ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DECISION DATE: April 5, 2013
PROJECT ANALYST: Julie Halatek
TEAM LEADER: Lisa Pittman
ASSISTANT CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: P-10071-12 / Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center / Develop a new licensed ambulatory surgery center with two GI Endoscopy rooms / Lenoir County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

The applicant, Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center (AMG), currently operates one existing unlicensed gastrointestinal room (GI endoscopy room) and a physician office located at 2541 North Queen Street in Kinston. The applicant proposes to obtain a license for an ambulatory surgical facility (ASF) for the existing functional GI endoscopy room and a second GI endoscopy room. The second room already exists but requires some additional equipment to be functional. Note: neither a license nor a certificate of need is required before the second room could be used. A certificate of need is required only because the applicant wants to obtain a license for an ASF with two GI endoscopy rooms.

The total projected capital cost for the proposal is less than two million dollars; therefore, Policy GEN-4 in the 2012 State Medical Facilities Plan (SMFP) is not applicable to this review. Furthermore, there are no other policies or need determinations in the 2012 SMFP applicable to the review of applications for GI endoscopy rooms. 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(2) Repealed effective July 1, 1987.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

AMG is an existing office-based GI endoscopy practice with one unlicensed, operational GI endoscopy room and a second room that exists but is not currently in use. To be functional, the second GI endoscopy room needs only some minor equipment. The existing office is located at 2541 North Queen Street in Kinston. The applicant proposes to develop a new ASF by obtaining a license for the two existing GI endoscopy rooms. The applicant does not need a certificate of need to develop and use the unlicensed GI endoscopy rooms. The applicant needs a certificate of need to obtain a license as an ASF.

Population to be Served

In Section III.7, page 87, the applicant provides current patient origin for its endoscopy center from March 26, 2012, when the facility opened, to October 13, 2012, as shown in the table below:

COUNTY	NO. OF PATIENTS	% OF TOTAL
Lenoir	659	42.60%
Onslow	502	32.45%
Duplin	165	10.67%
Greene	43	2.78%
Craven	32	2.07%
Carteret	31	2.00%
Pitt	31	2.00%
Wayne	29	1.87%
Jones	26	1.68%
Pender	8	0.52%
Other NC Counties*	10	0.65%
Other states**	11	0.71%
Total	1,547	100.00%

* "Other NC Counties" include Bertie, Durham, Guilford, Nash, New Hanover, Sampson, and Wilson.
* *"Other states" includes California, Florida, Georgia, Kentucky, Louisiana, New York, Ohio, Pennsylvania, and South Carolina.

In Section III.6, page 85, the applicant provides projected patient origin for the facility in Fiscal Years 2014 and 2015, as shown in the table below:

COUNTY	NO. OF PATIENTS	% OF TOTAL
Lenoir	1,182	42.60%
Onslow	900	32.45%
Duplin	296	10.67%
Greene	77	2.78%
Craven	57	2.07%
Carteret	56	2.00%
Pitt	56	2.00%
Wayne	52	1.87%
Jones	47	1.68%
Pender	14	0.52%
Other NC Counties*	18	0.65%
Other states**	20	0.71%
Total	2,775	100.00%

* "Other NC Counties" include Bertie, Durham, Guilford, Nash, New Hanover, Sampson, and Wilson.
* *"Other states" includes California, Florida, Georgia, Kentucky, Louisiana, New York, Ohio, Pennsylvania, and South Carolina.

The applicant states that its projected patient origin is based on annualizing the data from March 26, 2012 through October 13, 2012. Additionally, the applicant states that it held the number of patients constant from 2012 through 2016. The applicant states that keeping the numbers constant is a reasonable and conservative forecast, and assumes that referral patterns will stay constant, with no change in the number of physicians at the endoscopy center. The applicant states that the distribution of patients from outside the service area will vary from year to year. Finally, the applicant states that there are no known changes in the GI services provided in the service area through 2016. The applicant adequately identifies the population proposed to be served.

Demonstration of Need

In Section III.1, pages 59 – 79, the applicant describes the need for two licensed GI endoscopy procedure rooms in the Kinston area, and presents the methodology and assumptions it used to support the need. In Section III.1(a), page 59, the applicant states:

> *"In the Findings of Fact in G.S. 131E-175(11) the NC General Assembly found that: 'physicians providing gastrointestinal endoscopy services in unlicensed settings should be given an opportunity to obtain a license to provide those services to ensure the safety of patients and the provision of quality care.'"*

The applicant also states on page 60 that the need for its proposal is based on (but not limited to):

- *"The value of GI endoscopy procedures*
- *The health status and demographics of the service area*
- *Physician office based ambulatory service pricing and the role of health insurance*
- *Healthcare provider support for the project*

- *Convenient scheduling and access for outpatients*
- *The history of AMG gastroenterologists in serving the service area population at this location*
- *The need for gastroenterology services in the service area"*

In Section III.1, pages 60-61, the applicant discusses the value of GI endoscopy procedures. The applicant states that a colonoscopy is the most effective method of colon cancer screening in terms of sensitivity, specificity, and cost effectiveness. The applicant states that according to the Centers for Disease Control and Prevention, routine screening for colorectal cancer can reduce the number of deaths by at least 60 percent. Additionally, the applicant states that GI endoscopy is used for the detection and treatment of other diseases of the digestive tract, and it can be more accurate than x-rays for certain upper digestive system disorders.

On pages 61-66, the applicant discusses the health status and demographics of the service area. The applicant states that from 2004 to 2008 and in 2009, colorectal cancer was the second leading cause of cancer death in North Carolina. The applicant also states that eastern North Carolina has a higher concentration of colorectal cancer mortality than other parts of North Carolina. The applicant states that because early screening can prevent death from the associated cancers, its goal is to provide more access to screening. The applicant also states that African-Americans have a higher incidence of colorectal cancer than other populations and that there is a higher concentration of African-Americans in eastern North Carolina than in other areas of the state as well. The applicant's service area has a population of 24.5% African-American, while the statewide average is approximately 21.5% African-American (according to table III.3 on page 64 of the application). The applicant also provides the following table showing the incidence rates of colorectal cancer by county from 2004-2009:

County	**Rate per 100,000 population**
Carteret	45.0
Craven	44.5
Duplin	34.9
Greene	40.7
Jones	41.9
Lenoir	66.7
Onslow	46.1
Pender	33.7
Pitt	47.3
Wayne	52.7
North Carolina	**45.5**

*Source: Application page 64

Additionally, the applicant states that the population aged 65-75 in the proposed service area is expected to grow 17.5% from 2012 through 2016.

On pages 66-68, the applicant discusses the difference in health insurance coverage for GI endoscopy procedures depending on whether the procedure is performed in a hospital-based

facility or an outpatient ASF. The applicant states that, by way of example, Blue Cross Blue Shield of North Carolina (BCBSNC) places a much larger patient responsibility for overall costs on patients who have hospital-based GI endoscopy procedures as compared to procedures performed in an ASF. Ambulatory surgery patients are responsible only for a co-pay, whereas patients at hospital-based facilities are responsible for a deductible and co-insurance. The difference can be in the hundreds to even thousands of dollars, depending on the insurance policy. The applicant also states that the average annual income for the service area is consistently below the average for the state of North Carolina, with only Carteret County having a higher average annual income than the state average annual income.

The applicant states on page 68:

> *"On September 23, 2010, the Affordable Care Act (ACA) required private health insurers to cover recommended preventive health services without cost sharing for patients, such as copays and deductibles.*
>
> …
>
> *Payors have responded to the ACA mandate with carefully circumscribed definitions of 'screening.' As a result, many patients are still charged with copayments and deductibles for routine colonoscopies. Price remains an important consideration."*

The applicant states on page 41 that the AMG physician practice is currently certified by Medicare and Medicaid. The applicant also states on page 68:

> *"Medicare and Medicaid, who represent a substantial portion of AMG patients, require that such a facility be licensed."*

The applicant states on page 88:

> *"Patients and payors favor the lower charges at freestanding ambulatory surgery centers and some payors, like Medicare and Medicaid, require a license as a precondition to payment."*

The applicant further states on page 122:

> *"Because AMG will receive better reimbursement from certain payors once it is licensed, the applicant believes it is reasonable to assume that it will be able to accommodate more self-pay/indigent, Medicare and Medicaid patients upon being licensed."*

N.C.G.S. 131E-175(11) states:

> *'physicians providing gastrointestinal endoscopy services in unlicensed settings should be given an opportunity to obtain a license to provide those services to ensure the safety of patients and the provision of quality care.'*

By obtaining a license for its unlicensed GI endoscopy rooms, the ASF will be required to participate in the Medicare and Medicaid programs and must comply with the Center for Medicare and Medicaid Services' (CMS) Conditions of Participation and to obtain accreditation of the facility from a recognized accrediting body. Additionally, the applicant will be required to meet minimal licensure requirements and life safety requirements which will enhance the safety of the proposed facility. The facility will be subject to inspections by the Construction Section and surveys by the Acute Home Care Licensure and Certification Section in the Division of Health Service Regulation. Thus, patients will have assurance of safety and quality care.

Utilization

On pages 96-100, the applicant discusses historical utilization of the existing GI endoscopy room at AMG. On page 97, the applicant states that its projected utilization is based on the number of procedures performed in 2012 (annualized based on actual procedures performed between March 26, 2012 and October 13, 2012), which was 4,702 procedures. Based on the performance standard promulgated in N.C.G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility is currently operating at 313.5% of capacity [4,702 / 1,500 = 3.135]. Historical and projected utilization are illustrated in the table below:

Historical and Projected Utilization

Year	# of Rooms	# of Procedures**	Percent of Capacity***
3/26/12 – 10/13/12*	1	2,622	NA
CY 2012 (annualized)	1	4,702	313.5%
CY 2013	2	4,702	156.7%
CY 2014 (Year 1)	2	4,702	156.7%
CY 2015 (Year 2)	2	4,702	156.7%
CY 2016 (Year 3)	2	4,702	156.7%

* 29 weeks
** From Section IV, page 96
*** Calculated as follows: # of procedures / 1,500

The applicant's existing GI endoscopy room is currently operating at 313.5% of the minimum performance standard promulgated in 10A NCAC 14C .3903(b) and N.C.G.S. 131E-182(a) [4,702 / 1,500 = 313.5%]. Even if the applicant were already using the second room requested in this application, the facility would be operating at 157% of the minimum performance standard [4,702 / 3,000 = 157%]. Indeed, the facility is already performing enough procedures to justify three GI endoscopy rooms [4,702 / 1,500 = 3.135].

To project future utilization at AMG, the applicant held the annualized number of procedures performed at the facility in CY 2012 constant over the next three years. In Exhibit 42, the applicant provides letters of support from 19 area physicians. These physicians collectively project 5,307 referrals to AMG in Project Year Two. Projected utilization is based on reasonable, credible and supported assumptions, including historical utilization and the physician letters in Exhibit 42.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population proposed to be served has for two licensed GI endoscopy rooms which will ensure patient safety and quality care. Consequently, 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.

NA

(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 88-91, the applicant describes the alternatives considered, which include: 1) maintain the status quo; 2) develop a joint venture with another provider; 3) choose a different location; 4) develop a virtual colonoscopy screening center; and 5) develop a one room ASF for GI endoscopy. The applicant states that maintaining the status quo is not an effective alternative as it is no longer *"cost effective or convenient"* for patients and physicians to have outpatient GI endoscopy procedures done at hospitals. Additionally, maintaining the status quo, according to the applicant, would limit the applicant's ability to serve all the population in need in the service area because maintaining the status quo would not allow the applicant to be certified for Medicaid or Medicare.

The applicant states that a joint venture with another provider was not a feasible option. The applicant was affiliated with Kinston Medical Specialists, a GI endoscopy center in the same city, until 2010. The applicant states it was unable to negotiate ownership with the facility and wanted ownership in order to have more oversight on the scope and type of services.

Choosing a different location was ruled out as less effective and more costly. The proposed location is in the same building as the AMG physician office. Keeping the location the same saves on costs associated with travel, staffing, and construction. Additionally, the current location of AMG is approximately two minutes from Lenoir Memorial Hospital according to the applicant (and observed by the project analyst on a site visit on January 17, 2013) where the physician who owns the applicant has privileges. This also facilitates emergency care should it be necessary.

The applicant also considered a virtual colonoscopy screening center. However, according to the applicant, this would not necessarily be less expensive; is not Medicare approved; and only addresses screening for certain conditions—not treatment of those conditions. The applicant considered, as well, obtaining a license for just the functional room. While thus far

the applicant has operated with only one room, the applicant notes that it performed 4,702 procedures in CY 2012 (annualized, based on actual procedures performed between March 26, 2012 and October 13, 2012), which exceeds the minimum performance standard for two GI endoscopy rooms (3,000 procedures per year; 1,500 per year per room). The applicant states on page 91 of the application that the number of procedures is more flexibly accommodated by two GI endoscopy rooms. The second room needs only minor equipment to be functional.

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

The applicant adequately demonstrates that the proposal to develop a new licensed ambulatory surgical facility by obtaining a license for the two existing rooms is its most effective or least costly alternative. Consequently, the application is conforming to this criterion, and is approved subject to the following conditions:

1. **Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center shall materially comply with all representations made in the certificate of need application.**

2. **Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center 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.**

3. **Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center shall develop an ambulatory surgical facility with no more than two gastrointestinal endoscopy rooms and shall be licensed for no more than two gastrointestinal endoscopy rooms upon project completion.**

4. **Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center shall prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.**

5. **The facility fee charged by Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center shall be no more than $1,056 during the first three operating years of the licensed ambulatory surgical facility.**

6. **Atlantic Medical Group, P.C. d/b/a AMG Endoscopy Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the 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

In Section VIII.1, page 135, the applicant projects that the total capital cost will be $136,517. One GI endoscopy room already exists and is in use. The other room already exists and needs only minor equipment to make it functional. The applicant did not need a certificate of need to build and use the rooms. The applicant needs a certificate of need to obtain a license as an ASF. In Section IX.1, page 142, the applicant projects start-up costs in the amount of $5,000. The applicant states that start-up costs are modest because the center is already in operation. The initial start-up costs are for possible nurse training and an increase in supplies. In Section VIII.3, page 137, the applicant states that it will finance the capital cost with a conventional loan. The loan will be financed by the little bank, Inc. Exhibit 47 contains a letter signed by a Senior Vice President of the little bank, Inc., which states:

> *"We welcome the opportunity to assist with 100 percent financing for up to $150,000 of the fixed and working capital costs for AMG to develop the proposed freestanding GI endoscopy center. …*
>
> *"We have examined the financial position of the borrower, AMG, and found it to be adequate to support the proposed loan. We have also reviewed the proposal and related activities. Because of the delay in the project's commencement, due diligence will require the bank to re-evaluate the interest rate, terms of the loan and the borrowers' financial strength when the loan is executed."*

Exhibit 55 includes the amortization schedule for the loan. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the project.

Below is a table that shows the facility's projected average reimbursement for the 10 most commonly performed GI endoscopy procedures for the first three project years, as reported by the applicant on page 41. The facility charge will include nursing time, administrative time, supplies, medication, equipment use, operating room preparation and recovery time.

CPT CODE	PROCEDURE	FY 2014	FY 2015	FY 2016
43239	Upper GI endoscopy, Biopsy	$359	$363	$367
43244	Upper GI endoscopy / Ligation	$426	$432	$437
43249	Upper GI endoscopy w/ Esophagus Dilation	$397	$402	$407
45331	Sigmoidoscopy w/ biopsy	$215	$217	$220
45378	Diagnostic Colonoscopy	$382	$387	$391
45380	Colonoscopy w/ biopsy	$404	$409	$414
45383	Colonoscopy w/ lesion removal	$418	$423	$429
45385	Colonoscopy w/ lesion removal	$414	$419	$424
46083	Incision of thrombosed hemorrhoid, external	$64	$65	$65
46221	Ligate Hemorrhoid(s)	$115	$116	$117

The applicant states on page 40 that pathology charges will be billed to privately insured patients directly by AMG, while government insured patients will be billed by the pathology company (and those charges are not included in AMG's revenues). The facility charge will not include any ancillary services, such as laboratory work, radiology, anesthesia, emergency transportation or pharmacy that may be required before or after the GI procedure. The ancillary services will be billed to the payor by the respective provider company. Physician fees will be billed separately by physicians.

Below is a table which illustrates projected revenues (charges) and operating expenses (costs) for the facility for each of the first three project years, as reported by the applicant in the pro forma section of the application.

	FY 2014	**FY 2015**	**FY 2016**
Total Revenues	$1,713,930	$1,732,271	$1,750,678
Total Expenses	$752,852	$714,641	$729,027
Net Income	$961,078	$1,017,630	$1,021,651

As shown in the table above, the applicant projects revenues will exceed expenses in each of the first three project years. The assumptions used by the applicant in preparation of the pro formas, including projected utilization, are reasonable, credible and supported. See the Proformas tab of the application for the pro formas and assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicant adequately demonstrates 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 develop a new ASF in Kinston by obtaining a license for the two existing rooms (one operational, one requiring additional equipment to be operational). The proposed site is 2541 North Queen Street in Kinston, near Lenoir Memorial Hospital.

Regarding utilization of the existing GI endoscopy room at AMG thus far, the applicant states that 4,702 procedures were performed at the facility in CY 2012 (annualized based on the 2,622 procedures performed between March 26, 2012 and October 13, 2012). Based on the minimum performance standard promulgated in N.C.G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility is currently operating at 313.5% of capacity [4,702 / 1,500 = 313.5%]. If the second GI endoscopy room were in use the facility would be operating at 157% of capacity [4,702 / 3,000 = 157%]. Indeed, the facility is already performing enough procedures to justify three GI endoscopy rooms [4,702 / 1,500 = 3.135].

On page 92 of the application, the applicant states that there are currently 19 licensed providers of GI endoscopy services in the proposed service area, including 7 hospital-based and 12 free-standing, non-hospital based providers. In addition, the applicant provides a table that illustrates the FFY 2011 utilization at all 19 facilities, as shown in the following table:

HOSPITAL BASED	# OF GI ENDOSCOPY ROOMS	GI ENDOSCOPY PROCEDURES PERFORMED DURING FFY 2011*
Carteret General Hospital	2	934
CarolinaEast Medical Center	2	2,948
Lenoir Memorial Hospital	2	3,260
Onslow Memorial Hospital	3	4,672
Pender Memorial Hospital	1	259
Vidant Medical Center	2	5,608
Wayne Memorial Hospital	2	2,869
Subtotal	14	20,550
# of Procedures / 1,500	13.700	
# of Procedures / # of Rooms	1,467.9	
% of Regulatory Performance Std.	97.9%	
FREESTANDING, NON-HOSPITAL BASED		
The Surgical Center of Morehead City	1	1,743
CarolinaEast Internal Medicine	3	4,107
CCHC Endoscopy Center	3	5,746
Kinston Medical Specialists Endoscopy Center	2	383
Park Endoscopy Center	2	2,214
East Carolina Gastroenterology Endoscopy Center	1	2,150
Atlantic Gastroenterology Endoscopy Center	2	3,865
Carolina Digestive Diseases	2	4,238
East Carolina Endoscopy Center	3	1,915
Gastroenterology East**	3	3,767
Quadrangle Endoscopy Center	6	6,279
Goldsboro Endoscopy Center	4	3,517
Subtotal	32	39,925
# of Procedures / 1,500	26.617	
# of Procedures / # of Rooms	1,247.656	
% of Regulatory Performance Std.	83.2%	
TOTALS		
# of GI Endoscopy Rooms/Procedures	**46**	**60,475**
# of Procedures / 1,500	**40.32**	
# of Procedures / # of Rooms	**1,314.7**	
% of Regulatory Performance Std.	**87.7%**	

* From 2012 License Renewal Applications.

** 2012 LRA reported 3,767 patients but 0 procedures, so project analyst assumed one procedure per patient.

As shown in the table above in FFY 2011, on average 1,314.7 GI endoscopy procedures were performed per room in licensed facilities in the service area.

The following table illustrates the impact of including the two proposed GI endoscopy rooms and the procedures already being performed in those rooms in the inventory of existing GI endoscopy rooms in licensed facilities.

Service Area GI Endoscopy Room Utilization, FFY 2011

TYPE OF ROOM	EXISTING	PROPOSED	TOTAL	NO. PROCEDURES FFY 2011*	PROCEDURES PER ROOM	UTILIZATION
Freestanding, Non hospital-based	32	2	34	44,627	1,312.6	87.5%
Hospital-based	14	--	14	20,550	1,467.9	97.9%
Total service area	46	2	48	65,177	1,356.6	90.4%

*Includes the procedures performed at AMG in CY 2012 (annualized).

As shown in the above table, including the two proposed GI endoscopy rooms and the procedures already being performed in those rooms results in an average of 1,356.6 procedures per room for all 48 endoscopy rooms in licensed facilities as compared to an average of 1,314.7 procedures per room not including AMG.

Furthermore, the applicant states, on page 59 of the application, that N.C.G.S. 131E-175(11) states:

> *"'…physicians providing gastrointestinal endoscopy services in unlicensed settings should be given an opportunity to obtain a license to provide those services to ensure the safety of patients and the provision of quality care.'"*

By obtaining a license for its unlicensed GI endoscopy rooms, the ASF will be required to participate in the Medicare and Medicaid programs and must comply with the Center for Medicare and Medicaid Services' (CMS) Conditions of Participation and to obtain accreditation of the facility from a recognized accrediting body. Additionally, the applicant will be required to meet minimal licensure requirements and life safety requirements which will enhance the safety of the proposed facility. The facility will be subject to inspections by the Construction Section and surveys by the Acute Home Care Licensure and Certification Section in the Division of Health Service Regulation. Thus, patients will have assurance of safety and quality care.

A certificate of need is not required for the applicant to continue to use the existing unlicensed rooms.

While the proposal will increase the number of GI endoscopy rooms in licensed facilities, it will result in an increase of only two rooms. The 4,702 procedures being performed at AMG are not going to be performed in the existing licensed facilities if this project is not approved. What the proposal will do is increase access to Medicare and Medicaid recipients and ensures the safety of patients and the provision of quality care.

In summary, the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy rooms in licensed facilities in the proposed service area. Therefore, 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 125, and in Section VII.6, page 128, the applicant provides tables to illustrate projected staffing for the proposed GI endoscopy center, as shown in the following table:

FUNCTIONAL AREA	# FTE POSITIONS
Administration	
Professional Health Care Administrators	0.50
Nurse Manager (RN)	0.47
Office Manager	0.33
Billing Clerk	0.97
Receptionist/scheduler	0.67
Pre-Operative	
Nurse Manager (RN)	0.10
Registered Nurses (RN)	0.56
LPN	0.33
Medical Techs/Gastroenterology Tech	0.33
Post-operative	
Nurse Manager (RN)	0.10
Registered Nurses (RN)	0.56
LPN	0.33
Medical Techs/Gastroenterology Tech	0.33
Operating Room	
Medical Techs/Gastroenterology Tech	0.65
Certified Nurse Anesthetist (CRNA)	1,347.50*
Other/Reprocessing	
Medical Techs/Gastroenterology Tech	0.65
Total:	6.88

* The CRNA will be contracted; thus the table shows the amount of hours the CRNA will work per year instead of in FTE.

In Exhibit 43 the applicant provides a letter signed by Eric Ibegbu, M.D., in which he confirms his intent to serve as Medical Director of the proposed facility. Exhibit 3 contains a copy of Dr. Ibegbu's curriculum vitae which documents that the physician is board-certified in both internal medicine and gastroenterology.

In Section VII.3(b), page 126, the applicant states it anticipates no difficulty in recruiting the additional RN, since it has had no problems recruiting in the past. The applicant states that attractive benefits are offered to attract qualified applicants. The applicant notes that a

CRNA will be in the building at all times when it is open, and that the CNRA will be contracted through Carolina Anesthesia Associates. The billing for the CRNA will come from Carolina Anesthesia Associates. The applicant adequately documents the availability of sufficient health manpower and management personnel to provide the proposed GI endoscopy services. 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

The applicant identifies the necessary ancillary and support services in Section II.2, pages 18-19, which include the following:

- Anesthesia/CRNA
- Housekeeping/Laundry
- Pathology
- Laboratory
- Medical Waste
- Medical Records
- Pharmacy
- Billing
- Radiology
- Emergency Transportation
- Office/Clinical supplies
- Computer maintenance/software

On page 19 the applicant states pathology services will be billed to private insurance patients directly by AMG. Government insured patients will be billed by the pathology company (Miraca Life Sciences or AP Laboratories). Anesthesia/CRNA services are provided by Carolina Anesthesia Associates. Housekeeping and laundry are provided by ALSCO and Jason and Joshua Pratt. Pathology and laboratory services are provided by Miraca Life Sciences or AP Laboratories. Medical waste is taken care of by Stericycle. The applicant identifies all providers of ancillary services in the table on page 18.

The applicant discusses coordination with the existing health care system in Sections V.2 - V.6, pages 102 - 107. Exhibit 31 contains a copy of the hospital privileges of Dr. Ibegbu at Lenoir Memorial Hospital, Onslow Memorial Hospital, and Vidant Medical Center. Exhibit 32 contains the transfer agreement between AMG and Lenoir Memorial Hospital. The applicant discusses healthcare provider support for the project on page 69. The applicant states that at least 19 physicians have expressed a willingness to continue to refer patients to AMG. The applicant provides additional letters of support from other healthcare providers, as well as Lenoir Memorial Hospital. Please see Exhibit 34 for the letter of support from

Lenoir Memorial Hospital; Exhibit 41 for letters of support from healthcare providers; and Exhibit 42 for letters of support from referring physicians. See Exhibit 36 for letters of support from AMG patients.

Consequently, the applicant adequately demonstrates that all necessary ancillary and support services will be available and that the service 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.

NA

E.S.I. Investments, Inc. constructed and owns the building which is leased by AMG. The building was built in 2011-12. AMG is owned by Dr. Eric Ibegbu and E.S.I. Investments is partially owned by Dr. Ibegbu. E.S.I. Investments was not required to obtain a certificate of need to construct a building with unlicensed rooms in which to perform GI endoscopy procedures. In order to be licensed as an ASF with two GI endoscopy rooms, AMG must

obtain a certificate of need. AMG is already operating an unlicensed GI endoscopy center in the leased building. AMG is using only one room but the second room already exists. The second room just needs some equipment, costing only $66,517, to be functional. There is no renovation or construction necessary. The remainder of the capital cost is for preparation of the certificate of need application ($50,000) and contingency ($20,000). Therefore, this criterion is not applicable to this review.

(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 following table illustrates the current payor mix for AMG, as reported by the applicant in Section VI.12, page 121.

PAYOR CATEGORY	PERCENT OF TOTAL
Self Pay / Indigent	1.6%
Medicare	36.1%
Medicaid	7.2%
Commercial	6.8%
Blue Cross / Blue Shield	30.4%
Tricare	17.3%
Other	0.7%
Total	100.0%

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for counties in the service area and statewide.

COUNTY	TOTAL # OF MEDICAID ELIGIBLES AS % OF TOTAL POPULATION	TOTAL # OF MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION	% UNINSURED CY 2008-2009 (ESTIMATE BY CECIL G. SHEPS CENTER)
Carteret	14.0%	6.6%	19.5%

Craven	16.0%	6.5%	19.6%
Duplin	20.0%	7.6%	24.6%
Greene	21.0%	7.6%	24.6%
Jones	20.0%	9.8%	20.9%
Lenoir	25.0%	11.0%	21.1%
Onslow	11.0%	4.2%	23.4%
Pender	17.0%	7.4%	21.0%
Pitt	16.0%	6.7%	21.3%
Wayne	20.0%	8.3%	20.3%
Statewide	**17.0%**	**6.7%**	**19.7%**

The majority of Medicaid eligibles are children under the age of 21. This age group does not utilize the same health services at the same rate as older segments of the population, particularly the GI endoscopy services provided by the applicant.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 45.9% for those age 20 and younger and 30.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

In addition, the Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's 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 or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons utilizing health services.

The following table illustrates the historical payor mix for the 12 free-standing, non hospital-based GI endoscopy facilities in the proposed service area.

FACILITY*	PERCENT OF TOTAL			
	SELF PAY / INDIGENT	MEDICAID	MEDICARE / MEDICARE MANAGED CARE	ALL OTHER
The Surgical Center of Morehead City	0.5%	1.0%	59.1%	39.5%
CarolinaEast Internal Medicine	5.3%	3.2%	44.2%	47.3%

CCHC Endoscopy Center	0.3%	1.4%	46.1%	52.0%
Kinston Medical Specialists Endoscopy Center	2.2%	7.6%	52.8%	37.4%
Park Endoscopy Center	1.2%	4.9%	49.6%	44.2%
East Carolina Gastroenterology Endoscopy Center	2.8%	7.3%	22.0%	67.9%
Atlantic Gastroenterology Endoscopy Center	5.8%	0.5%	26.5%	67.2%
Carolina Digestive Diseases	3.0%	7.0%	55.0%	35.0%
East Carolina Endoscopy Center	11.3%	26.5%	33.2%	28.0%
Quadrangle Endoscopy Center	0.7%	1.7%	42.7%	54.9%
Goldsboro Endoscopy Center	0.1%	6.8%	53.1%	40.1%
Average	2.5%	4.4%	44.8%	48.1%

Source: 2012 License Renewal Applications
*Gastroenterology East was not included because no payor mix data was provided in its 2012 Licence Renewal Application.

The applicant demonstrates that medically underserved populations currently have adequate access to its existing services. 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

In Section VI.11, page 120, the applicant states:

> *"AMG Endoscopy Center has no public obligations under applicable regulations or agreements to provide uncompensated care, community service or access to care for medically underserved, minorities and handicapped persons. AMG will provide care to these groups as a responsible member of the community."*

In Section VI.10, page 120, the applicant states that no civil rights access complaints have been filed against the facility in the last five years (note: the facility has not yet been in operation for five years). The application is conforming to this criterion.

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

C

The following table illustrates the projected payor mix during the second operating year, as reported by the applicant in Section VI.14, page 122.

SECOND FULL PROJECT FISCAL YEAR PROJECTED PROCEDURES AS % OF TOTAL	
Self Pay / Indigent	2.0%
Medicare	36.8%
Medicaid	8.0%
Commercial	6.8%
Blue Cross / Blue Shield	29.1%
Tricare	17.3%
Total	**100.0%**

In Section VI.4, page 115, the applicant states *"AMG Endoscopy Center provides access to colorectal cancer screening and other gastrointestinal endoscopy procedures to all patients in need of care regardless of their ability to pay, insurance coverage, handicap, racial/ethnic background and gender."* Exhibit 22 contains a copy of the AMG Endscopy Center's Patient Rights and Responsibilities Policy, and Exhibit 24 contains a copy of AMG's Charity Care Policy. In Section VI.2, page 111, the applicant states that, *"AMG will continue to make its services available to all persons in need of medical care, including the low income, underserved, medically indigent, uninsured, and underinsured."*

The applicant states on page 41 that the AMG physician practice is currently certified by Medicare and Medicaid. The applicant also states on page 68:

> *"Medicare and Medicaid, who represent a substantial portion of AMG patients, require that such a facility be licensed."*

The applicant states on page 88:

> *"Patients and payors favor the lower charges at freestanding ambulatory surgery centers and some payors, like Medicare and Medicaid, require a license as a precondition to payment."*

The applicant further states on page 122:

> *"Because AMG will receive better reimbursement from certain payors once it is licensed, the applicant believes it is reasonable to assume that it will be able to accommodate more self-pay/indigent, Medicare and Medicaid patients upon being licensed."*

The applicant demonstrates that medically underserved populations will continue to have adequate access to the facility's services and 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.

In Section VI.9, page 118, the applicant states access to the proposed outpatient endoscopy services will be by physician referral. The applicant states that any licensed physician or physician extender is eligible to refer patients to the facility. Additionally, the applicant states that patients may "self-refer" to Dr. Ibegbu and any other AMG Endoscopy Center physician. The information provided in the application and exhibits is reasonable and credible and supports a finding of conformity with 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 101 and Exhibit 39, AMG states that it has an existing agreement with Miller-Motte College for medical assisting and medical clinical assistant internships, and will continue to offer those opportunities. Additionally, the applicant has extended offers to training programs at Craven Community College, East Carolina School of Nursing, Lenoir Community College, Pitt Community College, and Wayne Community College, as shown in Exhibit 38. The information provided is reasonable and credible and supports a finding of conformity with 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 currently provides GI endoscopy services to patients in its proposed service area in an unlicensed facility. It will continue to operate as an unlicensed GI endoscopy provider if the proposal is not approved. In Section V.7, pages 107-108, the applicant discusses how the proposed project will foster competition in the service area.

In Section III.9, page 92, the applicant states that there are currently 19 licensed providers of GI endoscopy services in the proposed service area, including 7 hospital-based and 12 free-standing, non-hospital based providers. In addition, the applicant provides a table that illustrates the 2011 utilization at all 19 facilities, as shown in the following table:

HOSPITAL BASED	# OF GI ENDOSCOPY ROOMS	GI ENDOSCOPY PROCEDURES PERFORMED DURING FFY 2011*
Carteret General Hospital	2	934
CarolinaEast Medical Center	2	2,948
Lenoir Memorial Hospital	2	3,260
Onslow Memorial Hospital	3	4,672
Pender Memorial Hospital	1	259
Vidant Medical Center	2	5,608
Wayne Memorial Hospital	2	2,869
Subtotal	14	20,550
# of Procedures / 1,500	13.700	
# of Procedures / # of Rooms	1,467.9	
% of Regulatory Performance Std.	97.9%	
FREESTANDING, NON-HOSPITAL BASED		
The Surgical Center of Morehead City	1	1,743
CarolinaEast Internal Medicine	3	4,107
CCHC Endoscopy Center	3	5,746
Kinston Medical Specialists Endoscopy Center	2	383
Park Endoscopy Center	2	2,214
East Carolina Gastroenterology Endoscopy Center	1	2,150
Atlantic Gastroenterology Endoscopy Center	2	3,865
Carolina Digestive Diseases	2	4,238
East Carolina Endoscopy Center	3	1,915
Gastroenterology East**	3	3,767
Quadrangle Endoscopy Center	6	6,279
Goldsboro Endoscopy Center	4	3,517
Subtotal	32	39,925
# of Procedures / 1,500	26.617	
# of Procedures / # of Rooms	1,247.656	
% of Regulatory Performance Std.	83.2%	
TOTALS		
# of GI Endoscopy Rooms/Procedures	**46**	**60,475**
# of Procedures / 1,500	**40.32**	
# of Procedures / # of Rooms	**1,314.7**	
% of Regulatory Performance Std.	**87.7%**	

*From 2012 License Renewal Applications (LRA)

**2012 LRA reported 3,767 patients but 0 procedures, so project analyst assumed one procedure per patient.

N.C.G.S. 131E-175(11) states:

> *"'physicians providing gastrointestinal endoscopy services in unlicensed settings should be given an opportunity to obtain a license to provide those services to ensure the safety of patients and the provision of quality care.'"*

By obtaining a license for its unlicensed GI endoscopy rooms, the ASF will be required to participate in the Medicare and Medicaid programs and must comply with the Center for Medicare and Medicaid Services' (CMS) Conditions of Participation and to obtain accreditation of the facility from a recognized accrediting body. Additionally, the applicant will be required to meet minimal licensure requirements and life safety requirements which will enhance the safety of the proposed facility. The facility will be subject to inspections by the Construction Section and surveys by the Acute Home Care Licensure and Certification Section in the Division of Health Service Regulation. Thus, patients will have assurance of safety and quality care.

See also Sections II, III, V, VI and VII 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 credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to obtain a license for an ASF with two GI endoscopy rooms based on current and projected utilization (see Section III, pages 72-79, and Section IV, pages 95-100 of the application) and that it is a cost-effective alternative (see Section III, pages 88-91 of the application);
- The applicant adequately demonstrates that it will continue to provide quality services (see Sections II and V.7, pages 107-109 of the application); and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations (see Sections III.4, page 82 and VI.2, pages 110-114 of the application).

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.

NA

(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 proposal submitted by AMG is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900, which are discussed below.

.3902 INFORMATION REQUIRED OF APPLICANT

.3902(a)(1) *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 provide the following information: (1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906.*

-C- In Section III.5, page 84, the applicant identifies the service area as Carteret, Craven, Duplin, Greene, Jones, Lenoir, Onslow, Pender, Pitt, and Wayne counties. Forty-three percent of patients come from Lenoir County; 32% of patients come from Onslow County; 11% of patients come from Duplin County; and the remaining 14% of patients come from the other counties in the identified service area.

.3902(a)(2) *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 provide the following information: … (2) with regard to services provided in the applicant's GI endoscopy rooms, identify:*

(A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located.

-C- AMG proposes to obtain a license for an ASF with two GI endoscopy rooms. The applicant currently performs these procedures in the existing unlicensed room. A second unlicensed room is already built but is not in use as some equipment must be added first.

(B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area.

-NA- Neither AMG nor the owner of AMG have any interest in any licensed health service facility located in the service area.

(C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months.

-C- In Section II.11, pages 32-33, the applicant provides the number of GI endoscopy procedures performed from March 26, 2012 through October 13, 2012 (2,622), identified by CPT code, in the applicant's existing unlicensed GI endoscopy room. Note: the facility began operations on March 26, 2012.

(D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project.

-C- In Section II.11, pages 34-35, the applicant provides the number of GI endoscopy procedures, identified by CPT code, projected to be performed in the proposed licensed ASF in each of the first three operating years of the project.

(E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months.

-NA- In Section II.11, page 36, the applicant states that AMG has performed only GI endoscopy procedures in the GI endoscopy rooms in its existing unlicensed room in the last 12 months.

(F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project.

-NA- In Section II.11, page 36, the applicant states that no procedures other than GI endoscopy procedures will be performed in the licensed GI endoscopy rooms.

(G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months.

-C- In Section II.11, pages 36-37, the applicant states that 1,547 patients (2,622 procedures) were served in the one GI endoscopy room at AMG between March 26, 2012 and October 13, 2012. AMG physicians also served an additional 1,841 patients at hospital-based facilities during the 12 month period October 2011 through September 2012.

(H) the *number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project.*

-C- In Section II.11, page 37, the applicant projects 2,775 patients (4,702 procedures) will be served in the proposed GI endoscopy rooms in each of the first three project years.

.3902(a)(3) *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 provide the following information: … (3) with regard to services provided in the applicant's operating rooms identify: (A) the number of existing operating rooms in the facility; (B) the number of procedures by type performed in the operating rooms in the last 12 months; and (C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project.*

-NA- The applicant does not have any operating rooms.

.3902(a)(4) *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 provide the following information: … (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located.*

-C- In Section II.11, page 38, the applicant states that the facility will be operated Monday through Friday from 8:30 AM to 2:00 PM, excluding holidays and days that AMG's physician attends continuing education courses (approximately 15 days, including holidays).

.3902(a)(5) *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 provide the following information: … (5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-NA- The applicant is not an existing licensed facility.

.3902(a)(6) *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 provide the following information: … (6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility.*

-C- In Section II.11, page 39, the applicant provides the type and average facility charges by CPT code projected during the first three operating years for the ten procedures projected to be performed most often at AMG.

.3902(a)(7) *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 provide the following information: … (7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge.*

-C- In Section II.11, page 39, the applicant states *"The facility charge will include nursing time, administrative time, supplies, medication, equipment use, as well as operating rooms preparation and recovery time."*

.3902(a)(8) *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 provide the following information: … (8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges.*

-C- In Section II.11, page 40, the applicant details which charges will not be included in the facility charges. Such charges include pathology charges for privately insured patients; anesthesia charges; ancillary services; and physician charges.

.3902(a)(9) *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 provide the following information: … (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-C- In Section II.11, page 40, the applicant states it is not an existing licensed facility. The applicant provides a table listing the 10 most commonly performed procedures since it opened in March 2012 on page 41.

.3902(a)(10) *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 provide the following information: … (10) the average reimbursement projected to be received for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.*

-C- In Section II.11, page 41, the applicant provides the average reimbursement projected to be received for the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility for the first three project years.

.3902(b) *An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:*

> *(1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;*

-C- In Exhibits 22 and 24 the applicant provides a copy of AMG's written administrative policies that prohibit the exclusion of GI endoscopy services to any patient on the bases listed in the rule.

(2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility;

-C- In Exhibit 23 the applicant provides a letter signed by Dr. Ibegbu that documents AMG's commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months of facility licensure.

(3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;

-C- In Exhibits 22 and 24 the applicant documents its policies regarding proposed services by indigent patients. The applicant also states in Section II.11, page 42, *"AMG…will not refuse procedures or treatment to anyone in need of care based on ability to pay…"*

(4) a written description of patient selection criteria including referral arrangements for high-risk patients;

-C- In Exhibits 25, 26, and 32, the applicant provides copies of patient selection criteria, including referral arrangements for high-risk patients.

(5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;

-C- In Section II.11, pages 43-45, the applicant provides the number of GI endoscopy procedures performed by physicians affiliated with AMG in licensed facilities in each of the last 12 months.

(6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern.

-C- In Section II.11, page 46, the applicant states that it expects Dr. Ibegbu will reduce the number of outpatient procedures performed at the three hospital facilities where he has previously performed procedures. The applicant states: *"This change will occur, because patients will have the choice of a lower charge for services and a less institutional setting."*

.3903 PERFORMANCE STANDARDS

.3903(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 have operating rooms and does not propose to add any operating rooms.

.3903(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 II.11, page 47, the applicant projects to perform 4,702 GI endoscopy procedures during each of the three project years, which is an average of 2,351 procedures per room (4,702 procedures / 2 procedure rooms = 2,351 procedures per room). See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

.3903(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.11, pages 47-48, the applicant demonstrates it will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at AMG.

.3903(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- Neither the applicant nor any related entity owns any operating rooms in the proposed service area.

.3903(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- In Section IV.1(d), pages 97-100, the applicant provides all assumptions and the methodology it used to project GI endoscopy procedures. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

.3904 SUPPORT SERVICES

.3904(a) *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 provide a copy of an agreement between the applicant and a pathologist for provision of pathology services.*

-C- In Section II.2, page 18, the applicant states pathology services are currently provided by Miraca Life Sciences or AP Laboratories. In addition, in Exhibit 7, the applicant provides a copy of the existing agreement for pathology services.

.3904(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 provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.*

-C- In Exhibit 27 the applicant provides a copy of AMG's conscious sedation policy.

.3904(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 provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.*

-C- In Exhibit 29 the applicant provides a copy of AMG's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases.

.3904(d) *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 provide:*

(1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county.

-C- In Section II.11, page 50, the applicant states that Dr. Ibegbu has privileges at Lenoir Memorial Hospital; Onslow Memorial Hospital; and Vidant Medical Center. See Exhibit 31 for associated documentation of these affiliations.

(2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges.

-C- See Exhibit 32 for a transfer agreement between AMG and Lenoir Memorial Hospital.

(3) documentation of a transfer agreement with a hospital in case of an emergency.

-C- See Exhibit 32 for a transfer agreement between AMG and Lenoir Memorial Hospital in case of an emergency.

.3905 STAFFING AND STAFF TRAINING

.3905(a) *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 identify the number of staff to be utilized in the following areas: (1) administration; (2) pre-operative; (3) post-operative; (4) procedure rooms; (5) equipment cleaning, safety, and maintenance; and (6) other.*

-C- In Section II.11, pages 51-52, the applicant states the proposed facility will have sufficient staff in the areas identified in this rule. There will be 2.94 FTEs for administration; 1.32 FTEs assigned to pre-operative; 1.32 FTEs assigned to post-operative; 0.65 FTEs assigned to procedure rooms; and 0.65 FTEs assigned to equipment cleaning, safety, and maintenance. The applicant projects to contract with Carolina Anesthesia Associates for anesthesia services.

.3905(b) *The 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 identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility.*

-C- In Section II.11, page 52, the applicant identifies the name and board certification status of one physician who will perform GI endoscopy procedures at AMG. In Exhibit 3 the applicant provides the curriculum vitae for the Medical Director, who is also the physician performing GI endoscopy procedures. The applicant notes that other physicians may later be credentialed at the facility.

.3905(c) *The 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 provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility.*

-C- In Section II.11, page 53, the applicant states that Article III of the Bylaws, Rules, and Regulations of AMG includes the criteria for extending privileges to medical personnel performing services at the facility. See Exhibit 15 for a copy of these Bylaws, Rules, and Regulations of AMG.

.3905(d) *If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:*

(1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;

(2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;

(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;

(4) at least one registered nurse shall be employed per procedure room;

(5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and,

(6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified.

-NA- AMG is currently accredited by The Accreditation Association for Ambulatory Health Care (AAAHC). This accreditation extends through April 2013. Exhibit 6 contains the accreditation information.

.3906 FACILITY

.3906(a) *An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.*

-C- The proposed licensed ASF will be located within an existing medical office building. Note: the space already exists; it just is not licensed. In Section II.11, pages 55-56, the applicant states that the licensed facility will be located in a separate suite separated by rated firewalls. The applicant also states that the licensed ASF will be a separately identifiable entity administratively and will be financially independent and distinct from the medical office portion.

.3906(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 commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project.*

-C- The applicant is already accredited by AAAHC. See Exhibit 6 for documentation.

.3906(c) *If the facility is not accredited at the time the application is submitted, 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:*

(1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.

(2) provide a floor plan of the proposed facility identifying the following areas: (A) receiving/registering area; (B) waiting area; (C) pre-operative area; (D) procedure room by type; and (E) recovery area.

(3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and,

(4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located.

-NA- The applicant was already accredited by the AAAHC at the time the application was submitted.