 52 weeks per year, with the exception of seven days for holidays.

(b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy 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 Section IV, page 60, and supplemental information received July 12, 2017 and July 18, 2017, the applicants project that Gastroenterology Associates will perform 10,121 GI endoscopy procedures during Project Year Two, CY 2020, using five licensed GI endoscopy procedure rooms, which is an average of 2,024 procedures per room (10,121 procedures / 5 GI endoscopy procedure rooms = 2,024 procedures per room).

The applicants provide the assumptions and methodology used to project utilization in Section III.1(b), pages 45-49, and supplemental information received July 12, 2017 and July 18, 2017. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

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

-C- In Section II, page 30, the applicants state they currently provide and will continue to provide upper endoscopy, esophagoscopy, and colonoscopy procedures upon project completion.

- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy 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 endoscopy 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 endoscopy 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 endoscopy 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.*
- NA- The applicants do not own or operate any surgical operating rooms in the service area.
- (e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*
- C- The applicants provide the assumptions and methodology used to project utilization in Section III.1(b), pages 45-49, and supplemental information received July 12, 2017 and July 18, 2017. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.