ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: December 11, 2013
PROJECT ANALYST: Gloria C. Hale
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: G-10162-13/ Rockford Digestive Health Endoscopy Center, LLC/ Develop a new licensed ambulatory surgical facility with one GI endoscopy room/ Surry 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, Rockford Digestive Health Endoscopy Center (RDHEC), LLC, currently has two existing unlicensed gastrointestinal (GI) endoscopy rooms and a physician office located at 951 Rockford Street in Mount Airy, Surry County. The applicant proposes to obtain a license for an ambulatory surgical facility with one GI endoscopy room.

The total projected capital cost for the proposal is less than two million dollars; therefore, Policy GEN-4 in the 2013 State Medical Facilities Plan (SMFP) is not applicable to this review. Furthermore, there are no other policies or need determinations in the 2013 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(2) Repealed effective July 1, 1987.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

RDHEC is an existing office-based GI endoscopy practice with two unlicensed GI endoscopy rooms. The existing office is located at 951 Rockford Street in Mount Airy, Surry County. The applicant proposes to develop a new ambulatory surgical facility by obtaining a license for one of the two existing GI endoscopy rooms. The applicant does not need a certificate of need to use the unlicensed GI endoscopy rooms, however the applicant does need a certificate of need to obtain a license as an ambulatory surgical facility.

Population to be Served

In Section III.7, page 39, the applicant provides patient origin for its GI endoscopy center from December 1, 2012 to June 30, 2013, as shown in the table below:

COUNTY	% OF TOTAL
Surry	75.6%
Stokes	15.2%
Carroll and Patrick*	9.2%
Total	100%

* Carroll and Patrick Counties are in Virginia.

In Section III.6, page 38, and in supplemental information, the applicant provides projected patient origin for the facility for Project Years 1 and 2, CY 2015 and CY 2016, respectively, as shown in the table below:

COUNTY	NO. OF PATIENTS CY 2015	% OF TOTAL CY 2015	NO. OF PATIENTS CY 2016	% OF TOTAL CY 2016
Surry	700	75.6%	1,000	66.7%
Stokes	125	13.5%	300	20.0%
Carroll and Patrick*	100	10.8%	200	13.3%
Total	925	100%	1,500	100%

* Carroll and Patrick Counties are in Virginia.

The applicant states that its projected patient origin is based on its historical data, with its primary service area being Surry and Stokes counties and its secondary service area being Carroll and Patrick counties in the state of Virginia.

Demonstration of Need

In Section III.1, pages 31–35, the applicant describes the need for one licensed GI endoscopy room in Mt. Airy. Assumptions and methodology to support the need are discussed by the applicant in Section III.1, pages 31-35, and in supplemental information. In Section III.1(a), page 31, the applicant states:

"The Certificate of Need law includes specific findings of fact related to gastrointestinal endoscopy services:
G.S. 131E-175 Finding of fact.

(11) 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.

(12) The demand for gastrointestinal endoscopy services is increasing at a substantially faster rate than the general population given the procedure is recognized as a highly effective means to diagnose and prevent cancer."

In addition, the applicant states, on page 31, that the *"State Medical Facilities Plan includes no policies, regulations or need determinations that limit the number of gastrointestinal rooms that may be approved."*

Moreover, the applicant states that screening services, including endoscopic procedures, will increase as the population ages. The American Cancer Society recommends colonoscopy screenings for persons aged 50 or older and for younger persons who have a family history of colorectal cancer. The importance and effectiveness of colorectal cancer screening is supported by the Center for Disease Control in a report from July 6, 2010 which stated *"…if current trends in 'health behavior, screening, and treatment' continue, the mortality rate of colorectal cancer will decrease by 36% by 2020 compared to mortality rates in 2000."*

The applicant further states, on page 33, that screening tests are particularly important because:

- *"Cancer prognosis is dependent upon the stage of diagnosis*
- *Identifying cancer at the earliest stages will reduce mortality rates*
- *Early detection allows for removal of precancerous polyps*
- *Early detection and treatment will hold down healthcare costs"*

In supplemental information, the applicant states that according to the NC Office of Budget and Management, population growth for Surry County and Mt. Airy, Surry County, from 2000 to 2008, was 3.0% and 28%, respectively. In Section III, page 31, the applicant states that according to the North Carolina Office of State Demographics, *"by 2017, the population of people between the ages of 65 and 85 will increase by 2310 people."* In addition, as stated on page 31, *"As the senior population ages, the demand for healthcare services, including endoscopic procedures, will increase. The American Cancer Society recommends colonoscopy screenings for all persons over 50 years of age…"*

In supplemental information, the applicant states that colon/rectal cancer rates were higher in Surry County than the state as a whole, at 46.1 per 100,000 persons compared to 43.4 per

100,000 persons, respectively, from 2006-2010.[1] In addition, the applicant states in supplemental information, *"It is important to note that in parts of the country with limited access to licensed providers, the incidence may be artificially lower as the patients may not be having the colonoscopy, which aids in the diagnosis of the cancer."*

Moreover, in Section III, page 30, the applicant states that its unlicensed GI endoscopy services are underutilized due to insurer requirements for licensure and accreditation. In Section II.6, page 14, the applicant states,

> *"During the past three years, the Rockford Digestive Health Specialists, PA medical staff has maintained a Physician and a nurse practitioner. Due to lack of accreditation and/or licensure our ability to perform endoscopic procedures in our office has dwindled. Many insurance companies …have all denied us access to continue to perform procedures in our office. Patients with these health plans must be seen at the hospital. This deprives the patient of the choice to have access to the procedure in an outpatient freestanding ASC setting."*

Further, the applicant states in Section II, page 15, that there is a shortage of gastroenterologists in the region and patients from the area are accessing already overwhelmed ambulatory GI endoscopy services an hour away in Winston-Salem, Forsyth County. In Section III, page 40, the applicant discusses the lower cost to patients in obtaining GI endoscopy procedures in a licensed ambulatory surgical facility as compared to a hospital-based service, as follows:

> *"Reimbursement policies for Medicare, Medicaid and commercial insurance provide lower reimbursement and lower co-pays for GI endoscopy procedures performed in a licensed ambulatory surgery facility as compared to hospital-based procedures. Therefore the reimbursement guidelines encourage patients to choose an ambulatory surgery facility for GI endoscopy procedures. Also, Rockford Digestive Health Specialists generally understands that hospital-based endoscopy procedure rooms often have higher charges and patient co-pays as compared to the outpatient procedure rooms."*

In Section II, pages 14-15, the applicant states that the conversion of its medical practice from an unlicensed GI endoscopy service to a licensed ambulatory surgical center will allow it to grow and expand patient access in the rural community of Mt. Airy.

[1] NC Center for Health Statistics. www.schs.state.nc.us/schs/CCR/incidence/2010/5yearRates.pdf

Utilization

In Section IV(d), page 43, and in supplemental information, the applicant provides historical and projected utilization of the existing GI endoscopy room at RDHEC. Historical and projected utilization are illustrated in the table below:

RDHEC
Historical and Projected Utilization
GI Endoscopy Procedures

	CY 2011	CY 2012	Interim Project Year, CY 2013*	Interim Project Year, CY 2014	Project Year 1, CY 2015	Project Year 2, CY 2016	Project Year 3, CY 2017
Number of GI Endoscopy Procedures	202	190	65	190	925	1,500	1,600

*CY 2013 includes procedures performed January 1, 2013 – June 30, 2013 only.

The applicant's existing GI endoscopy room is currently operating at 4.3% of the minimum performance standard promulgated in 10A NCAC 14C .3903(b) and N.C.G.S. 131E-182(a) [65 / 1,500 = 4.3%].

To project future utilization at RDHEC, the applicant provides the following methodology in supplemental information:

"Step 1: Identify the Population over 50 from 2012
Population over 50 in Stokes & Surry"

County	Over 50 yrs. old	Total population
Surry	28,181	73,754
Stokes	18,747	47,026
Total	**46,928**	**120,780**

Source:
http://www.osbm.state.nc.us/ncosbm/facts_and_figures/socioeconomic_data/population_estimates/county_estimates.htm

"Step 2: Apply rate for people with Colonoscopy
80% every 10 years, 20% negative result – every 3 years[2]

Convert these to annual rates each year
80%/10 8%
20%/3 7%
Total: 15%

[2] CDC Guideline, http://www.cdc.gov/cancer/colorectal/basic_inifo/screening/guidelines.htm

Next, Rockford assumed that 80% of the population over 50 would need a colonoscopy every 10 years. The remaining 20% would have a negative result that would result in the need for a review every 3 years. These percentages were converted to annual rates by dividing by the respective frequency. (80% was divided by 10 and 20% was divided by 3). These percentages were then used to calculate the potential market size.

Step 3: Apply rate to determine lower (GI endoscopy) *rate"*

Surry County 2012 population over age 50 x .08 (8% eligible per year) {28,181 x .08 = 2,254}
Surry County 2012 population over age 50 x .07 (7% eligible per year) {28,181 x .07 = 1,973}
Total Surry County market for lower GI endoscopies (2,254 + 1,973 = 4,227)

Stokes County 2012 population over age 50 x .08 (8% eligible per year) {18,747 x .08 = 1,500}
Stokes County 2012 population over age 50 x .07 (7% eligible per year) {18,747 x .07 = 1,312}
Total Stokes County market for lower GI endoscopies (1,500 + 1,312 = 2,812)

"Next, Rockford reviewed the growth rate from the North Carolina Demographer's office. The rates are relatively flat with Stokes experiencing a -.8% growth rate and Surry at .1%. Because these could be within a reasonable standard deviation of 1%, the rate was considered flat and no growth rate was applied for the project years

Step 5: Project Upper GI (endoscopies)

6% population, 50% seek treatment and need Upper Endoscopy procedure[3]"

Surry County 2012 population over age 50 x .06 (6% eligible per year) x .50 (percent population seeking treatment) {(28,181 x .06 = 1,691) x .50 = 846}

Stokes County 2012 population over age 50 x .06 (6% eligible per year) x .50 (percent population seeking treatment) {18,747 x .06 = 1,125) x .50 = 563}

Surry County total = 846
Stokes County total = 563

"Step 6: Calculate Total Potential Market of Individuals who may need Endoscopy…The Upper GI were added to the lower (GI) *in these two counties"*

Surry County: 4,227 + 846 = 5,073
Stokes County: 2,812 + 563 = 3,375

[3] http://gi.org/guideline/diagnosis-and-management-of-gastroesophageal-reflux-disease/

"Step 7: Estimate unmet need in these two counties…the amount of procedures provided by current providers was subtracted from the potential need in Step 6. This results in a calculation of unmet need."

The applicant provided the number of GI endoscopy procedures provided to Surry, Stokes, and Virginia residents by current providers in those counties and Virginia in 2012, based on 2013 License Renewal Applications, in supplemental information as follows:

Facility	RDHEC	Northern Hospital, Surry County	Pioneer Community Hospital, Stokes County	Hugh Chatham Hospital, Surry County	Forsyth Medical Center, Forsyth County	NC Baptist Hospital, Forsyth Hospital	Digestive Health Specialists, Forsyth County	Salem Gastro. Associates, Forsyth County	Total
Surry County patients	145	1,599	26	570	425	364	269	450	3,703
Stokes County patients	29	54	208	0	464	364	707	380	2,177
Virginia patients	16	517	3	17	125	726	48	100	1,536
Total patients, all origins	190	2,219	269	1,494	6,191	10,448	5,995	6,522	7,416 [33,328]
% of patients from Surry, Stokes & Virginia	100%	98%	88%	39%	16%	14%	17%	14%	[22%]

Note: Corrections to the data are provided by the Project Analyst in brackets.

Surry County potential need (Step 6) minus the number of GI endoscopy procedures performed in Surry County is equal to estimated unmet need (5,073 – 3,703 = 1,370)

Stokes County potential need (Step 6) minus the number of GI endoscopy procedures performed in Stokes County is equal to estimated unmet need (3,375 – 2,177 = 1,198)

Total estimated unmet need (1,370 + 1,198 = 2,568)

The applicant states, in supplemental information, *"Note that the need exceeds the projected volumes that Rockford asserts it will provide after the proposed project is in operation."*

In Step 8, the applicant provides, in supplemental information, its utilization projections for project years 1 – 3, based on its historical patient origin and its capacity to meet the need, as follows:

Patient Origin	Project Year 1 (CY 2015)	Project Year 2 (CY 2016)	Project Year 3 (CY 2017)
Surry	700	1,000	1,100
Stokes	125	300	300
Other	100	200	200
Total	925	1,500	1,600

The applicant states, in supplemental information,

> *"…after carefully considering the maximum market of unmet need from Step 7, Dr. Pfitzner and Mrs. Phillips considered how much of that unmet need could be met by the proposed project. They also carefully considered when they would be able to grow to meet the need. Note that it takes 3 years to get to the Surry projection of 1,100 and 2 years to get to Stokes and the other counties. The reason it takes 3 years for Surry is that it's a higher volume of patients that need to be attracted back to the facility. It is important to note that Rockford does not claim to attract all of the patients and Rockford does not intend to take patients away from existing providers."*

In Exhibit 21 and clarified in supplemental information, the applicant provides letters of support from three Mt. Airy Internal Medicine physicians.

Projected utilization is based on reasonable, credible and supported assumptions, including historical utilization and the physician letters included in Exhibit 21.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population proposed to be served has for one licensed GI endoscopy room. 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, page 39, the applicant describes the alternatives considered, which include: 1) maintaining the status quo; and 2) developing a licensed ambulatory surgical facility with two GI procedure rooms. The applicant states that maintaining the status quo is not an

effective alternative since its volume of procedures has decreased over the last three years due to a lack of licensure and accreditation. In Section III, page 30, the applicant states that insurance company requirements for licensure and certification are the cause of this underutilization, and further states, in Section II, page 18, that *"a licensed room is essential to the* [sic] *ensure that we can continue to provide access to high-quality and cost-effective services."*

For its second alternative, the applicant determined that developing a licensed ambulatory surgical facility with two GI procedure rooms would be difficult to support given its historical utilization and its projection of 1,500 GI endoscopy procedures in Project Year Two, despite having obtained licensure. The applicant states it can reassess whether a second licensed endoscopy room is necessary in the future to meet growing demand.

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 one existing room 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. **Rockford Digestive Health Endoscopy Center, LLC shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, Rockford Digestive Health Endoscopy Center, LLC shall materially comply with the last made representation.**

2. **Rockford Digestive Health Endoscopy Center, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **Rockford Digestive Health Endoscopy Center, LLC shall develop an ambulatory surgical facility with no more than one gastrointestinal endoscopy room and shall be licensed for no more than one gastrointestinal endoscopy room upon project completion.**

4. **Rockford Digestive Health Endoscopy Center, LLC 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 Rockford Digestive Health Endoscopy Center, LLC shall be no more than $1,285 during the first three operating years of the licensed ambulatory surgical facility.**

6. **Rockford Digestive Health Endoscopy Center, LLC 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 7, the applicant projects that the total capital cost will be $100,000. The applicant states that $100,000 will be used for contingency in the event there are any upgrades needed to the facility in order to meet licensure standards. Two GI endoscopy rooms already exist and are in use. The applicant did not need a certificate of need to develop and use the two GI endoscopy rooms. However, the applicant needs a certificate of need to obtain a license as an ambulatory surgical facility and will seek licensure of one of its two GI endoscopy rooms to perform GI endoscopy procedures. In Section IX.1, page 74, the applicant indicates that there are no project start-up costs. In Section VIII.10(b), page 71, the applicant states that it will finance the capital cost with the available financial resources of Dr. Glenn Pfitzner, the gastroenterologist on staff and co-owner of Rockford Digestive Health Specialists, P.A. and GHP Properties, LLC. GHP Properties, LLC owns the GI endoscopy practice. The co-owners of GHP Properties, LLC are Dr. Glenn Pfitzner and Helen Pfitzner. In supplemental information, the applicant provides a letter signed by Dr. Glenn Pfitzner indicating the availability of these funds which states:

> *"The two owners of GHP Properties, LLC will provide the funds for the contingency out of equity investment."*

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant provides the facility's projected average reimbursement for the eight most commonly performed GI endoscopy procedures for each of the first three full project years, CY 2015, CY 2016 and CY 2017, in supplemental information, illustrated in the table below:

CPT CODE	PROCEDURE	FY 2015	FY 2016	FY 2017
43235	Esophagogastroduodenoscopy	$353	$356	$360
43239	Upper GI endoscopy, Biopsy	$391	$395	$400
43249	Upper GI endoscopy w/ Esophagus Dilation	$432	$438	$443
44394	Colonoscopy thru stoma w/ polypectomy	$422	$426	$430
45378	Diagnostic Colonoscopy	$416	$421	$426
45380	Colonoscopy w/ biopsy	$440	$445	$451
45383	Colonoscopy w/ ablation	$455	$461	$467
45385	Colonoscopy w/ lesion removal	$451	$456	$462

Note: Reimbursement amounts have been rounded to the nearest whole dollar by the Project Analyst

The applicant provides the following in supplemental information, *"The charges include all services provided at the facility including clinical supportive care, supplies and real estate (building, waiting area, and rest rooms.)…The charges do not include physician's professional fees. All charges are based on the basis of cost to deliver the procedure.*

…

The facility charge will include nursing time, administrative time, linens, supplies, equipment use, room preparation and recovery time. A separate charge will be made for anesthesia."

The audited financial statements for RDEHC for the years ended December 31, 2012 and 2011 are included in Section XIII (tab 13) of the application. As of December 31, 2012, the applicant had cash and cash equivalents of $25,646, total assets of $32,510, and -$24,214 in net assets (total assets less total liabilities). Although the applicant shows a net loss of -$24,214 as of December 31, 2012, it provides documentation, in the form of a signed letter from the co-owner of RDHEC and its parent company, GHP Properties, LLC, in supplemental information, attesting to the availability of owner's equity to fund all contingency costs of the project. (Contingency costs of $100,000 are the only capital cost of the project.) Therefore, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

The applicant provides pro forma financial statements for the first three years of the project. The applicant projects that revenues will exceed operating expenses in the first and third operating years of the project, but will not exceed operating expenses in the second operating year of the project, as illustrated in the table below:

RDEHC GI Endoscopy Services	**CY 2015 Project Year 1** 01/01/15 - 12/31/15	**CY 2016 Project Year 2** 01/01/16 - 12/31/16	**CY 2017 Project Year 3** 01/01/17 – 12/31/17
Gross Patient Revenue	$3,589,045	$4,854,365	$5,168,642
Deductions from Gross Patient Revenue	$2,163,574	$2,926,343	$3,115,798
Net Patient Revenue	$1,425,471	$1,928,022	$2,052,844
Total Expenses	$1,391,608	$1,930,402	$1,963,096
Net Income	$35,863	$-380	$89,748

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See supplemental information, Form D of the pro formas, and the assumptions following the pro forma financial statements for information regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth 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

RDHEC is an existing office-based GI endoscopy practice with two unlicensed GI endoscopy rooms. The existing office is located at 951 Rockford Street in Mount Airy, Surry County. The applicant proposes to develop a new ambulatory surgical facility by obtaining a license for one of its two existing GI endoscopy rooms.

The applicant states that 190 GI endoscopy procedures were performed at the facility in CY 2012 and that 65 GI endoscopy procedures were performed in CY 2013, January 1, 2013 through June 30, 2013. 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 4.3% of capacity [65/1,500 = 4.3%].

There are currently 11 licensed providers of GI endoscopy services in the proposed service area and vicinity, including seven hospital-based and four freestanding, non-hospital based providers. The table below illustrates the FFY 2012 utilization at all 11 facilities,

HOSPITAL BASED	**# OF GI ENDOSCOPY ENDOSCOPY ROOMS**	**# OF GI ENDOSCOPY PROCEDURES PERFORMED DURING FFY 2012***
Forsyth Medical Center	4	12,812
North Carolina Baptist Hospital	10	18,470
Wilkes Regional Medical Center	2	982
Hugh Chatham Memorial Hospital	4	1,692
Northern Hospital of Surry County	2	2,219
Pioneer Community Hospital of Stokes**	1	269
Yadkin Valley Community Hospital	1	24
Subtotal	24	36,444
# of Procedures / 1,500	24.3	
# of Procedures / # of Rooms	1,518.5	
% of Regulatory Performance Std.	101.2%	
FREESTANDING, NON-HOSPITAL BASED		
Salem Gastroenterology Associates, P.A.	4	7,475
Digestive Health Specialists, P.A.	2	7,587
Piedmont Endoscopy Center	4	6,993
WFUBMC Endoscopy Center	2	1,666
Subtotal	12	23,721
# of Procedures / 1,500	15.8	
# of Procedures / # of Rooms	1,976.8	
% of Regulatory Performance Std.	131.8%	
TOTALS		
# of GI Endoscopy Rooms/Procedures	**36**	**59,920**
# of Procedures / 1,500	**39.9**	
# of Procedures / # of Rooms	**1,664.4**	
% of Regulatory Performance Std.	**111%**	

* From 2013 License Renewal Applications (LRA)
** 2013 LRA reported 269 patients but did not indicate number of procedures, therefore the Project Analyst assumed one procedure per patient

As shown in the table above, in FFY 2012, on average 1,664.4 GI endoscopy procedures were performed per room in licensed facilities in the service area and surrounding counties. This exceeds the minimum standard of 1,500 GI endoscopy procedures.

The following table illustrates the impact of including the one proposed GI endoscopy room and the procedures already being performed in this room in the inventory of existing GI endoscopy rooms in licensed facilities, as follows:

Service Area GI Endoscopy Room Utilization, FFY 2012

TYPE OF ROOM	EXISTING	PROPOSED	TOTAL	NO. PROCEDURES FFY 2012*	PROCEDURES PER ROOM	UTILIZATION
Freestanding, Non-hospital based	12	1	13	23,911	1,839.3	122.6%
Hospital based	24	--	24	36,444	1,518.5	101.2%
Total service area	36	1	37	60,355	1,631.2	108.8%

*Includes the procedures performed at RDHEC in CY 2012

As shown in the above table, including the one proposed GI endoscopy room and the procedures already being performed in this room results in an average of 1,627.8 procedures per room for all 36 endoscopy rooms in licensed facilities in the service area, as compared to an average of 1,664.4 procedures per room, not including RDHEC.

Furthermore, the applicant states, on page 31 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 one of its unlicensed GI endoscopy rooms, the ambulatory surgical facility 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, including obtaining accreditation of the facility from a recognized accrediting body. This, in turn, will increase access to Medicare and Medicaid recipients. Additionally, the applicant will be required to meet minimum licensure and life safety requirements which will enhance the safety of the proposed facility, assuring patient safety and 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 supplemental information, and in Section VII.2, page 59, the applicant provides current staffing and projected staffing for the proposed second full fiscal year of the project, as shown in the following table:

EMPLOYEE CATEGORY	CURRENT # FTE POSITIONS	SECOND FULL FISCAL YEAR (CY 2016) # FTE POSITIONS
Professional Health Care Administrator	.5	.5
Nurse Practitioner	.5	.5
Registered Nurses (RN)	0	3.0
Licensed Practical Nurse (LPN or LNV)	2.0	2.0
Surgical Technicians	0	1.0
Receptionist	1.0	1.0
Billing Clerk	0.5	0.5
Medical Records/Administrator	0	0.5
Medical Record Technicians	0	0.5
Total:	4.5	9.5

In supplemental information, the applicant states that Dr. Glenn Pfitzner and the Professional Health Care Administrator/Nurse Practitioner *"help with reception, scheduling, medical records and billing activities, particularly since the volume of patients has dropped in recent years."*

In Exhibit 22, the applicant provides a letter signed by Dr. Glenn Pfitzner, confirming his intent to serve as Medical Director of the proposed facility. Exhibit 4 contains a copy of Dr. Pfitzner's resume which documents that he is board-certified in internal medicine - gastroenterology.

In Section VII.3(b), pages 59-60, the applicant states it has an ongoing recruitment and retention program and that current candidates for future employment are being researched from an existing pool of applicants. Additional recruitment resources, such as newspaper advertising, clinical training programs, and physician and staff contacts will be utilized. The applicant states that it will provide at least two ACLS certified staff persons and at least one BCLS staff person at all times when patients are present, thereby exceeding the regulatory requirement of one ACLS and one BCLS staff person present. 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.

The applicant states, in Section II.2, page 13,

> *"Ancillary and support services are provided as need* [sic] *according to relationships with local area providers as noted in II.1. For example, lab services are provided by Lab Corp, Inc., pharmacy consults are provided by Wally's Pharmacy. Physician consults are provided as necessary by relationships with the local medical community. It is important to note that Rockford Digestive Health Specialist, P.A. is an existing provider of these services and has all of the necessary agreements and business relationships in place to provide endoscopy services."*

In addition, the applicant provides a table in Section II.1, page 12, illustrating ancillary services such as sterile processing, patient registration and billing, and medical records are provided by facility staff. Housekeeping is provided by existing facility staff and contracted for when needed.

The applicant discusses coordination with the existing health care system in Section V, pages 45 – 48. RDHEC has an existing transfer agreement in place with Northern Hospital of Surry County and Dr. Glenn Pfitzner has medical staff privileges there in addition to Hugh Chatham Memorial Hospital, also in Surry County. The applicant states, on page 45, that this arrangement allows Dr. Pfitzner to "*transfer and admit patients as well as coordinate care for inpatients, outpatients and emergency patients."* A copy of RDHEC's transfer agreement with Northern Hospital of Surry County is provided in Exhibit 8. In addition, the applicant states that it has "*long established relationships with the local healthcare community including primary care physicians, area hospitals, and community agencies."* Letters of support from area physicians are provided in Exhibit 21.

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

RDHEC leases the building it provides GI endoscopy services in from GHP Properties, LLC. The building which houses these services was built in 2008 to meet Division of Health Service Regulation licensure requirements for a freestanding ambulatory surgical facility with two GI procedure rooms. RDHEC is owned by Rockford Digestive Health Specialists, P.A. Rockford Digestive Health Specialists, P.A. was not required to obtain a certificate of need to perform GI endoscopy procedures in unlicensed rooms. In order to become licensed as an ambulatory surgical facility with one GI endoscopy room, RDHEC must obtain a certificate of need. There is no renovation or construction necessary. The capital cost for the project, $100,000, is intended as a contingency cost in the event any up fit or changes are necessary to meet state requirements for licensure. 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 payer mix for RDHEC, CY 2012, as reported by the applicant in Section VI.12, pages 53-54.

PAYER CATEGORY	PERCENT OF TOTAL
Self Pay / Indigent	1.7%
Commercial Insurance	82.0%
Medicare/ Medicare Managed Care	5.0%
Medicaid	9.0%
Managed Care	2.3%
Other	0%
Total	100%

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, JUNE 2010	TOTAL # OF MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION, JUNE 2010	% UNINSURED CY 2008-2009 (ESTIMATE BY CECIL G. SHEPS CENTER)
Surry	20.4%	9.0%	19.1%
Stokes	14.3%	6.4%	16.6%
Statewide	**16.5%**	**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 48.6% for those age 20 and younger and 31.6% 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 payer mix, FFY 2012, for the four freestanding, non- hospital based GI endoscopy facilities in the proposed service area and vicinity:

FACILITY	PERCENT OF TOTAL			
	SELF PAY / INDIGENT	MEDICAID	MEDICARE / MEDICARE MANAGED CARE	ALL OTHER
Salem Gastroenterology Associates, P.A.	0.9%	1.3%	38.1%	59.8%
Digestive Health Specialists, P.A.	2.0%	3.3%	29.7%	65.0%
Piedmont Endoscopy Center	2.2%	2.0%	37.2%	58.6%
WFUBMC Endoscopy Center	0.7%	0%	9.1%	90.1%
Average	1.6%	2.0%	33.3%	63.1%

Source: 2013 License Renewal Applications

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 53, the applicant states:

> *"Rockford Digestive Health Specialists, P.A. has no federal obligations to provide uncompensated care. The applicant chooses to provide uncompensated care in the office practice, in the Endoscopy Center and as part of their professional services at Northern Hospital of Surry County."*

In Section VI.10, page 53, the applicant states that no civil rights access complaints have been filed against the facility or the parent company. 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, CY 2016, as reported by the applicant in its pro formas and in supplemental information:

PROJECTED PROCEDURES BY PAYER CY 2016 PROJECT YEAR 2	
Self Pay/ Indigent	5.2%
Commercial Insurance	30.2%
Medicare/ Medicare Managed Care	53.8%
Medicaid	6.0%
Managed Care	0%
Other	4.9%
Total	**100.0%**

In Section VI.2, page 50, the applicant states that it currently does and will continue to provide services *"to all the above listed categories of patients"*, in reference to question two in Section VI that lists low income persons, racial and ethnic minorities, women, handicapped persons, elderly, and other underserved persons including the medically indigent, the uninsured and the underinsured. In addition, the applicant states, on page 50, that the facility will be designed for use by handicapped persons and will be accessible to all patients regardless of their ability to pay. The applicant provides its charity care policy in Exhibit 25.

The applicant states, in Section VI.6, page 51, that it currently utilizes multiple strategies for expanding access to screening tests and endoscopy procedures, including participation in Medicare and Medicaid, and accepting charity care referrals from the Surry County Health Department. Exhibit 15 includes a copy of the applicant's Medicare enrollment record.

In Section III.4, page 37, the applicant states that it intends for its facility to become licensed and accredited to provide services per Medicare and Medicaid program regulations and further states,

> *"The project will expand access to health services for the medically underserved by providing endoscopy procedures to patients that are indigent, lack health insurance, or are otherwise medically underserved."*

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.

C

In Section VI.9, page 52, the applicant states that the facility receives patient referrals from *"a large base of primary care physicians in the region."* In addition, in Section III.8, page 40, the applicant states that it will accept referrals from hospitals, the health department and other healthcare organizations. Exhibit 21 contains letters of support from community physicians. The information provided in the application 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 45, the applicant states that it, *"…will be open to assisting health professional training programs and students if the training is aligned with the services provided by the applicant."* 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. There are no licensed, freestanding GI endoscopy facilities in Surry or Stokes counties, the two North Carolina counties in RDHEC's primary service area. The applicant states, in Section II.6, page 14, that as an unlicensed and non-accredited GI endoscopy

facility, many insurance companies are unwilling to contract with them for GI endoscopy procedures. However, the applicant states, in Section II.7, page 15, that "*More people are seeking screening procedures in ambulatory centers due to cost constraints."* The applicant further states costs to the patient, such as co-pays and co-insurance, are often much lower than in a hospital based setting. Obtaining licensure of the facility and accreditation would enable the applicant to provide lower cost GI endoscopy procedures and increase access for Medicare and Medicaid patients, thereby increasing access to needed health care services. The applicant states, in Section V.6, page 47, that "*its proposal is the most effective and least costly alternative to meet the current and future procedure volume*."

There are currently 11 licensed providers of GI endoscopy services in the proposed service area and vicinity, including seven hospital-based and four freestanding, non-hospital based providers. The table below illustrates the FFY 2012 utilization at all 11 facilities,

HOSPITAL BASED	**# OF GI ENDOSCOPY ROOMS**	**GI ENDOSCOPY PROCEDURES PERFORMED DURING FFY 2012***
Forsyth Medical Center	4	12,812
North Carolina Baptist Hospital	10	18,470
Wilkes Regional Medical Center	2	982
Hugh Chatham Memorial Hospital	4	1,692
Northern Hospital of Surry County	2	2,219
Pioneer Community Hospital of Stokes**	1	269
Yadkin Valley Community Hospital	1	24
Subtotal	24	36,444
# of Procedures / 1,500	24.3	
# of Procedures / # of Rooms	1,518.5	
% of Regulatory Performance Std.	101.2%	
FREESTANDING, NON-HOSPITAL BASED		
Salem Gastroenterology Associates, P.A.	4	7,475
Digestive Health Specialists, P.A.	2	7,587
Piedmont Endoscopy Center	4	6,993
WFUBMC Endoscopy Center	2	1,666
Subtotal	12	23,721
# of Procedures / 1,500	15.8	
# of Procedures / # of Rooms	1,976.8	
% of Regulatory Performance Std.	131.8%	
TOTALS		
# of GI Endoscopy Rooms/Procedures	**36**	**59,920**
# of Procedures / 1,500	**39.9**	
# of Procedures / # of Rooms	**1,664.4**	
% of Regulatory Performance Std.	**111.0%**	

* From 2013 License Renewal Applications (LRAs)
** 2013 LRA reported 269 patients but did not indicate # of procedures, therefore project analyst assumed one procedure per patient

The data provided in the table above indicates that the GI endoscopy facilities in the applicant's primary service area and vicinity are operating, on average, above the 2013 SMFP standard of 1,500 procedures per year. Hospital based GI endoscopy facilities are operating at 101.2% of capacity, while freestanding GI endoscopy facilities are operating at 131.8% of capacity.

In addition, the applicant cites N.C.G.S. 131E-175(11) in Section III, page 31, which 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 one of its unlicensed GI endoscopy rooms, the RDHEC 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 minimum licensure and life safety requirements which will enhance the safety of the proposed facility.

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 ambulatory surgical facility with one GI endoscopy room based on current and projected utilization (see Section IV, page 43, and supplemental information) and that it is a cost-effective alternative (see Section III, page 40 of the application);
- The applicant adequately demonstrates that it will continue to provide quality services (see Section II, pages 13 - 16 and Exhibit 12); and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations (see Section III.4, page 37, Section VI, pages 50-51, and Exhibit 25 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 RDHEC 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.1, page 31, the applicant identifies the service area as Surry and Stokes counties in North Carolina, and Patrick and Carroll counties in Virginia. Approximately 96 percent of patients come from these four counties.

.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- RDHEC proposes to obtain a license for an ambulatory surgical facility with one GI endoscopy room. RDHS has two existing procedure rooms, however it seeks to use only one of the rooms to perform GI endoscopy procedures as a licensed center.

(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- RDHEC does not own or 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 supplemental information, the applicant provides the number of GI endoscopy procedures, identified by CPT code, performed in CY 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 supplemental information, 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, page 18, and in supplemental information, the applicant states that RDHEC has performed only GI endoscopy procedures in its existing unlicensed GI endoscopy rooms 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, page 18, and in supplemental information, 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, page 18, the applicant states that 190 procedures were performed in the two GI endoscopy rooms at RDHEC in CY 2012. RDHEC's physician also performed 1,196 procedures at Northern Hospital of Surry County in 2012. In supplemental information, the applicant states *"The number of patients equals the number of procedures."*

(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 supplemental information the applicant projects 925 procedures will be performed in Year One (CY 2015), 1,500 in Year Two (CY 2016), and 1,600

in Year Three (CY 2017) in the proposed GI endoscopy room. In supplemental information, the applicant states *"The number of patients equals the number of procedures."*

.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, page 19, the applicant states that the facility will be operated Monday through Friday from 8:00 AM to 5:00 PM. In addition, as stated in Section II, page 21, the facility will operate five days a week and 52 weeks per year, excluding ten days for holidays, physician vacation, and continuing education time.

.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 supplemental information, the applicant provides the type and average facility charges, by CPT code, that are projected during the first three operating years for eight procedures projected to be performed most often at RDHEC. The applicant states, in supplemental information, *"Note that because we are a specialty, our top procedure list is limited to 8 most frequent procedures."* The applicant further states,

in supplemental information, that RDHEC performs eight types of procedures only and it projects these eight types to be performed during the first three project years.

.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 supplemental information, the applicant states *"The charges include all services provided at the facility including supportive care, supplies and real estate (building, waiting area, and rest rooms). The charges do not include physician's professional fees. All charges are based on the basis of cost to deliver the procedure."* In addition, the applicant states in supplemental information that the facility charge will include, *"nursing time, administrative time, linens, supplies, equipment use, room 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 supplemental information, the applicant states *"The charges do not include physician's professional fees. A separate charge will be made for anesthesia."*

.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.*

-NA- The applicant is not an existing licensed facility. In supplemental information, the applicant provides a table listing the eight most commonly performed procedures in CY 2012. The applicant further states, in supplemental information, that RDHEC performed eight types of procedures only.

.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 supplemental information, the applicant provides the average reimbursement projected to be received for the eight GI endoscopy procedures which the applicant projects will be performed most frequently in the facility for the first three project years. In supplemental information, the applicant states, *"Note that because we are a specialty, our top procedure list is limited to 8 most frequent procedures."* The applicant further states, in supplemental information, that RDHEC performs eight types of procedures only and it projects these eight types to be performed during 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- The applicant provides a copy of RDHEC's written administrative policy that prohibits 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 supplemental information, the applicant provides a letter signed by the co-owner of RDHEC stating *"Rockford Digestive Health Specialists will participate in and comply with conditions of participation in Medicare and Medicaid programs within three months after 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 Section II, page 20, the applicant states that it *"will accept charity care referrals from the Health Department in Surry County."* In addition, in Exhibit 25, the applicant provides its policy and procedures for providing charity care.

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

-C- The applicant provides a description of patient selection criteria, including referral arrangements for high-risk patients in Exhibit 5 of the application and in supplemental information.

(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 IV, page 43, and in supplemental information the applicant states that Dr. Glenn Pfitzner of RDHEC performed 1,196 GI endoscopy procedures at Northern Hospital of Surry County during CY 2012.

(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- The applicant states, in Section II, page 21, that it does not expect utilization to be reduced at other existing or approved GI endoscopy facilities.

.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, page 43, and in supplemental information, the applicant projects to perform 1,500 GI endoscopy procedures during CY 2016, the second project year. 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, page 22, and in supplemental information, the applicant states it will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy

procedures, as reflected in its utilization projections, types of procedures performed and its list of projected charges.

.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- The applicant does not own 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- The applicant states all assumptions and methodology used in projecting GI endoscopy utilization in Section III, pages 30-35, and in supplemental information. 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- The applicant provides a copy of an agreement with Laboratory Corporation of America for these services in Exhibit 6.

.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- The applicant provides a copy of its policy on Administration of Sedatives and Analgesics, including tracking and responding to adverse reactions and unexpected outcomes, in supplemental information.

.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- The applicant provides a copy of its procedures for cleaning and monitoring its equipment and procedure room in supplemental information.

.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- The applicant includes a copy of Dr. Glenn Pfitzner's resume which indicates that he is on staff at Northern Hospital of Surry County, and therefore, has privileges there.

(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- Exhibit 8 contains a transfer agreement between RDHEC and Northern Hospital of Surry County.

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

-C- Exhibit 8 contains a transfer agreement between RDHEC and Northern Hospital of Surry County.

.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 VII.6, page 62, the applicant indicates that the proposed facility will have sufficient staff in the areas identified in this rule. Specifically, there will be 2.0 FTEs for administration; 2.00 FTEs assigned to pre-operative; 2.00 FTEs assigned to post-operative; 2.00 FTEs assigned to the procedure room; and 1.00 FTE assigned to equipment cleaning, safety, and maintenance.

.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- Exhibit 19 contains the resume of the one physician who will perform GI endoscopy procedures at RDHEC. The resume indicates that he is board certified in internal medicine – gastroenterology.

.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, page 24, the applicant states that it will perform a background check, verify licensure and medical education, and consider work history in extending privileges to medical personnel performing services at the facility.

.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.

-C- The applicant states, in Section II, page 25, *"Upon licensure of Rockford Digestive Endoscopy Center, LLC the organization intents* [sic] *to immediately apply for AAAHC accreditation."* (AAAHC is Accreditation Association for Ambulatory Health Care.) In addition, the applicant provides a letter in Exhibit 22, indicating that Dr. Glenn Pfitzner has agreed to become the medical director of the facility. He is board certified in gastroenterology by the American Board of Internal Medicine and has privileges at Northern Hospital of Surry County as evidenced in his resume provided in Exhibit 4. Moreover, the applicant states, on page 25, that more than one registered nurse will be employed per procedure room, and that additional staff will be employed to assist in the procedure room as indicated in Section VII, page 62. Lastly, the applicant states, on page 25, that Dr. Pfitzner is ACLS certified and will be present when the procedure is performed and during post-operative recovery, and that at least one other health care professional with BCLS certification will be present in the facility.

.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 applicant states, on page 14, that its proposed licensed ambulatory surgical facility will be located within an existing medical office building that is *"adjacent to and physically separate from"* its medical practice office. The two offices are separated by firewalls and secured doorways. The applicant further states, on page 14, *"This separation of both the ASC facility and the financial structure will be maintained with the proposed project."*

.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 states, in Section II, page 25, "*Upon licensure of Rockford Digestive Endoscopy Center, LLC the organization intents* [sic] *to immediately apply for AAAHC accreditation.*" (AAAHC is Accreditation Association for Ambulatory Health Care.)

.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.

-C- The applicant states, on page 27, "*the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.*" In addition, the applicant provides a copy of its floor plan in supplemental information which identifies its receiving/registering area, waiting area, pre-operative rooms, procedure rooms by type, and recovery rooms. The applicant states in Section II, page 14, that its medical practice and the GI endoscopy procedure area are separated by firewalls and secured doorways. The applicant currently occupies the facility space under a lease. A copy of the lease is provided in Exhibit 2.