

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: February 28, 2018

Findings Date: March 5, 2018

Project Analyst: Tanya S. Rupp

Assistant Chief: Lisa Pittman

Project ID #: G-11442-17

Facility: Kernersville Endoscopy Center

FID #: 170526

County: Forsyth

Applicant: Gastroenterology Associates of the Piedmont, PA

Project: Relocate two existing GI endoscopy rooms from Piedmont Endoscopy Center in Winston-Salem to a new ambulatory surgical facility with two endoscopy procedure rooms in Kernersville

### 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 of the Piedmont, PA (GAP), the applicant, proposes to relocate two existing gastrointestinal endoscopy (GI endoscopy) procedure rooms from an existing facility, Piedmont Endoscopy Center (PEC) in Winston-Salem, and develop an ambulatory surgery center (ASC), Kernersville Endoscopy Center (KEC), in an existing medical office building in Kernersville. PEC is currently licensed for four GI endoscopy rooms. Following the relocation of the two rooms as proposed in this application, PEC will be licensed for two GI endoscopy rooms and KEC will be licensed for two GI endoscopy rooms. Both facilities are located in Forsyth County. In Section II.1, pages 25 - 26, the applicant states that GAP currently provides a broad array of GI endoscopy, upper endoscopy, small bowel enteroscopy and colonoscopy procedures and that no new service, equipment or types of procedures are planned or proposed for the proposed KEC ASC.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2017 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2017 State Medical Facilities Plan (SMFP)
- offer a new institutional health service for which there are any policies in the 2017 State Medical Facilities Plan (SMFP)

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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

## C

GAP, the applicant, proposes to relocate two licensed GI endoscopy procedure rooms from its existing facility in Winston-Salem, and develop KEC, an ASC in Kernersville in leased space in an existing medical office building owned by Regional Wellness, LLC, an unrelated entity.

### **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) states that “*Service Area*” means the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. Therefore, the proposed service area for this review, as defined by the applicant in Section III.6, page 74, is Forsyth, Guilford, Rockingham and Stokes counties. The applicant may also serve residents of counties not included in its proposed service area.

In Section III.1, page 47, the applicant provides current patient origin for the existing GAP facilities, and in Section III.6, page 74, the applicant projects patient origin for GI endoscopy services at KEC. The following table shows current and projected patient origin:

GASTROINTESTINAL ASSOCIATES OF THE PIEDMONT PATIENT ORIGIN (CASES) BY COUNTY			
COUNTY	CURRENT (2017)	KEC PROJECTED OY2 (CY 2020)	
	% OF PATIENTS	# OF CASES/PTS	% OF PATIENTS
Forsyth	58.03%	1,484	59.33%
Guilford	17.22%	440	17.61%
Rockingham	4.56%	101	4.04%
Stokes	10.68%	237	9.49%
Other counties	9.51%	237	9.51%
<b>Total</b>	<b>100.00%</b>	<b>2,497</b>	<b>100.00%</b>

Totals may not sum due to rounding

On page 74, the applicant states that projected patient origin is based on GAP's 2017 patient origin. The applicant adequately identifies the population proposed to be served.

### Analysis of Need

In Section III.1, pages 39 - 70, the applicant describes the factors which it states justify the need for the proposed project, including:

- Historical utilization trends at Gastrointestinal Associates of the Piedmont (page 40);
- Scheduled long-term (two year) closure of I-40 Business in Forsyth County; particularly in the Winston-Salem area (pages 41 - 43);
- GAP historical patient origin (pages 44 - 49);
- The health status of the projected population to be served relative to GI endoscopy procedures (pages 49 - 53);
- Demographic distribution and health risk factors of the population to be served by KEC (pages 53 – 57);
- Other factors such as the existence of an unmet case need in the counties to be served by KEC and the lower cost of providing GI endoscopy services in GAP facilities compared to regional averages (page 58);
- Physician letters of support documenting a commitment to continue to serve patients in the proposed location and an estimate of the number of cases that were referred to each physician in 2016 (Exhibit 10); and

The applicant adequately demonstrates the need to relocate two existing licensed GI endoscopy procedure rooms and to develop an ASC in Kernersville.

Projected Utilization

In Section IV.1, page 87, the applicant provides the calendar year (CY) projected utilization at KEC as shown in the following table.

	<b>INTERIM HALF FY (7/1/18 – 12/31/18)</b>	<b>FIRST FULL FY (CY 2019)</b>	<b>SECOND FULL FY (CY 2020)</b>	<b>THIRD FULL FY (CY 2021)</b>
# of Rooms	2	2	2	2
# of Procedures	1,449	3,009	3,121	3,233

As shown in the table above, the applicant projects to perform 3,121 GI endoscopy procedures in the two licensed GI endoscopy rooms (1,560 procedures per room) during the second year following project completion. 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 IV.1, pages 88 - 95, the applicant provides the methodology and assumptions used to make the above projections, which are summarized below:

- Step 1: The applicant analyzed historical population data of patients served at its existing locations and identified those who were closer to the Kernersville area. The applicant determined that 90.49% of all patients from Kernersville and east originated from the counties proposed to be served (Forsyth, Guilford, Rockingham and Stokes).
- Step 2: Using data from the first three quarters of 2017, the applicant annualized reported cases for all patients coming from those counties. The applicant found the following county distribution of historical patients:

**GAP Numbers of Patients by County**

COUNTY	CALENDAR YEAR		
	2015	2016	2017*
Forsyth	1,214	1,297	1,289
Guilford	342	375	383
Rockingham	78	86	101
Stokes	215	189	237
<b>Total</b>	<b>1,849</b>	<b>1,947</b>	<b>2,011</b>

\*Annualized  
 Source: table page 89

- Steps 3 - 4: The applicant developed a trendline analysis of the number of cases reported, and projected the total number of cases to be served from the four counties. Procedures were calculated using a ratio of 1.25, which the applicant developed in Step 5, below. See the following table, from page 91:

**KEC Projected Cases from Counties Served**

CASES	YEAR			
	INTERIM 2018	2019	2020	2021
Total Cases in Four Counties	2,098	2,179	2,260	2,341
Total Procedures in Four Counties	2,622	2,723	2,825	2,926

- Step 5: The applicant calculated the historical number of procedures per case by dividing the historical number of procedures by the historical number of cases. The applicant assumes the number of procedures per case (1.25) will remain constant.
- Step 6: The applicant projected the number of cases that will originate from outside the four counties, to determine a total number of cases that will be served by KEC.
- Step 7: The applicant multiplied the total number of cases projected to be served by 1.25, the number of procedures per case determined by calculations in Steps 3 and 4. The following table illustrates the projected number of procedures to be performed in each of the first three project years:

CASES	YEAR			
	INTERIM 2018	2019	2020	2021
Total Cases KEC	1,159	2,408	2,497	2,587
Total Procedures KEC	1,449	3,009	3,121	3,233

On page 93, the applicant states the utilization projections are reasonable and conservative, based on actual GAP utilization, ZIP code analysis and population growth projections.

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

**Access**

In Section III.9(b), page 83, the applicant states the project will have a positive impact on access to GI endoscopy services in Forsyth County because it offers GI endoscopy services on complex patients and offers same-day appointments, which other providers in the area do not do. Additionally, with the closure of I-40 Business by the NC DOT, the applicant will offer GI endoscopy services in an area of the county in which patients will be better served by those services. In Section VI.12 and VI.13, page 110, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, based on GAP's 2016 payor mix:

PAYOR	% OF TOTAL
Self Pay / Indigent	1.0%
Medicare / Medicare Managed Care	45.0%
Medicaid	3.0%
Managed Care	50.0%
Other	1.0%
<b>Total</b>	<b>100.0%</b>

The applicant does not define “other”

The projected payor mix is reasonable.

The Agency reviewed the:

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

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects 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.

C

The applicant proposes to relocate two existing GI endoscopy procedure rooms from Piedmont Endoscopy Center in Winston-Salem to a new facility, Kernersville Endoscopy Center in Kernersville. Both facilities are in Forsyth County.

*Table 6E: Endoscopy Room Inventory* on page 86 in the 2017 SMFP consists of data submitted by GI endoscopy services providers on their 2016 License Renewal Applications (LRAs). The Forsyth County providers and reported utilization are illustrated in the following table:

PROVIDER	LOCATION	# GI ENDO ROOMS	# PROC.	# PROC. / ROOM
Digestive Health Endoscopy Center of Kernersville	208 Broad St., Kernersville	2	3,297	1,649
Digestive Health Specialists, P.A.	2025 Frontis Plaza Blvd, Wintson-Salem	2	6,784	3,392
Gastroenterology Associates of the Piedmont (PEC)	1901 S. Hawthorne Rd., Winston-Salem	4	7,218	1,805
Gastroenterology Associates of the Piedmont (SEC)	875 Bethesda Rd., Winston-Salem	4	11,164	2,791
North Carolina Baptist Hospital	Medical Center Blvd., Winston-Salem	10	18,357	1,836
Novant Health Forsyth Medical Center	3333 Silas Creek Pkwy., Winston-Salem	4	3,137	784
Wake Forest Baptist Health Outpatient Endoscopy	101 Charlois Blvd., Winston-Salem	2	2,324	1,162
<b>Total / Average</b>		<b>28</b>	<b>52,281</b>	<b>1,867</b>

Source: 2016 License Renewal Applications and 2017 SMFP, Table 6E, page 86

According to the data, PEC performed a total of 7,218 total procedures in four GI endo rooms in FY 2015, as reported on the 2016 LRA. The *Performance Standards* in 10A NCAC 14C .3903(b) require an applicant to reasonably project to perform an average of “*at least 1,500 GI endoscopy procedures only per GI endoscopy room, in each licensed facility that the applicant or a related entity owns in the propose service area, during the second year of operation following completion of the proposed project.*” The performance standards in the Administrative Rules are a guide for minimum utilization. In FY 2015, PEC performed an average of 1,805 GI endoscopy procedures per room [ $7,218 / 2 = 1,805$ ], which is a utilization rate of 120% [ $1.805 \text{ procedures} / 1,500 = 1.20$ ]. Additionally, in Section III.1, page 40, the applicant states that in FY 2016 both PEC facilities combined performed a total of 2,343 procedures per room, which is a utilization of 156% [ $18,744 \text{ total procedures} / 8 \text{ rooms} = 2,343 \text{ average procedures per room}$ .  $2,343 / 1,500 = 1.56$ ]. According to the 2017 LRA, PEC performed 6,364 procedures in four rooms, which is 106% of the minimum utilization threshold [ $6,364 / 4 = 1,591$ ;  $1,591 / 1,500 = 1.06$ ].

Cumulatively, all of the GI endo rooms in Forsyth County performed an average of 124% utilization [ $1,867 \text{ average procedures per room} / 1,500 = 1.24$ ]. Each one of the outpatient facilities performed in excess of the minimum threshold utilization. According to MapQuest®, the two GAP facilities are one-tenth of one mile apart. In addition, the proposed MOB to which two of the four GI endo rooms are proposed to be relocated (KEC) is approximately 10.5 miles from PEC.

In Section IV.1, pages 94 – 95, the applicant discusses the impact the proposed relocation of two GI endoscopy procedure rooms to its Kernersville location will have on the remaining rooms in Winston-Salem. On page 95, the applicant states it subtracted the projected number of procedures to be performed in the proposed Kernersville facility from the number of procedures to be performed in the county, since the patients who will be served at the proposed location are GAP’s existing patients. See the following table from page 95, which summarizes these projections:

**Projected GAP Procedures Both Locations**

CASES/PROCEDURES	INTERIM (CY 2018)	CY 2019	CY 2020	CY 2021
Cases Entire Practice	15,526	15,895	16,264	16,633
Cases Kernersville	1,159	2,408	2,497	2,587
Remaining Cases Winston-Salem	14,367	13,487	13,767	14,046
Remaining Procedures Winston-Salem	18,001	16,902	17,252	17,603
Remaining Rooms Winston-Salem	6	6	6	6
Procedures / Room Required by Rules	1,500	1,500	1,500	1,500
Percent of Threshold Utilization	200%	188%	192%	196%

The GAP Winston-Salem facility will continue to have adequate capacity to meet the needs of its patients following the relocation of two GI endoscopy procedure rooms to the proposed Kernersville facility.

In Section III.1, pages 41 – 43, the applicant discusses the impact that the NC Department of Transportation’s proposal to temporarily close and renovate a portion of I-40 Business will have on the Winston-Salem area. Specifically, the applicant states that the closure of that portion of I-40 Business that flows from Winston-Salem to Kernersville will not only close off the most direct route from Kernersville to the GAP facilities in Winston-Salem, but it will also increase traffic onto the main I-40. According to the applicant on page 42: *“Together these factors will create a barrier to care at GAP’s Winston-Salem based facilities.”* Furthermore, on page 46, the applicant states that its Winston-Salem based GI endoscopy centers have historically served patients from counties that a facility based in Kernersville would better serve.

Notably, 26 of the 28 existing licensed GI endoscopy procedure rooms in Forsyth County are in Winston-Salem. Two are in Kernersville. This project seeks to relocate two existing GI endo rooms from Winston-Salem to Kernersville, such that Kernersville will then have four GI endo rooms and the remaining 24 will remain in Winston-Salem. Relocating two of the four rooms from Winston-Salem to KEC in Kernersville will not have an adverse effect on the patients currently being served at PEC in Winston-Salem.

**Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- 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 applicant adequately describes the methodology and assumptions used to project utilization.
- The applicant provides historical data, projected demographics and verifiable sources which support its projections.



- The applicant relies on historical data and its experience to project the extent to which all residents, including underserved groups, will have access to the proposed services.

Therefore, the application is conforming to this Criterion.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

#### CA

The applicant proposes to relocate two existing GI endoscopy procedure rooms from Piedmont Endoscopy Center in Winston-Salem to a new facility, Kernersville Endoscopy Center in Kernersville. Both facilities are in Forsyth County.

In Section III.8, pages 81 - 82, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo – the applicant states that while this alternative may save costs associated with relocating two GI endo rooms, it fails to address the needs of the patients who face adversity from the proposed closure of I-40 Business, and fails to address the needs of the patient population currently served at GAP's Winston-Salem facilities who could be better served in a facility in Kernersville. Therefore, the applicant does not consider maintaining status quo to be an effective alternative.
- Add rooms to PEC rather than relocate – the applicant states that adding GI procedure rooms to PEC, while addressing the historical and projected increase in utilization would not address the impending closure of I-40 Business and the resulting issues its patients will face. Therefore, the applicant does not consider this to be an 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.

#### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- 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 because the applicant adequately demonstrates 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 of the Piedmont, P.A. shall materially comply with all representations made in the certificate of need application.**
- 2. Gastroenterology Associates of the Piedmont, P.A. shall relocate no more than two licensed gastrointestinal endoscopy procedure rooms from Piedmont Endoscopy Center to Kernersville Endoscopy Center.**
- 3. Upon completion of the project, Gastroenterology Associates of the Piedmont, P.A. shall be licensed for no more than two gastrointestinal endoscopy procedure rooms at Piedmont Endoscopy Center, and no more than two gastrointestinal endoscopy procedure rooms at Kernersville Endoscopy Center.**
- 4. Gastroenterology Associates of the Piedmont, P.A. 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.**
- 5. The procedure rooms shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
- 6. Procedures performed in the procedure rooms shall not be reported for billing purposes as having been performed in an operating room and shall not be reported on the facility's license renewal application as procedures performed in an operating room.**
- 7. Gastroenterology Associates of the Piedmont, P.A. 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.**
- 8. For the first three years of operation following completion of the project, Gastroenterology Associates of the Piedmont, P.A. shall not increase charges more than 5% of the charges projected 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.**
- 9. 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, Gastroenterology Associates of the Piedmont, P.A. 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.**

**10. Gastroenterology Associates of the Piedmont, P.A. 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 applicant proposes to relocate two existing GI endoscopy procedure rooms from Piedmont Endoscopy Center in Winston-Salem to a new facility, Kernersville Endoscopy Center in Kernersville. Both facilities are in Forsyth County.

#### **Capital and Working Capital Costs**

In Section VIII.1, pages 121 - 123, the applicant states that GAP will incur the following capital costs associated with the project:

- Moveable Equipment Purchase / Lease           \$635,371
- Contingency Fee                                       \$ 75,000
- Total:   \$710,371

In Section IX.1 and IX.2, page 131, the applicant projects \$150,111 in total working capital, which includes \$57,059 in start-up expenses and \$93,051 in initial operating expenses.

On page 121, the applicant states the owner of the building will incur additional capital costs which will be incorporated into the owner's operating lease.

#### **Availability of Funds**

In Section VIII.8, page 128, the applicant states that the proposed project will be funded with a line of credit from a bank. Exhibit 17 contains a November 4, 2017 letter from the Sr. Vice

President of First Citizens Bank which states the bank has worked with GAP in the past, and GAP maintains a standing line of credit in the amount of \$1.5 million. Exhibit 17 also contains a November 15, 2017 letter signed by the CEO of GAP which commits to utilize the funds for the development of the proposal project. The applicant adequately demonstrates the availability of funds for the capital and working capital needs of the project.

### **Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation of the Kernersville facility following completion of the project. In the pro forma financial statement (Forms B and C), the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

**Kernersville Endoscopy Center, First Three Project Years**

	<b>1<sup>ST</sup> FULL FISCAL YEAR</b>	<b>2<sup>ND</sup> FULL FISCAL YEAR</b>	<b>3<sup>RD</sup> FULL FISCAL YEAR</b>
Total Procedures	3,009	3,121	3,233
Total Gross Revenues (Charges)	\$3,020,586	\$3,289,591	\$3,577,946
Total Net Revenue	\$1,294,939	\$1,370,255	\$1,448,925
Average Net Revenue per Procedure	\$430	\$439	\$448
Total Operating Expenses (Costs)	\$1,007,099	\$1,092,408	\$1,110,188
Average Operating Expense per Procedure	\$334	\$350	\$343
Net Income	\$268,548	\$256,838	\$315,885

In addition, in Form B, the applicant demonstrates the entire facility (GAP Kernersville and GAP Winston-Salem) projects that revenues will exceed operating expenses in the first three operating years of the project.

The assumptions used by the applicant 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. The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- 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 applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.
- The applicant adequately demonstrates sufficient funding for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

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

The applicant proposes to relocate two existing GI endoscopy procedure rooms from Piedmont Endoscopy Center in Winston-Salem to a new facility, Kernersville Endoscopy Center in Kernersville. Both facilities are in Forsyth County.

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 applicant using county lines, from which the applicant projects to serve patients. Therefore, the service area for this review, as defined by the applicant in Section III.6, page 74, is Forsyth, Guilford, Rockingham and Stokes counties. The applicant may also serve residents of counties not included in its proposed service area.

The 2017 SMFP, Table 6E, on page 86 lists the following providers of GI endoscopy services in Forsyth County:

**Forsyth County Providers of GI Endoscopy Services**

FACILITY	LOCATION	# OF ROOMS	# PROCEDURES
Digestive Health Endoscopy Center of Kernersville	Kernersville	2	3,297
Digestive Health Specialists, P.A.	Winston-Salem	2	6,784
Gastrointestinal Associates of the Piedmont (PEC)	Winston-Salem	4	7,218
Gastrointestinal Associates of the Piedmont (Salem EC)	Winston-Salem	4	11,164
North Carolina Baptist Hospital	Winston-Salem	10	18,357
Novant Health Forsyth Medical Center	Winston-Salem	4	3,317
Wake Forest Baptist Health Outpatient Endoscopy	Winston-Salem	2	2,324
<b>Total</b>		<b>28</b>	<b>52,281</b>

In Section III.9 (d), page 84, the applicant states that it does not expect the proposed KEC ASC project to result in the unnecessary duplication of existing resources in Forsyth County. The applicant states:

*“...procedures for patients originating from eastern areas affected by the I-40 Business closure will be diverted to the Kernersville Endoscopy Center facility for more convenient service. Because the project involves re-locating rooms and not adding or reducing inventory, this re-location will enhance rather than reduce the number of cases that the GAP practice can service.”*

This project does not propose to increase the inventory of GI endoscopy procedure rooms in Forsyth County; rather, it proposes to relocate two existing, licensed GI endoscopy procedure rooms from an area of Winston-Salem that is soon to be impacted by the North Carolina DOT’s plan to renovate I-40 Business in that area. This application proposes to relocate existing rooms to improve access to GI endoscopy services by existing and future patients who will likely be impacted by the NC DOT’s plans.

The applicant adequately demonstrates the need to develop the proposed ASC with two relocated licensed GI endoscopy rooms, based on the number of patients currently served and proposed to be served in the future. The applicant projects performing 3,121 GI endoscopy procedures in two rooms during the second full operating year following project completion, which is 1,560 procedures per room per year. 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).

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 applicant adequately demonstrates 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 Section VII.2, page 114, the applicant states it will add 3.0 registered nurses, 3.0 licensed practical nurses, 1.0 nursing aid and 1.0 front desk staff full-time equivalent (FTE) positions for the proposed licensed GI endoscopy service for the second full operating year, CY2020. The applicant states it will proportionally allocate remaining staff from existing staff positions at the two GAP locations in Winston-Salem.

The applicant discusses the availability of required personnel, stating that its HR staff retain a list of current and potential employees who are interested in GAP positions and anticipates no problems in hiring new staff. In Section VII.8, page 118, the applicant states that a total of 14 board-certified gastroenterologists are expected to utilize the facility. Exhibit 10 provides a copy of a petition/form letter signed by each physician indicating an intent to practice at KEC.

In Section VII.9, page 119, the applicant identifies Christopher Connelley, MD, as the KEC medical director.

The applicant adequately documents the availability of sufficient health manpower and management personnel to staff the proposed GI endoscopy procedure rooms at KEC. 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 Sections II.1, pages 24 - 27 and II.2, pages 28 - 29, the applicant discusses the necessary ancillary and support services it will provide for the proposed ASC. A table is provided on page 28 that lists all of the services needed and indicates the facility staff or contracted provider who will provide each of the services. Exhibit 28 contains documentation of agreements for pathology, emergency, pharmacy and anesthesia services. Exhibit 6 contains a patient transfer agreement between the applicant and Novant Health Forsyth Medical Center. In Section V.3(d), page 98, the applicant states that GAP physicians have practice privileges at area hospitals, and Table V.1 on page 99 identifies those hospitals.

In Section V.4, page 100, the applicant states that, as an established community member, GAP has long established relationships with the local healthcare community, area hospitals, homeless shelters and community agencies.

### **Conclusion**

The Agency reviewed the following:

- the application, including any exhibits and supplemental information
- 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 applicant demonstrates the availability of ancillary and support services for the proposed ASC;
- The applicant demonstrates that the proposed services will be coordinated with the existing healthcare system by providing copies of existing agreements;

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health

service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

C

The applicant proposes to develop an ASC with two licensed GI endoscopy procedure rooms in a medical office building that it will lease from a third party. Exhibit 23 contains the floor plan of the medical office building showing the firewalls and physical separation of the endoscopy suite. In Section VIII.1, page 121, the applicant states that the estimated site, construction and up fit will be incurred by the building owner.



In Exhibit 14, the applicant provides a November 8, 2017 letter from a licensed architect that states the building will be compliant with all local, state and federal requirements and that applicable energy saving features are incorporated into the renovation plans.

In Section XI.8, page 142, the applicant describes the methods that will be used by the facility to maintain efficient energy operations and contain the costs of utilities. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. The applicant adequately demonstrates 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.

### **Conclusion**

The Agency reviewed the application and exhibits. Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant demonstrates that the cost and design of the ASC represent the most reasonable alternative;
- The applicant demonstrates 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

The proposed ASC is not yet developed and thus has no current information to report. However, the applicant currently provides services in two locations in Winston-Salem; therefore, the information for those locations, reported in Section VI.12, page 109 is provided in the table below:

**GAP Payor Mix Both Facilities Calendar Year 2016**

<b>PAYOR CATEGORY</b>	<b>% OF TOTAL</b>
Self Pay / Indigent	1.0%
Medicare / Medicare Managed Care	45.0%
Medicaid	3.0%
Managed Care	50.0%
Other*	1.0%
<b>Total</b>	<b>100.0%</b>

\*"Other" was not identified by the applicant

- (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

In Section VI.11, page 109, the applicant states that GAP has no public obligations to provide uncompensated care, community service or access to care by medically underserved, minorities and handicapped persons.

- (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 110, the applicant projects that 48% of the patients who will receive services at KEC in the second operating year (CY 2020) will have some or all of their services paid for by Medicare or Medicaid, as summarized in the table below.

**Projected Payor Mix KEC, Second Full Operating Year**

<b>PAYOR CATEGORY</b>	<b>% OF TOTAL</b>
Self Pay / Indigent	1.0%
Medicare / Medicare Managed Care	45.0%
Medicaid	3.0%
Managed Care	50.0%
Other*	1.0%
<b>Total</b>	<b>100.0%</b>

\*"Other" was not identified by the applicant

On page 110, the applicant states that the above payor mix is based on GAP's historical experience.

The applicant adequately demonstrates the extent to which medically underserved groups are likely to have access to the services offered at KEC. 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 V.2(d), page 97, the applicant states that KEC will accept patient referrals from area hospitals and physicians in the community, with which GAP has existing well-established relationships. The applicant adequately demonstrates 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.

C

In Section V.1, page 96, the applicant states that KEC will serve as a clinical training site for residents in gastroenterology, physician assistant and nursing programs. The applicant further states that GAP has long-standing clinical training affiliations with Wake Forest University School of Medicine. Exhibit 9 contains a copy of a letter from the CEO of GAP to Wake Forest University, communicating the proposed new site and offering KEC to be utilized as a clinical training site. The information provided by the applicant 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.

C

The applicant proposes to relocate two existing GI endoscopy procedure rooms from an existing facility in Winston-Salem, and develop KEC, an ASC, in an existing medical office building in Kernersville.

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 applicant using county lines, from which the applicant projects to serve patients. Therefore, the service area for this review, as defined by the applicant in Section III.6, page 74, is Forsyth, Guilford, Rockingham and Stokes counties. The applicant may also serve residents of counties not included in its proposed service area.

The 2017 SMFP, Table 6E, on page 86 lists the following providers of GI endoscopy services in Forsyth County:

**Forsyth County Providers of GI Endoscopy Services**

FACILITY	LOCATION	# OF ROOMS	# PROCEDURES
Digestive Health Endoscopy Center of Kernersville	Kernersville	2	3,297
Digestive Health Specialists, P.A.	Winston-Salem	2	6,784
Gastrointestinal Associates of the Piedmont (PEC)	Winston-Salem	4	7,218
Gastrointestinal Associates of the Piedmont (Salem EC)	Winston-Salem	4	11,164
North Carolina Baptist Hospital*	Winston-Salem	10	18,357
Novant Health Forsyth Medical Center*	Winston-Salem	4	3,317
Wake Forest Baptist Health Outpatient Endoscopy	Winston-Salem	2	2,324
<b>Total</b>		<b>28</b>	<b>52,281</b>

In Section V.7, page 101, the applicant discusses how the proposed project will foster competition, stating:

*“GAP combines the latest in medical technology with leading board-certified gastroenterologists to provide quality and affordable outpatient care in a highly personalized setting. The staff is comprised of a team of experienced and highly trained nurses and support staff. In addition, the proposed project will foster competition by providing expanded access to GI endoscopy services in an effective and convenient outpatient location in Kernersville, NC.”*

In Section V.7, page 101, the applicant states the project will offer board-certified gastroenterologists and the latest medical technology to provide quality and affordable services to its patients. Additionally, the applicant states the proposed project will foster competition in the area by providing expanded access to GI endoscopy services in Forsyth County. See also Sections II, III, V, VI, and VII of the application where the applicant discusses the impact of the project on cost effectiveness, quality, and access.

The information provided by the applicant 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 applicant adequately demonstrates the need for the project and that it is a cost-effective alternative. (See Sections III, VIII and X of the application and any exhibits.)

- The applicant adequately demonstrates it will provide quality services. (See Sections I and II in the application and any exhibits.)
- The applicant demonstrates that it will provide adequate access to medically underserved populations. (See Section VI of the application and any exhibits.)

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.

C

In Section I.13(c), page 16, the applicant states that it currently operates two licensed GI endoscopy centers in North Carolina, both of which are located in Winston-Salem. In Section II.12(a), page 38, the applicant states that GAP has never had its license revoked. 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 neither facility was found to be out of compliance with one or more Medicare conditions of participation. At this time, both facilities continue to be in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at the existing facility, the applicant provides sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

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 applicant does not propose to operate any surgical operating rooms. .
- (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 III, pages 39 - 70, the applicant provides the methodology and assumptions with which it projects utilization. The applicant projects that KEC will perform 3,121 GI endoscopy procedures during CY 2020, the second year of operation, in the two licensed GI endoscopy procedure rooms at KEC, which exceeds the 1,500 procedure per GI endoscopy room requirement in the second year of operation following completion of the project [ $3,121 / 2 = 1,560$ ].
- (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 36, the applicant states:
- “GAP currently provides upper endoscopy, esophagoscopy, and colonoscopy procedures in its established facilities. It expects to provide these procedures at Kernersville Endoscopy Center.”*
- (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 applicant does 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 applicant provides the assumptions and methodology used to project utilization in Section III, pages 39 - 70. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.