ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: September 26, 2014

PROJECT ANALYST: Julie Halatek
INTERIM CHIEF: Martha J. Frisone

PROJECT I.D. NUMBER: J-10281-14 / Wake Endoscopy Center, LLC and Five GIS Rex Properties, LLC / Develop a new licensed ambulatory surgical facility with two GI endoscopy rooms / Johnston 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.

C

Wake Endoscopy Center, LLC (WEC) and Five GIS Rex Properties, LLC (Five GIS) propose to develop a new licensed ambulatory surgical facility (ASF) with two gastrointestinal (GI) endoscopy rooms to be located at 900 South Lombard Street in Clayton in Johnston County. The facility will be managed by Raleigh Medical Group, P.A. (RMG).

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2014 State Medical Facilities Plan (SMFP).

There is one policy in the 2014 SMFP applicable to the review of the application. Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES states:

> *"Any person proposing a capital expenditure greater than $2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.*

In approving a certificate of need proposing an expenditure greater than $5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 are required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

In Section III.4, page 62, the applicants state:

"The proposed project is consistent with the objectives of Policy Gen-4. Specifically, the proposed renovated facility will use modern energy conservation practices and methods, featuring energy efficiency and water conservation. The facility HVAC and electrical systems are designed to meet all requirements of the latest energy code adopted by the State, as well as the latest edition of ASHRAE 90.1. ASHRAE 90.1 is the industry standard for energy efficient buildings. All lighting systems are designed to meet the requirements of ASHRAE 90.1, and the adopted State energy code. Water fixtures (such as toilets and faucets) will be designed as low flow to conserve water."

The applicants' statement adequately describes the project's plan to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4 and is conforming to this criterion.

(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

WEC and Five GIS propose to develop Clayton Endoscopy, a new licensed ASF with two GI endoscopy rooms, to be located at 900 South Lombard Street in Clayton in Johnston County. The facility will be managed by RMG.

Population to be Served

In Section III.6, page 64, the applicants assume that 100% of the patients utilizing Clayton Endoscopy will be residents of Johnston County. On page 63, the applicants state *"This is based on WEC's historical experience providing GI endoscopy services to residents from Johnston County and the methodology … described in Section III.1."* The applicants adequately identify the population proposed to be served.

Need Analysis

In Section III.1, pages 36 – 61, the applicants describe all of the factors which they state support a need to develop the proposed ASF with two GI endoscopy rooms in Clayton. On page 36, the applicants summarize these factors as follows:

- "*Currently no licensed freestanding GI endoscopy rooms are located in Johnston County.*
- *Johnston County population is increasing steadily.*
- *Johnston County residents age 55 and older are projected to increase an average 3.5% annually during the next four years.*
- *As the average age of the Johnston County population increases, cancer incidence will increase as well.*
- *Johnston County residents have a higher colorectal cancer incidence rate compared to North Carolina.*
- *Obtaining cost-effective care remains a relevant factor for Johnston County patients seeking licensed outpatient GI endoscopy services."*

On pages 36-39, the applicants discuss endoscopy services. On page 38, the applicants discuss three of the most common GI endoscopy procedures performed – upper GI endoscopy, colonoscopy, and sigmoidoscopy. Based on the experience of the applicants, approximately 25 percent of outpatient endoscopy procedures are upper GI endoscopy procedures, and approximately 75 percent of outpatient endoscopy procedures are colonoscopy or sigmoidoscopy procedures. On page 39, the applicants discuss gastroesophageal reflux disease (GERD), a common condition requiring an upper GI endoscopy to diagnose.

On pages 40-45, the applicants discuss colorectal cancer screening. On page 40, the applicants state:

> *"According to data from the North Carolina Central Cancer Registry (NCCCR), colorectal cancer is the second leading cause of cancer-related deaths in North Carolina. However, it is one of the few cancers that can be prevented through early detection."*

On pages 42-44, the applicants provide guidelines obtained from the American Cancer Society (ACS) regarding recommended colon cancer screening. These guidelines were developed by the ACS, the American College of Radiology, and the US Multi-society Task Force on

Colorectal Cancer (a consortium representing other physician groups). According to these guidelines, people with an average risk of colon cancer should be screened starting at age 50 and every 10 years after, but people at increased risk should begin screening prior to age 50 – in some cases as young as age 10. The guidelines suggest repeat screening anywhere from every 3 months to every 10 years depending on risk category and findings.

On pages 46-47, the applicants discuss third-party payor trends and the Affordable Care Act. On page 46, the applicants state that research shows that individuals, including those with insurance, are less likely to seek health services when they have to pay out-of-pocket costs. The applicants state that the Affordable Care Act eliminated out-of-pocket costs for preventative services. However, the applicants state that there have been reports of asymptomatic patients undergoing screening for cancer who have been billed for services they expected would be fully covered under the Affordable Care Act. See full discussion on pages 46-47. On page 48, the applicants state that the proposed ASF will offer a lower cost structure compared to the existing hospital-based GI endoscopy services.

On pages 47-49, the applicants discuss Johnston County demographics. Citing information obtained from the North Carolina Office of State Budget and Management (NCOSBM), the applicants state that both the total population and the population age 55 and older are projected to increase faster than the population of North Carolina as a whole. The following table combines data provided by the applicants (Johnston County) and data obtained by the Project Analyst (statewide).

Projected Population							
	2014	**2015**	**2016**	**2017**	**2018**	**4-Year CAGR***	**% Growth Total**
Johnston County All Age Groups	179,053	181,192	183,330	185,469	187,608	1.2%	4.8%
Statewide All Age Groups	9,956,488	10,055,337	10,156,537	10,258,255	10,360,693	1.0%	4.1%**
Johnston County Age 55 & Older	41,938	43,464	44,993	46,536	48,185	3.5%	14.9%
Statewide Age 55 & Older	2,689,673	2,766,353	2,841,145	2,914,649	2,987,672	2.7%	11.1%

Note: All population projections were obtained from NCOSBM; however, the Project Analyst accessed the statewide data following the most recent update which took place after the applicants submitted the application.

* CAGR stands for Compound Annual Growth Rate.

** On page 47, the applicants state that the CAGR for the population of the state as a whole would be 4.3% between 2014 and 2018; however, the Project Analyst calculated a CAGR of 4.1% based on the updated data. This difference is immaterial to the conformity of the application with any review criteria.

The data above shows that between 2014 and 2018, the population age 55 and over is projected to grow almost three times as fast as the total population of Johnston County.

On pages 48-49, the applicants state that, according to the NCCCR, as the 55 and older population of Johnston County increases, so will the incidence of colorectal cancer. The applicants provide the following information on page 48:

2007 – 2011 Johnston County Colorectal Cancer Incidence Rate (per 100,000 population)		
Group	**Johnston County**	**North Carolina**
All Ages	43.1	41.5
Age 65+	205.1	194.8

Applicants' Source: NCCCR, produced April 2014

On page 49, the applicants discuss financial resources and provide a comparison of the Johnston County per capita income with the North Carolina per capita income for 2012 using data obtained from the United States Census Bureau. According to the applicants, the Johnston County per capita income is $22,671 and the North Carolina per capita income is $25,285. The applicants state:

> *"Based on a comparison of income per capita, Johnston County residents have comparatively fewer economic resources to 1) travel long distances for endoscopy services and 2) pay for comparatively higher GI endoscopy charges and out of pocket expenses. Thus, it is particularly important that Johnston County have sufficient local access to cost effective endoscopy services to accommodate the needs of local residents."*

On pages 49-50, the applicants discuss the inventory of GI endoscopy rooms in licensed facilities in Johnston County. On page 49, the applicants state: *"Currently, there are no licensed, freestanding non-hospital based GI endoscopy rooms in Johnston County."* (Emphasis in original.) The applicants state that they compared utilization of GI endoscopy rooms in ASFs and hospital-based GI endoscopy rooms in Wake County. The data was obtained by the applicants from the 2014 SMFP. On page 50, the applicants state:

> *"during FY2012, 55,192 GI endoscopy procedures were performed in 27 licensed freestanding endoscopy rooms. Based on the performance standard of 1,500 procedures per GI endoscopy room defined in 10A NCAC 14C .3903 (b) & (c), the 27 existing Wake County GI endoscopy rooms located in licensed freestanding facilities operated at 136 percent capacity (55,192 / 27 rooms / 1,500 procedures). Comparatively, during FY 2012, 11,274 GI endoscopy procedures were performed in 11 hospital-based GI endoscopy rooms, representing utilization of only 68 percent capacity (11,274 / 11 rooms / 1,500 procedures).*
>
> *Hospital-based GI endoscopy rooms are similarly underutilized in Johnston County. According to its 2014 License Renewal Application, Johnston Health's three licensed hospital-based GI endoscopy rooms operated at 77 percent of the CON utilization threshold targets (3,480 procedures / 3 rooms / 1,500). Many patients leave Johnston County to seek more affordable GI endoscopy services in other counties. For example, during 2013 WEC served 910 Johnston County patients at its Lake Drive GI endoscopy facility."*

On pages 50-52, the applicants discuss the outmigration of Johnston County residents for GI endoscopy services. The following table reproduces the table provided by the applicants on page 51 of the application.

Johnston County Residents Outmigration to Other Counties for GI Endoscopy Services			
Year	**Total Patients – Johnston County**	**Patients leaving Johnston County**	**% Outmigration**
FY2010	6,199	3,943	63.6%
FY2011	6,138	4,041	65.8%
FY2012	7,184	4,974	69.2%

* Applicants' source: FY2010-FY2012 Endoscopy Patient Origin Report provided by Division of Health Service Regulation, Medical Facilities Planning Branch

Following the table, the applicants state:

> *"In FY2012, 4,974 patients left Johnston County to obtain endoscopy services. This is more than two times the number of Johnston County patients who received endoscopy services in Johnston County. Furthermore, the number of patients leaving Johnston County for GI endoscopy services increased over 26% from FY2010 to FY2012. WEC suspects that this is because there are more cost-effective options in other counties that are not available locally. As described previously, last year WEC served 910 Johnston County patients at its Lake Drive GI endoscopy facility. WEC provides this information regarding patient outmigration as evidence of the need for local access to licensed, cost-effective freestanding endoscopy services in Johnston County.*
>
> *The FY2012 Endoscopy Patient Origin Report indicates that the vast majority of residents who leave Johnston County for endoscopy services are traveling to Wake County (47.08%). As described previously, based on information provided in the 2014 SMFP, the 27 existing Wake County GI endoscopy rooms located in licensed freestanding facilities operated at 136 percent capacity (55,192 / 27 rooms / 1,500 procedures) during FY2012. Therefore, Johnston County residents must compete with Wake County residents for access to Wake County GI endoscopy rooms that are operating above practical capacity. This is certainly true at WEC's Lake Drive facility, which is currently operating at 163% capacity.*
>
> *It is not reasonable to expect that residents of Johnston County should have to travel to Wake County to obtain access to more cost effective, licensed freestanding endoscopy services. In order to receive treatment for most routine diagnostic services (such as colonoscopies or endoscopies), patients need not travel out of county. Thus, it is not consistent with the State's basic health planning principles of expanding access to services, and of promoting cost-effective approaches."*

On page 52, the applicants state that there are negative implications for patients who have to leave Johnston County for services, such as increased costs associated with travel and time away from work. Moreover, patients may postpone or delay scheduling a recommended screening *"because cost effective licensed services are not more conveniently available close to home."*

On page 52, the applicants discuss WEC and physician support for the proposal. The applicants state:

> *"WEC physicians have a long history of serving Johnston County patients via their eight (8) existing gastroenterology clinics, including one located in Clayton on Highway 42. As a result WEC has a large, existing base of patients and referral sources in Johnston County. Last year, WEC served 910 Johnston County patients at its Lake Drive GI endoscopy facility. In addition, WEC's physicians performed hundreds of GI endoscopy procedures on Johnston County residents at local hospitals, including Johnston Medical Center – Clayton. The proposed Clayton Endoscopy will enable WEC physicians to provide their patients with more cost effective licensed GI endoscopy services in a convenient location, closer to home.*
>
> *WEC has also received support from a local gastroenterologist in Johnston County who intends to utilize the proposed Clayton Endoscopy. Dr. Richard Lee serves Johnston County patients at his clinic in Smithfield (Neuse Gastroenterology, PA) and performs his procedures at Johnston Medical Center – Smithfield and Johnston Medical Center – Clayton. Clayton Endoscopy will enable Dr. Lee to provide a more cost effective service for his GI endoscopy patients."*

The applicants adequately demonstrate the need the population to be served has for the proposed project.

Projected Utilization

In Section III.1, pages 53-61, the applicants provide the assumptions and methodology used to project utilization at Clayton Endoscopy, which are described below.

"Step 1: Service Area Population"

The applicants identify the service area for Clayton Endoscopy as Johnston County. The applicants provide the following population projections for Johnston County from NCOSBM:

Johnston County Population					
	2014	**2015**	**2016**	**2017**	**2018**
Johnston County Population	179,053	181,192	183,330	185,469	187,608

Applicants' Source: NCOSBM

"Step 2: GI Endoscopy Procedure Rate"

On page 53, the applicants provide the statewide GI endoscopy utilization rate per thousand population for federal fiscal years 2010, 2011 and 2012, as shown below:

North Carolina GI Endoscopy Procedures Performed in Licensed Facilities GI Endoscopy Use Rate per 1,000 Population			
Year	**NC Population**	**GI Endo Procedures**	**GI Endo Use Rate**
FY2010	9,574,477	564,997	59.011
FY2011	9,666,068	574,908	59.477
FY2012	9,765,229	579,316	59.324

Applicants' Source: NCOSBM & 2012-2014 SMFPs
Note: Totals may not foot due to rounding.

The applicants state that the CAGR for GI endoscopy procedures (in licensed facilities) between FY2010 and FY2012 is 1.3 percent but the CAGR for the total population during the same period is 1.0 percent.

On page 54, the applicants state:

> *"The number of GI endoscopy patients is not equal to the total number of GI endoscopy procedures. By dividing the number of total endoscopy procedures by the total number of patients, a 'procedure per patient ratio' can be determined. The 'procedures per patient ratio' can then be multiplied by the number of GI endoscopy patients to determine the number of GI endoscopy procedures performed on Johnston County residents. …"*

The applicants provide the following information on page 54:

GI Endoscopy Ratio of Procedures to Patients WEC's Lake Drive Facility & North Carolina*			
	Patients	**Procedures**	**Ratio**
North Carolina	498,549	579,316	1.16
WEC Lake Drive	8,609	9,780	1.14

* The applicants state that they based the calculations on WEC's FY2013 utilization as reported in their 2014 LRA and the FY2012 statewide utilization as reported in the 2014 SMFP and FY2012 GI Endoscopy Patient Origin Report (the most recent data available).

The applicants state they then calculated the FY2012 GI endoscopy use rate for Johnston County, as shown below:

Johnston County GI Endoscopy Use Rate per 1,000 population				
Year	**Population**	**GI Endoscopy Patients***	**GI Endoscopy Procedures****	**GI Endoscopy Use Rate**
FY2012	174,933	7,184	8,348	47.72

Note: Totals may not foot due to rounding.
***** **Applicants' Source:** DHSR Planning Branch GI Endoscopy Patient Origin Report
****** The applicants state this calculation was made by multiplying the number of patients by the North Carolina Procedure per Patient Ratio calculated above (1.16).

On page 55, the applicants state:

> *"The FY2012 GI endoscopy use rate for Johnston County is lower compared to the State GI endoscopy use rate. This is due to the lack of local access to more cost effective licensed freestanding GI endoscopy rooms. As described previously, there are no licensed freestanding GI endoscopy rooms in Johnston County. As a result, more than two-thirds of Johnston County GI endoscopy patients travel to another county to receive services. However, many Johnston County residents do not have the financial means to travel to another county for GI endoscopy services, or to pay higher out of pocket costs for hospital-based GI endoscopy services in Johnston County. As a result, many patients forego or postpone recommended GI endoscopy procedures. This results in a comparatively lower utilization rate than North Carolina.*
>
> *Given local access to more cost effective, licensed freestanding GI endoscopy services, WEC reasonably assumes the Johnston County GI endoscopy use rate will gradually increase to a rate more comparable to the North Carolina GI endoscopy utilization rate. WEC conservatively projects the FY2012 Johnston County GI endoscopy use rate to remain constant until Clayton Endoscopy becomes operational. The FY2012 Johnston County GI endoscopy use rate is approximately 80.4% of the North Carolina GI endoscopy use rate (47.72 / 59.32). WEC projects the Johnston County GI endoscopy use rate to increase to 90% of the FY2012 statewide use rate during the first project year (2016) and to 95% during the second and third project years (2017-2018)."*

The applicants provide the following information on page 55:

Johnston County Projected GI Endoscopy Use Rate per 1,000 Population						
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Johnston Co. GI Endoscopy Use Rate / 1,000 popul.	47.72	47.72	47.72	50.43	56.36	56.36
% of FY2012 Statewide GI Endo Use Rate (59.32)	80.4%	80.4%	80.4%	85.0%	95.0%	95.0%

On pages 55-56, the applicants state:

> *"The projected Johnston County GI endoscopy use rate is supported by several factors including:*

- *increased access to more cost effective licensed GI endoscopy services,*
- *growth of aging Johnston County residents,*
- *in 2018, the median age of Johnston County residents (38.43) will be comparable to the median age of North Carolina (38.71)[19],*
- *comparatively higher cancer incidence rates for Johnston County residents,*
- *letters of support from local physicians (Exhibit 17),*
- *increased education and public awareness about GI endoscopy procedures,*
- *third-party payor trends and The Affordable Care Act."* (Note: Footnote 19 in the quote lists the source for the 2018 median age information as NCOSBM.)

"Step 3: Johnston County GI Endoscopy Procedures Based on Use Rate"

On page 56, the applicants projected total Johnston County GI endoscopy procedures (all facilities), as shown below:

Johnston County Projected GI Endoscopy Procedures Based on Use Rates from Step 2					
	2014	**2015**	**2016**	**2017**	**2018**
GI Endoscopy Procedures	8,544	8,647	9,245	10,453	10,573

Note: The applicants state the formula used was (Johnston County Population / 1,000) x Projected GI Endoscopy Use Rate per 1,000 = Johnston County GI Endoscopy Procedures.

"Step 4: GI Endoscopy Market Share"

On pages 56-59, the applicants discuss the projected market share for Clayton Endoscopy and how they arrived at their projections. The applicants state that they project the number of procedures performed on Johnston County residents at WEC's Lake Drive facility will remain constant through the third project year and that 95 percent of its Johnston County patients will shift to Clayton Endoscopy upon project completion. The applicants provide the following information on page 56:

Clayton Endoscopy Projected GI Endoscopy Procedures and Market Share based on Shift of Patients from WEC's Lake Drive facility						
		2014	**2015**	**2016**	**2017**	**2018**
A.	Johnston Co. GI Endo Procedures	8,544	8,647	9,245	10,453	10,573
B.	WEC – Lake Drive Johnston Co. GI Endoscopy Procedures	1,034	1,034	1,034	1,034	1,034
C.	WEC – Lake Drive Johnston Co. GI Endoscopy Procedures Shift to Clayton Endoscopy (B x 95%)			982	982	982
D.	Estimated Market Share (C / A)			10.6%	9.4%	9.3%

On pages 56-57, the applicants state:

> *"During 2013, WEC's Lake Drive facility performed approximately 1,034 GI endoscopy procedures on Johnston County residents. For purposes of projecting utilization for the proposed Clayton Endoscopy, WEC projects this number to remain*

constant through the third project year, and that 95% of its Johnston County patients who historically travelled to Lake Drive for GI endoscopy procedures would shift to Clayton Endoscopy. Thus, WEC's GI endoscopy estimated market share for these Johnston County patients is approximately 10% during project year 1 and 9% during project years 2-3. …

…

Shifting patients from WEC's Lake Drive facility to the proposed Clayton Endoscopy is reasonable and practical. During CY2013, WEC's Lake Drive facility performed 9,780 GI endoscopy procedures in its four GI endoscopy rooms. Based on the utilization threshold of 1,500 procedures per GI endoscopy room, WEC's Lake Drive facility is operating at approximately 163% of practical capacity (9,780 / 1,500 / 4). Thus, shifting patients from Lake Drive to Clayton Endoscopy will decompress capacity constraints at Lake Drive. More importantly, it makes practical sense that these Johnston County patients would choose to utilize Clayton Endoscopy. The proposed facility will be geographically much more convenient for Johnston County residents compared to WEC's Lake Drive facility. Patients are instructed not to return to work after a GI endoscopy procedure, thus it is logical that patients and their families would prefer to utilize a facility that is close to home."

On page 57, the applicants state that the number of procedures performed at WEC's Lake Drive facility represents only a portion of the total number of Johnston County residents served by WEC's physicians. The applicants state that due to the high utilization of WEC's Lake Drive facility, WEC physicians also perform GI endoscopy procedures on Johnston County residents in outpatient hospital-based GI endoscopy rooms in both Wake and Johnston counties. The applicants state that these WEC physicians intend to perform these procedures at Clayton Endoscopy to provide more cost effective and convenient services to their Johnston County patients. On pages 57-58, the applicants state:

"it is reasonable and logical for WEC to project an increase in market share based on the following:

- *The GI endoscopy procedure use rate is conservative because it is based only on the number of GI endoscopy procedures at existing <u>licensed</u> facilities.*

- *WEC examined the GI endoscopy patient origin data provided by DHSR Planning Section and determined that over 69 percent of Johnston County's endoscopy patients leave the county to obtain endoscopy procedures at licensed freestanding facilities in other counties. The future WEC market share projections assume that, based on the convenience and cost savings afforded by Clayton Endoscopy, fewer patients will leave Johnston County to obtain GI endoscopy procedures in other counties.*

- *WEC physicians have a long history of serving Johnston County patients via their eight (8) existing gastroenterology clinics, including one located in Clayton on*

Highway 42. As a result WEC has a large, existing base of patients and referral sources in Johnston County. Six of WEC's physicians have signed letters of intent to perform GI endoscopy procedures at the proposed Clayton Endoscopy. Please refer to Exhibit 17.

- *WEC has received support from a local gastroenterologist in Johnston County who intends to utilize Clayton Endoscopy. Dr. Richard Lee serves Johnston County patients at his clinic in Smithfield (Neuse Gastroenterology, PA) and performs his procedures in hospital based GI endoscopy rooms. Thus, the proposed Clayton facility will enable Dr. Lee to provide a more cost effective service for his GI endoscopy patients. Please refer to Exhibit 17 for a letter of support from Dr. Lee.*

- *WEC also expects to gain market share because hospitals typically have higher patient charges for outpatient GI endoscopy procedures compared to WEC's projected charges.*

- *WEC will implement a Johnston County marketing program to increase local awareness for the proposed Clayton Endoscopy facility. Elements of the marketing program include changes to the WEC website to provide information regarding the proposed facility, direct mailings to referring physicians in Johnston County, and presentations by physicians and physician assistants at health education events and community and civic groups."* (Emphasis in original.)

On page 59, the applicants project additional market share capture at Clayton Endoscopy in addition to the procedures projected to shift from WEC's Lake Drive facility. The following table illustrates the resulting total projected total market share for Clayton Endoscopy.

Clayton Endoscopy Projected GI Endoscopy Market Share			
	2016	**2017**	**2018**
Market Share from WEC – Lake Drive Shift of Johnston Co. Patient Procedures	10.6%	9.4%	9.3%
Additional Johnston Co. GI Endoscopy Market Share	15.0%	20.0%	20.0%
Total Projected Market Share	25.6%	29.4%	29.3%

On page 59, the applicants state:

"WEC proposes to increase the inventory of licensed GI endoscopy rooms in Johnston County from three to five. WEC projects a market share of 29.4% during the second project year (2017), which is much less compared to its proposed share of GI endoscopy rooms in Johnston County (2 ÷ 5 = 40%). The remaining 71% market share may include Johnston County residents who receive inpatient GI endoscopy services, Johnston County residents who choose to receive hospital-based outpatient GI endoscopy services and Johnston County residents who decide to continue to travel outside the county to receive services."

"Step 5: Project GI Endoscopy Procedures"

On pages 59-60, the applicants state that, to project the number of GI endoscopy procedures that will be performed at Clayton Endoscopy during the first three project years, they multiplied the projected GI endoscopy procedures calculated in Step 3 above by the market share projected in Step 4 above, as shown in the table below:

Clayton Endoscopy Projected GI Endoscopy Procedures			
	2016	**2017**	**2018**
GI Endoscopy Procedures	2,369	3,073	3,097

On page 60, the applicants state that physician letters of support provided in Exhibit 17 support the annual number of procedures projected to be performed at Clayton Endoscopy. Five physicians estimate that they will perform at least 200 procedures annually at Clayton Endoscopy for a total of at least 1,000 procedures annually. One physician estimates he will perform at least 1,200 procedures annually at Clayton Endoscopy and one physician estimates he will perform at least 1,500 procedures annually at Clayton Endoscopy. On page 60, the applicants state:

> *"The physician procedure projections are based on the voluntary written commitment of the physicians who intend to utilize the proposed Clayton facility. They are based on the large established base of patients in Johnston County, and based on the physicians' historical experience providing GI endoscopy services to these patients. The sum of the projected GI endoscopy procedures for the physicians who intend to utilize Clayton Endoscopy equal* [sic] *3,700 GI endoscopy procedures, which exceeds the projected number of procedures described in WEC's methodology. This underscores the reasonableness of WEC's assumptions and projected utilization for the proposed project."*

Projected utilization is based on reasonable and adequately supported assumptions regarding population growth, GI endoscopy utilization rates, the number of patients expected to shift from WEC's Lake Drive facility to Clayton Endoscopy and reduced outmigration of Johnston County GI endoscopy patients to facilities located in other counties, particularly Wake County.

Access

In Section VI.4(a), page 79, the applicants state:

> *"Clinical services at Clayton Endoscopy will be non-restrictive relative to low-income persons, social, racial and ethnic minorities, women, handicapped persons, private pay, Medicare and Medicaid beneficiaries, uninsured indigent persons, underserved indigent patients and fully insured patients. Based on historical access at WEC facilities, Clayton Endoscopy will render appropriate medical care to all persons in need of such care, regardless of their ability to pay."*

In Section VI.6, page 81, the applicants state:

> *"As an example of its commitment to providing access to care for the medically underserved, WEC physicians participate in Project Access of Wake County. Project Access links people without health insurance into a local network of clinics, laboratories, pharmacies and hospitals that donate their efforts to help those in need. WEC provides all of its services to Project Access patients, e.g., office visits, surgery, etc. During 2013, WEC provided healthcare services to 54 Project Access patients. WEC's physician owners will strive to identify and coordinate with Johnston County programs to make Clayton Endoscopy available to medically indigent patients who need GI endoscopy services."*

Exhibit 12 contains copies of WEC's patient financial policies and procedures, including a non-discrimination policy; a patient's rights policy; and a policy regarding care for Project Access patients.

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

Conclusion

In summary, the applicants adequately identify the population to be served and adequately demonstrate the need the population to be served has for a licensed ASF with two GI endoscopy rooms in Clayton in Johnston County. 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 64-67, the applicants describe the alternatives considered, which include:

- Maintain the Status Quo: The applicants state this is not an effective alternative because it does nothing to increase access to lower cost services in Johnston County. The applicants state that GI endoscopy rooms in licensed ASFs in Wake County, where many Johnston County residents go for services, are already operating above practical

capacity, and that Johnston County residents already compete with Wake County residents for access to GI endoscopy rooms in licensed ASFs.

- Utilize WEC's Existing GI Endoscopy Rooms: The applicants state this is not an effective alternative as it is almost identical to maintaining the status quo. The applicants state that WEC's Lake Drive facility is already operating above practical capacity. The applicants have ownership in Wake Forest Endoscopy Center, but the applicants state that due to the distance from Clayton (almost 30 miles and 35 minutes to drive) and Smithfield (almost 42 miles and 47 minutes to drive) this is not an effective alternative for Johnston County residents.

- Utilize Local Hospital-Based GI Endoscopy Rooms: The applicants state that this is not an effective alternative because it is almost identical to the maintaining the status quo. In addition, it is not the most cost-effective alternative for patients. The applicants note that there are no GI endoscopy rooms in licensed ASFs in Johnston County. The patient's out-of-pocket costs tend to be higher if the procedure is performed in a hospital-based GI endoscopy room. The applicants note that Johnston County residents have fewer resources than the state as a whole, so local, cost-effective access to GI endoscopy services is important to Johnston County residents.

- Pursue a Joint Venture: The applicants state that, *"A joint venture is not a realistic option for the proposed project."* The applicants state that WEC is an existing provider that will leverage its existing management services and professional relationships to provide cost-effective and efficient services to Johnston County residents. The applicants further state that WEC will extend privileges to any physician that meets its credentialing criteria.

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

The applicants adequately demonstrate that the proposal to develop a licensed ASF with two GI endoscopy rooms is the most effective or least costly alternative to meet the identified need. Consequently, the application is conforming to this criterion and is approved subject to the following conditions:

1. **Wake Endoscopy Center, LLC and Five GIS Rex Properties, LLC shall materially comply with all representations made in the certificate of need application.**

2. **Wake Endoscopy Center, LLC and Five GIS Rex Properties, 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. **Wake Endoscopy Center, LLC and Five GIS Rex Properties, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare**

Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years of completion of the facility.

4. **Wake Endoscopy Center, LLC and Five GIS Rex Properties, LLC shall develop no more than one ambulatory surgical facility with no more than two gastrointestinal endoscopy rooms and shall be licensed for a total of no more than two gastrointestinal endoscopy rooms upon completion of this project.**

5. **The maximum charge at Clayton Endoscopy shall be no more than $1,571 during a three year period beginning January 1, 2016.**

6. **Wake Endoscopy Center, LLC and Five GIS Rex Properties, 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.**

7. **Wake Endoscopy Center, LLC and Five GIS Rex Properties, 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, pages 94-96, the applicants separately project the capital cost that each applicant will be responsible for, as follows:

- Five GIS, which will buy the property and renovate the building that will be leased to WEC for the proposed facility, projects that its share of the capital costs will be $2,014,588, including $900,000 for the purchase of the property; $58,900 for site costs; $852,890 for renovation costs; and $202,798 for miscellaneous costs.
- WEC, which will lease the land and building from Five GIS, projects that its share of the capital costs will be $876,630, including $549,738 for fixed equipment purchases and leases; $171,159 for information technology hardware and software purchases and leases; and $155,733 for other costs.

Thus, the total capital cost of the project is projected to be $2,891,218.

In Section IX.1, page 102, WEC projects start-up costs in the amount of $40,000, and initial operating expenses in the amount of $120,000, for a total working capital requirement of $160,000. Five GIS will not be responsible for any working capital.

Availability of Funds

In Section VIII.3, page 98, Five GIS states that it will finance the $2,014,588 capital cost with a conventional loan from SunTrust Bank. Exhibit 18 contains a letter dated April 15, 2014, signed by the First Vice President of the Medical Specialty Group at SunTrust, which states:

> *"We are pleased to issue this letter regarding our willingness to providing* [sic] *financing associated with the proposed new GI endoscopy facility in Clayton. SunTrust has enjoyed a long-term banking relationship with FIVE GIS REX PROPERTIES, LLC. Specific to this CON project, the Bank has examined the financial position of FIVE GIS REX PROPERTIES, LLC and found it to be adequate to support the proposal. SunTrust is willing to provide financing to FIVE GIS REX PROPERTIES, LLC for this project up to $2,100,000, which will be to fund the purchase of the property and necessary up-fit proposed for the Clayton GI Endoscopy Center project.*
>
> *SunTrust is aware of the lengthy CON process and its effect on cost and funding dates. Accordingly, SunTrust is prepared to address changes as they may occur."*

In Section VIII.3, page 98, WEC states that it will finance the $876,630 capital cost with $37,000 from its accumulated reserves; $334,967 through a bank line of credit and $504,663 through a vendor equipment lease. In Section IX, page 102, WEC states that it will finance the $160,000 working capital cost with the bank line of credit. Exhibit 18 contains a letter dated April 14, 2014, signed by the President of WEC, which states:

> *"Wake Endoscopy Center (WEC) has sufficient accumulated reserves to fund the capital cost needed for the proposed development of our GI endoscopy center in Clayton. WEC anticipates funding a portion of the project capital cost with its accumulated reserves. The unaudited financial statements show that WEC has these funds currently available. WEC has committed the funds necessary from accumulated reserves to complete this project. Upon issuance of a CON for this project, WEC will use the available funds for the proposed project."*

Exhibit 18 also contains a letter dated April 10, 2014, signed by the First Vice President of the Medical Specialty Group at SunTrust, which states:

> *"We are pleased to issue this letter regarding our willingness to providing financing associated with the proposed new GI endoscopy facility in Clayton. SunTrust has enjoyed a long-term banking relationship with Wake Endoscopy Center. Specific to this CON project, the Bank has examined the financial position of Wake Endoscopy Center and found it to be adequate to support the proposal. SunTrust has an established line of credit with Wake Endoscopy Center of $1,000,000, which is available to fund the capital costs and working capital for the proposed Clayton GI Endoscopy Center project.*
>
> *SunTrust is aware of the lengthy CON process and its effect on cost and funding dates. Accordingly, SunTrust is prepared to address changes as they may occur."*

Exhibit 18 also contains a proposal for WEC from Olympus Financial Services for a vendor equipment lease.

Exhibit 19 contains a balance sheet for WEC which shows that, as of February 28, 2014, WEC had $648,275 in total equity (assets minus liabilities). Exhibit 19 also contains a balance sheet for WEC which shows that, as of December 31, 2013, WEC had $969,588.62 in net income for the previous 12 months.

The applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project.

Financial Feasibility

The table below shows the projected charges for the 10 most commonly performed GI endoscopy procedures for the first three operating years, as reported by the applicants in Section II.11, page 24:

Clayton Endoscopy Projected GI Endoscopy Procedure Charges CY2016 – CY2018				
CPT Code	**Description**	**CY2016**	**CY2017**	**CY2018**
45378	COLONOSCOPY FLX DX W/WO COLLJ SPECIMENS	$1,252	$1,252	$1,252
45385	COLSC FLX PROX SPLENIC FLXR RMVL LES SNARE TQ	$1,571	$1,571	$1,571
45380	COLONOSCOPY W/BIOPSY SINGLE/MULTIPLE	$1,346	$1,346	$1,346
43239	UPPER NDSC BIOPSY SINGLE/MULTIPLE	$1,078	$1,078	$1,078
43235	UPPER GI NDSC DX W/WO COLLECTION SPECIMEN	$908	$908	$908
43248	UPR GI NDSC INSJ GUIDE WIRE DILATE ESOPHAGUS	$1,080	$1,080	$1,080
45330	SIGMOIDOSCOPY FLX DX W/WO COLLJ SPECIMENS	$550	$550	$550
45331	SIGMOIDOSCOPY FLX W/BIOPSY SINGLE/MULTIPLE	$698	$698	$698
43249	UPR GI NDSC INSJ GUIDE BALLOON	$925	$925	$925
43245	UPR GI NDSC DILAT GSTR OUTLET FOR OBSTCJ	$1,568	$1,568	$1,568

In response to comments, the applicants state that inclusion of CPT Code 43245 in the table on page 24 was an error. CPT Code 43760 should have been included since a few more of those procedures are projected in the third operating year (6) than for CPT Code 43245 (2).

On page 24, the applicants state that the charges include *"professional and technical fees, reflecting charges for procedure room and recovery room time, nursing time, administrative time, linens, medications, billable medical supplies, equipment use, and other miscellaneous fees.*" Anesthesiology, pathology fees, radiology services, pre-operative lab work, and any necessary emergency transportation will be billed separately by the appropriate provider.

In the projected revenue and expense statement, the applicants project that revenues will exceed operating costs in each of the first three operating years based on an average gross charge of $1,307 per procedure and including deductions for contractual allowance from third-party payors.

The following table illustrates the projected revenue and expenses for Clayton Endoscopy during each of the first three operating years, as reported by the applicants in the financial pro formas:

	CY2016	CY2017	CY2018
Total Revenue*	$2,425,225	$3,145,855	$3,170,540
Expenses	$1,770,471	$1,883,732	$1,917,871
Profit	$654,753	$1,262,123	$1,252,669

* Total Revenue = Net Revenue + Other Revenue

The applicants state that the financial pro formas are based on WEC's experience operating a similar facility in Raleigh. The applicants adequately demonstrate that the assumptions used for the financial pro formas, including projected utilization, costs and charges are reasonable and adequately supported. See Section III, pages 53-61, for the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. See Tab 13 of the application for the financial pro formas and assumptions. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate the availability of sufficient funds for the capital and working capital needs of the project. Furthermore, they adequately demonstrate the immediate and long-term financial feasibility of the proposal based on 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 applicants propose to develop a new licensed ASF with two GI endoscopy rooms at 900 South Lombard Street in Clayton in Johnston County. The facility will be managed by RMG.

There are currently two existing and one approved GI endoscopy rooms located in Johnston County. All of these are owned and operated by Johnston Health. Two are located on the Smithfield campus and one will be located on the Clayton campus. Johnston Health is approved to add a GI endoscopy room on the Clayton campus as part of Project I.D. #J-8105-08.

On pages 46-47, the applicants discuss third-party payor trends and the Affordable Care Act. On page 46, the applicants state that research shows that individuals, including those with insurance, are less likely to seek health services when they have to pay out-of-pocket costs. The applicants state that the Affordable Care Act eliminated out-of-pocket costs for preventative services. However, the applicants state that there have been reports of asymptomatic patients undergoing screening for cancer who have been billed for services they expected would be fully covered under the Affordable Care Act. See full discussion on pages

46-47. On page 48, the applicants state that the proposed ASF will offer a lower cost structure compared to the existing hospital-based GI endoscopy services.

The following table reproduces the table provided by the applicants on page 51 of the application.

Johnston County Residents Outmigration to Other Counties for GI Endoscopy Services			
Year	**Total Patients – Johnston County**	**Patients leaving Johnston County**	**% Outmigration**
FY2010	6,199	3,943	63.6%
FY2011	6,138	4,041	65.8%
FY2012	7,184	4,974	69.2%

* Applicants' source: FY2010-FY2012 Endoscopy Patient Origin Report provided by Division of Health Service Regulation, Medical Facilities Planning Branch

Following the table, the applicants state:

> *"In FY2012, 4,974 patients left Johnston County to obtain endoscopy services. This is more than two times the number of Johnston County patients who received endoscopy services in Johnston County. Furthermore, the number of patients leaving Johnston County for GI endoscopy services increased over 26% from FY2010 to FY2012. WEC suspects that this is because there are more cost-effective options in other counties that are not available locally. As described previously, last year WEC served 910 Johnston County patients at its Lake Drive GI endoscopy facility. WEC provides this information regarding patient outmigration as evidence of the need for local access to licensed, cost-effective freestanding endoscopy services in Johnston County.*
>
> *The FY2012 Endoscopy Patient Origin Report indicates that the vast majority of residents who leave Johnston County for endoscopy services are traveling to Wake County (47.08%). As described previously, based on information provided in the 2014 SMFP, the 27 existing Wake County GI endoscopy rooms located in licensed freestanding facilities operated at 136 percent capacity (55,192 / 27 rooms / 1,500 procedures) during FY2012. Therefore, Johnston County residents must compete with Wake County residents for access to Wake County GI endoscopy rooms that are operating above practical capacity. This is certainly true at WEC's Lake Drive facility, which is currently operating at 163% capacity.*
>
> *It is not reasonable to expect that residents of Johnston County should have to travel to Wake County to obtain access to more cost effective, licensed freestanding endoscopy services. In order to receive treatment for most routine diagnostic services (such as colonoscopies or endoscopies), patients need not travel out of county. Thus, it is not consistent with the State's basic health planning principles of expanding access to services, and of promoting cost-effective approaches."*

On page 52, the applicants state that there are negative implications for patients who have to leave Johnston County for services, such as increased costs associated with travel and time away from work. Moreover, patients may postpone or delay scheduling a recommended

screening *"because cost effective licensed services are not more conveniently available close to home."*

The applicants adequately demonstrate that it is reasonable to assume that Johnston County residents currently choosing to leave Johnston County for GI endoscopy services would choose to utilize the proposed Clayton Endoscopy if the location is more convenient and their out-of-pocket expense is lower. Therefore, the applicants adequately demonstrate that the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy rooms in Johnston County. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

In Section VII.2, page 87, and in Section VII.6, page 90, the applicants provide projected staffing for the proposed facility, as shown below:

Clayton Endoscopy Proposed Staffing CY2016		
Employee Category	**Annual Salary**	**Staff FTEs**
Professional Health Care Administrators		
Administrator	$103,476	0.33
Clinical Personnel		
Nurse Supervisor	$63,849	1.0
RN – Pre-Op/Procedure/Post-Op	$59,335	2.5
LPN – Pre-Op	$41,314	1.0
BSN – Post-Op	$49,338	1.0
Endoscopy Technician	$32,069	2.0
Support Personnel		
Receptionist/Scheduler	$24,280	1.0
Total		**8.83**

The applicants project sufficient RN FTEs so that there will be at least one RN in each of the two proposed GI endoscopy rooms during a procedure and one each in the preoperative and postoperative areas. Exhibit 4 contains a letter signed by Kerry Whitt, M.D., in which he confirms his intent to serve as Medical Director of the proposed facility. The exhibit also contains a copy of Dr. Whitt's curriculum vitae which documents that he is board-certified in both internal medicine and gastroenterology.

In Section VII.3(b), page 88, the applicants state they do not anticipate any difficulty in filling the newly created positions. The applicants state that they will use RMG employees to staff Clayton Endoscopy similar to the arrangement at WEC's Lake Drive facility. In addition, in Section VII.7(a), page 91, the applicants state the physicians of WEC will also serve as physicians for the proposed Johnston County facility. Additionally, in Section VII.8(a), page

91, the applicants project that seven of the WEC physicians will initially use the Johnston County facility, and that as the practice grows, additional physicians will join the staff.

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

In Section II.2, page 11, the applicants state the following services are needed to support the proposed facility:

- Pre and Post-operative nursing
- Equipment decontamination and sterilization
- Medical Records
- Billing & Insurance
- Administration
- Patient Education
- Anesthesia
- Pathology
- Housekeeping & Laundry services

On page 12, the applicants state that RMG, which will manage the proposed facility, operates its own pathology lab. Professional interpretation of pathology specimens will be provided by Miraca Life Sciences. Exhibit 11 contains a copy of the current certificate of compliance for the existing lab as well as a copy of the contract between RMG and Miraca Life Sciences. Housekeeping and laundry services will be provided through contracts. The remaining services will be provided by RMG employees.

In Section V, pages 71-75, the applicants describe how their proposal has been coordinated with the existing health care system. The applicants state that they have an established transfer agreement with Rex Hospital in Raleigh and provide a letter in Exhibit 13 from Rex Hospital, confirming the transfer agreement. Rex Hospital is located approximately 24.4 miles away (a 25 minute drive time) from the proposed site of Clayton Endoscopy.

During the written comment period, the CON Section received a letter on April 22, 2014, which states:

> *"I am the medical director of the Johnston Medical Center Clayton Emergency Department and I am writing to inform you that our emergency department is available*

to assist in the care of any patient with any emergency condition associated with any gastroenterology procedure performed by Dr. Kerry Whitt or one of his associates."

Johnston Health's Clayton campus is located approximately 2.2 miles away (a three minute drive time) from the proposed site of Clayton Endoscopy and is the closest emergency department to the proposed site of Clayton Endoscopy.

The applicants state that Clayton Endoscopy will accept referrals from hospitals where the referring physicians have privileges. In Exhibit 16, the applicants provide a copy of WEC's policy that describes how physicians may obtain privileges at Clayton Endoscopy. The applicants state that WEC physicians do not accept emergency room call at Johnston Health but do accept emergency room call at Wake County hospitals. The applicants also state that Dr. Lee, a physician expected to utilize Clayton Endoscopy, accepts emergency room call at both the Clayton and the Smithfield campus of Johnston Health.

Exhibit 17 contains three letters of support for the proposed project from three physicians who practice in Johnston County and refer patients for GI endoscopy services.

The applicants adequately demonstrate that necessary ancillary and support services will be provided and that the proposed services will be coordinated with the existing health care system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

(11) Repealed effective July 1, 1987.

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

C

Five GIS proposes to acquire an existing medical office building, renovate the portion to be used for Clayton Endoscopy and then lease that portion to WEC. WEC will contract with RMG to operate the facility.

In Section XI, pages 108-109, and Exhibit 15, the applicants document that the existing medical office building is currently zoned for use as an ASF. In Section XI, page 112, the applicants state that the proposed ASF will utilize 4,096 square feet of the existing building. The applicants also state that the remaining 1,500 square feet will be used by Clayton Gastroenterology for a medical clinic. Due to a common staff break room, bathroom, and nourishment room, the applicants state that, to err on the side of caution, they included the entire square footage of the existing building for purposes of calculating the capital cost of the project.

Exhibit 15 contains a line drawing of the proposed ASF as well as a copy of a construction estimate, prepared by GMK Associates, Inc., that is consistent with the construction cost projected in Section VIII.1 of the application.

In Section XI, pages 115-116, the applicants state:

> *"The proposed renovated facility will use modern energy conservation practices and methods, featuring energy efficiency and water conservation.*
>
> *The facility HVAC and electrical systems are designed to meet all requirements of the latest energy code adopted by the State, as well as the latest edition of ASHRAE 90.1. ASHRAE 90.1 is the industry standard for energy efficient buildings. All lighting systems are designed to meet the requirements of ASHRAE 90.1, and the adopted State energy code. Water fixtures (such as toilets and faucets) will be designed as low flow to conserve water."*

The applicants adequately demonstrate that the cost, design, and means of construction represent the most reasonable alternative for the proposed project and that the proposed project will not unduly increase the cost of providing services or the cost and charges to the public. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. Furthermore, the applicants adequately demonstrate that energy saving features have been incorporated into the construction plans. Therefore, the application is conforming to this criterion.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

NA

(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;

NA

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

C

In Section VI.14, page 85, the applicants provide the projected payor mix at Clayton Endoscopy during the second operating year, as shown below:

Clayton Endoscopy Payor Mix Second Full Operating Year (CY 2017) Projected Procedures as Percent of Total Utilization	
Self-Pay/Indigent/Charity	3.0%
Medicare	28.3%
Medicaid	4.1%
Commercial/BCBS	48.6%
Managed Care	16.1%
Total	**100.0%**

In Section VI.4(a), page 79, the applicants state:

> *"Clinical services at Clayton Endoscopy will be non-restrictive relative to low-income persons, social, racial and ethnic minorities, women, handicapped persons, private pay, Medicare and Medicaid beneficiaries, uninsured indigent persons, underserved indigent patients and fully insured patients. Based on*

historical access at WEC facilities, Clayton Endoscopy will render appropriate medical care to all persons in need of such care, regardless of their ability to pay."

In Section VI.6, page 81, the applicants state:

"As an example of its commitment to providing access to care for the medically underserved, WEC physicians participate in Project Access of Wake County. Project Access links people without health insurance into a local network of clinics, laboratories, pharmacies and hospitals that donate their efforts to help those in need. WEC provides all of its services to Project Access patients, e.g., office visits, surgery, etc. During 2013, WEC provided healthcare services to 54 Project Access patients. WEC's physician owners will strive to identify and coordinate with Johnston County programs to make Clayton Endoscopy available to medically indigent patients who need GI endoscopy services."

Exhibit 12 contains copies of WEC's patient financial policies and procedures, including a non-discrimination policy; a patient's rights policy; and a policy regarding care for Project Access patients.

The applicants demonstrate that medically underserved populations will 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(a), page 83, the applicants state that access to the proposed GI endoscopy services will be by physician referral, including licensed physicians on staff at WEC, licensed physicians who are not on staff at WEC, and free care clinic referrals. 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(c), page 71, the applicants state that WEC has existing agreements with ECPI College of Technology, School of Health Science at Medical Careers Institute and with Campbell University's Physician Assistant Program. Documentation of these agreements was provided in Exhibit 10. On page 71, the applicants state that *"Clayton Endoscopy will be available to students in training programs."* 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 applicants propose to develop a new licensed ASF with two GI endoscopy rooms at 900 South Lombard Street in Clayton in Johnston County. The facility will be managed by RMG.

There are currently two existing and one approved GI endoscopy rooms located in Johnston County. All of these are owned and operated by Johnston Health. Two are located on the Smithfield campus and one will be located on the Clayton campus. Johnston Health is approved to add a GI endoscopy room on the Clayton campus as part of Project I.D. #J-8105-08.

On page 51, the applicants provide the following information:

- During FFY 2012, 7,184 Johnston County residents received GI endoscopy services.
- 4,974 of those 7,184 Johnston County residents or 69.2% utilized a facility located outside of Johnston County.
- The percentage of Johnston County residents utilizing a facility located outside of Johnston County has increased since FFY 2010.

In Section V.7, pages 75-76, the applicants discuss how any enhanced competition in the service area will promote the cost-effectiveness, quality, and access to the proposed services. See also Sections II, III, V, VI, and VII where the applicants discuss the impact of the project on cost-effectiveness, quality, and access.

The information in the application is reasonable and adequately demonstrates that any enhanced competition includes 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 applicants adequately demonstrate that the proposed freestanding ASF with two GI endoscopy rooms is needed by the population proposed to be served and that it is a cost-effective alternative. The discussion regarding need found in Criterion (3) is incorporated herein by reference and the discussion regarding unnecessary duplication found in Criterion (6) is incorporated herein by reference.

- The applicants adequately demonstrate that the proposed facility will provide quality services.

- The applicants demonstrate that the proposed facility will provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

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 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. The specific criteria are discussed below.

.3902 INFORMATION REQUIRED OF APPLICANT

(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 the following information:

(1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906;

-C- In Section II.11, page 20, the applicant states that the proposed service area for Clayton Endoscopy is Johnston County.

(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- In Section II.11, page 20, the applicants state that they will operate a total of two GI endoscopy rooms in the proposed facility.

(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 the applicants nor any related entities currently own or operate any GI endoscopy rooms in Johnston County.

(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;

-NA- The applicants do not currently own or operate any GI endoscopy rooms in Johnston County.

(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, page 21, the applicants provide the number of GI endoscopy procedures, identified by CPT code, projected to be performed in the proposed facility in each of the first three operating years of the project, as shown below:

Clayton Endoscopy Projected GI Endoscopy Procedure by CPT Code				
CPT Code	**Description**	**CY2016**	**CY2017**	**CY2018**
45378	COLONOSCOPY FLX DX W/WO COLLJ SPECIMENS	862	1,118	1,126
45385	COLSC FLX PROX SPLENIC FLXR RMVL LES SNARE TQ	676	877	884
45380	COLONOSCOPY W/BIOPSY SINGLE/MULTIPLE	352	456	460
43239	UPPER NDSC BIOPSY SINGLE/MULTIPLE	297	385	388
43235	UPPER GI NDSC DX W/WO COLLECTION SPECIMEN	81	105	106
43248	UPR GI NDSC INSJ GUIDE WIRE DILATE ESOPHAGUS	59	77	77
43760	CHANGE SASTROSTOMY TUBE PERCUTANEOUS W/O GUIDE	4	6	6
45331	SIGMOIDOSCOPY FLX W/BIOPSY SINGLE/MULTIPLE	11	14	14
45330	SIGMOIDOSCOPY FLX DX W/WO COLLJ SPECIMENS	11	14	14
43249	UPR GI NDSC INSJ GUIDE BALLOON	4	6	6
43255	UPR GI NDSC CONTROL BLEEDING ANY METHOD	1	1	1
44361	ENDOSCOPY UPPER	1	2	2
45338	SGMDSC FLX RMVL TUM POLYP/OPT LES SNARE TQ	2	3	3
43244	UPR GI NDSC BAND LIG ESOPHGL&/GSTR VARICES	0	1	1
44364	ENTEROSCOPY .2ND PRTN W/RMVL LESION SNARE	1	1	1
43247	UPPER GI NDSC DX W/FOREIGN BODY REMOVAL	1	1	1
43251	UPR GI NDSC RMVL TUM POLYP/OTH LES SNARE TQ	1	1	1
45335	SGMDSCFLX DIRED SBMCSL NJX ANY SBST	1	1	1
43245	UPR GI NDSC DILAT GSTR OUTLET FOR OBSTCJ	1	2	2
45340	SIGMOIDOSCOPY FLX DILAT BALO 1/MORE STRIXS	0	1	1
45386	COLSC FLX PROX SPLENIC FLXR DILAT BALO 1/> STRI	1	1	1
44388	COLONOSCOPY STOMA DX W/WO COLLJ SPEC SPX	1	1	1
45338	SGMDSC FLX RMVL TUM POLYP/OPH LES SNARE TQ	0	1	1
TOTAL		**2,369**	**3,073**	**3,097**

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

-NA- The applicants do not currently own or operate any GI endoscopy rooms in Johnston County.

(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 22, the applicants state that they do not project to perform any non-GI endoscopy procedures at Clayton Endoscopy.

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

-NA- The applicants do not currently own or operate any GI endoscopy rooms in Johnston County.

(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 22, the applicants project to serve 2,085 patients during the first operating year, 2,705 patients during the second operating year and 2,726 patients during the third operating year.

(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 applicants do not have any operating rooms.

(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 23, the applicants state that the facility will operate Monday through Friday, 7:30 a.m. to 4:00 p.m., 52 weeks per year, excluding holidays.

(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 applicants propose a new facility.

(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 24, the applicants provide the type and average facility charges by CPT code projected during the first three operating years for the 10 procedures projected to be performed most often at Clayton Endoscopy, as shown below:

Clayton Endoscopy Projected GI Endoscopy Procedure Charges				
CPT Code	**Description**	**CY2016**	**CY2017**	**CY2018**
45378	COLONOSCOPY FLX DX W/WO COLLJ SPECIMENS	$1,252	$1,252	$1,252
45385	COLSC FLX PROX SPLENIC FLXR RMVL LES SNARE TQ	$1,571	$1,571	$1,571
45380	COLONOSCOPY W/BIOPSY SINGLE/MULTIPLE	$1,346	$1,346	$1,346
43239	UPPER NDSC BIOPSY SINGLE/MULTIPLE	$1,078	$1,078	$1,078
43235	UPPER GI NDSC DX W/WO COLLECTION SPECIMEN	$908	$908	$908
43248	UPR GI NDSC INSJ GUIDE WIRE DILATE ESOPHAGUS	$1,080	$1,080	$1,080
45330	SIGMOIDOSCOPY FLX DX W/WO COLLJ SPECIMENS	$550	$550	$550
45331	SIGMOIDOSCOPY FLX W/BIOPSY SINGLE/MULTIPLE	$698	$698	$698
43249	UPR GI NDSC INSJ GUIDE BALLOON	$925	$925	$925
43245	UPR GI NDSC DILAT GSTR OUTLET FOR OBSTCJ	$1,568	$1,568	$1,568

In response to comments, the applicants state that inclusion of CPT Code 43245 in the table on page 24 was an error. CPT Code 43760 should have been included, since a few more of those procedures are projected in the third operating year (6) than for CPT Code 43245 (2). This error is not sufficient to make the application nonconforming to this Rule given the small number of procedures projected for each CPT code and the small difference between the two projections.

(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 24, the applicants state:

> *"GI endoscopy charges will be inclusive of GI professional and technical fees, reflecting charges for procedure room and recovery room time, nursing time, administrative time, linens, medications, billable medical supplies, equipment use, and other miscellaneous fees."*

(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 24, the applicants state:

> *"Anesthesia charges are not included, and will be billed separately by the anesthesiologist. If a tissue biopsy is required, pathology fees will be billed separately by the physician and thus are not associated with this project. Also, if any radiology services are required there will be a separate billing from a radiologist. If any pre-operative laboratory work is necessary, the patient will be billed directly by the lab. Any necessary emergency transportation will be billed separately by the emergency transportation provider."*

(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; and

-NA- The applicants propose a new facility.

(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 25, the applicants provide the average reimbursement projected to be received for the 10 GI endoscopy procedures which the applicants project will be performed most frequently in the facility for the first three project years, as shown below:

Clayton Endoscopy
Projected Average Reimbursement

CPT Code	Description	CY2016	CY2017	CY2018
45378	COLONOSCOPY FLX DX W/WO COLLJ SPECIMENS	$663	$663	$663
45385	COLSC FLX PROX SPLENIC FLXR RMVL LES SNARE TQ	$841	$841	$841
45380	COLONOSCOPY W/BIOPSY SINGLE/MULTIPLE	$733	$733	$733
43239	UPPER NDSC BIOPSY SINGLE/MULTIPLE	$462	$462	$462
43235	UPPER GI NDSC DX W/WO COLLECTION SPECIMEN	$482	$482	$482
43248	UPR GI NDSC INSJ GUIDE WIRE DILATE ESOPHAGUS	$520	$520	$520
45330	SIGMOIDOSCOPY FLX DX W/WO COLLJ SPECIMENS	$450	$450	$450
45331	SIGMOIDOSCOPY FLX W/BIOPSY SINGLE/MULTIPLE	$516	$516	$516
43249	UPR GI NDSC INSJ GUIDE BALLOON	$462	$462	$462
43245	UPR GI NDSC DILAT GSTR OUTLET FOR OBSTCJ	$881	$881	$881

In response to comments, the applicants state that inclusion of CPT Code 43245 in the table on page 25 was an error. CPT Code 43760 should have been included, since a few more of those procedures are projected in the third operating year (6) than for CPT Code 43245 (2). This error is not sufficient to make the application nonconforming to this Rule given the small number of procedures projected for each CPT code and the small difference between the two projections.

(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 Exhibit 12, the applicants provide a copy of WEC'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 2, the applicants provide an April 14, 2014 letter, signed by Dr. Neeraj Sachdeva, M.D., that states Clayton Endoscopy'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 Exhibit 12, the applicants provide copies of relevant patient financial policies and procedures that assure the proposed GI endoscopy services will be accessible by indigent patients without regard to their ability to pay. In addition, in Section II.11, page 26, the applicants state:

> *"As stated in Section VI, all persons will have access to the proposed GI endoscopy services. WEC will render appropriate medical care to all persons in need of such care, regardless of their ability to pay."*

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

-C- In Exhibit 7, the applicants provide 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, page 26, the applicants state that 9,780 GI endoscopy procedures were performed by WEC in its Lake Drive facility during CY2013, and 2,346 GI endoscopy procedures were performed by WEC in its Wake Forest facility during CY2013.

(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 27, the applicants discuss the rationale for shifting patients from WEC's Lake Drive facility in Raleigh. The applicants state:

> *"the proposed shift of patients will not have a negative impact on WEC's Lake Drive facility. As described in Section III.1, WEC projects*

approximately 930 procedures will shift to the proposed Clayton facility. During CY2013, WEC's Lake Drive facility performed 9,780 GI endoscopy procedures which equates to 163% of practical capacity (9,780 ÷ 1,500 ÷ 4). Thus, despite a reduction of 930 procedures and conservatively projecting no growth in utilization, WEC's Lake Drive facility will continue to operate well above practical capacity upon completion of the proposed project (9,780 – 930 = 8,850 ÷ 1,500 ÷ 4 = 148%)."

.3903 PERFORMANCE STANDARDS

(a) In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.

-NA- Although the applicants do not have operating rooms, in Section II.11, page 27, they state their commitment to operating their facility in conformity with this rule.

(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.

-C- In Section III.1, page 60, and Section IV, page 70, the applicants project to perform 2,369 procedures during the first operating year, 3,073 procedures during the second operating year and 3,097 procedures during the third operating year. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. The application is conforming to this Rule.

In written comments, Johnston Health alleged that the applicants proposed a service area limited to Johnston County because they could not be found conforming to this Rule if their proposed service area included Wake County where the applicants have two ASFs with a total of six existing and one approved GI endoscopy rooms. The Agency notes that there is nothing in the Certificate of Need law or administrative regulations that expressly required these applicants to include Wake County in their proposed service area. However, for the sake of argument, had they included Wake County in their proposed service area, an analysis of the number of GI endoscopy procedures performed in the two Wake County facilities during CY 2013 shows that those seven GI endoscopy rooms would most likely be utilized at an average of more than 1,500 procedures per room, as shown in the following table.

Wake County Facility	# of Existing and Approved GI Endoscopy Rooms	# of GI Endoscopy Procedures Performed during CY 2013
WEC's Lake Drive Facility	4	9,780
Wake Forest Facility	3	2,346
Subtract Procedures Projected to Shift from WEC's Lake Drive Facility to Clayton Endoscopy		1,034
Total		11,092
Average # of GI Endoscopy Procedures per Room (7)		1,584.6

Source: Section II.11, page 26, and Section III.1, page 56.

In the application that resulted ultimately in the approval of a third GI endoscopy room at the Wake Forest facility, WEC projected that patients currently utilizing WEC's Lake Drive facility would shift to the Wake Forest facility and there is no reason to believe that that shift will not happen once the third room is developed. Moreover, the facility in Wake Forest is not particularly convenient for the majority of Johnston County residents. In addition, the analysis in the table above does not include any projected increase in utilization of either Wake County facility; however, it does take into account the projected shift to the proposed Johnston County facility.

(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, page 21, the applicants document that they will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at Clayton Endoscopy.

(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 applicants nor any related entity own any operating rooms in Johnston County.

(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 III.1, pages 36-61, the applicants provide all assumptions and methodology used to project GI endoscopy procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

.3904 SUPPORT SERVICES

(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.11, page 29, the applicants state pathology services will be provided by RMG with professional interpretation services provided by Miraca Life Sciences. Exhibit 11 contains documentation of the contracts between the applicants and these providers.

(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- Exhibit 5 contains a copy of WEC's clinical policies and procedures relating to GI endoscopy procedures that will be utilized by Clayton Endoscopy. These include the use of conscious sedation and anesthesia.

(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- Exhibit 5 contains a copy of WEC's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases which will be utilized by Clayton Endoscopy.

(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 30, the applicants state that Dr. Kerry Whitt, who will serve as the facility's Medical Director, has affiliate privileges at Johnston Health's Clayton campus and Dr. Lee, a physician expected to utilize Clayton Endoscopy, has admitting privileges at Johnston Health's Smithfield campus. The applicants also state that other physicians projected to utilize Clayton Endoscopy have privileges at existing hospitals in Wake County. Exhibit 21 contains copies of information from the North Carolina Medical Board website for some of the physicians proposed to utilize Clayton Endoscopy, including documentation of admitting privileges at existing hospitals in Johnston and Wake counties.

(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- In Section II.11, page 10, the applicants state they will accept referrals from Rex Hospital. Exhibit 13 includes a letter from Rex Hospital documenting an agreement between Clayton Endoscopy and Rex Hospital. Dr. Kerry Whitt has admitting privileges at Rex Hospital. See Exhibit 21.

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

-C- Exhibit 13 contains a letter from Rex Hospital stating that it will accept patients transferred from Clayton Endoscopy. Additionally, a letter was received by the CON Section during the written comment period from the Medical Director of the Emergency Department at Johnston Health's Clayton campus stating that that facility is *"available to assist in the care of any patient with any emergency condition."*

.3905 STAFFING AND STAFF TRAINING

(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.2, page 90, the applicants provide the information about proposed staffing as required by this Rule. In Section II.11, page 10, the applicants indicate that equipment cleaning, safety and maintenance will be provided by the endoscopy technicians.

(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 31, the applicants list the name and board certification status of seven physicians who will perform GI endoscopy procedures at Clayton Endoscopy. Exhibit 4 contains the curriculum vitae for the Medical Director who is one of the seven physicians.

(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 32, the applicants state that all physicians who will utilize Clayton Endoscopy must be board eligible or board certified in gastroenterology and must have completed an accredited gastroenterology training program; or must be board eligible in general surgery or colon and rectal surgery. Exhibit 16 contains a copy of the credentialing criteria to be used by the facility in extending privileges to medical personnel who may provide services in the proposed facility.

(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;

-C- In Section II.11, page 32, the applicants state that Dr, Kerry Whitt, M.D., is a board certified Gastroenterologist and will serve as Medical Director. Exhibit 4 contains a copy of Dr. Whitt's curriculum vitae.

(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;

-C- Exhibit 16 contains a copy of WEC's credentialing policy that will be utilized by Clayton Endoscopy, which mandates that physicians must be board eligible or board certified in gastroenterology and must have completed an accredited gastroenterology training program; or must be board eligible in general surgery or colon and rectal 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;

-C- In Section II.11, page 33, the applicants state that all physicians with practice privileges at Clayton Endoscopy 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;

-C- In Section II.11, page 33, the applicants state that at least one registered nurse will be employed per procedure room at Clayton Endoscopy. In Section VII.2, page 87, the applicants provide a staffing chart that illustrates proposed staffing for Clayton Endoscopy, which documents plans to employ at least one registered nurse per procedure room.

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

-C- In Section II.11, page 33, the applicants state that additional staff or patient care technicians will be employed to provide assistance in the procedure rooms at Clayton Endoscopy. In Section VII.2, page 87, the applicants provide a staffing chart that illustrates proposed staffing for Clayton Endoscopy, which documents plans to employ other staff and patient care technicians.

(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- In Section II.11, page 33, the applicants state that at 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 will be BCLS certified. Exhibit 9 contains copies of job descriptions for the registered nurse positions which document that the registered nurses will be certified consistent with the requirements of this Rule.

.3906 FACILITY

(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.

-NA- Clayton Endoscopy is not proposed to be located in a physician office or a general acute care hospital.

(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- In Section II.11, page 34, the applicants state that Clayton Endoscopy will pursue accreditation from the Accreditation Association for Ambulatory Health Care within one year of completion of the proposed project.

(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.

-C- In Section II.11, page 34, the applicants state that the physical environment of the facility was designed by an architect licensed in North Carolina and will conform 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.

-C- Exhibit 15 contains a floor plan that delineates the areas identified by this Rule.

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

-C- Exhibit 15 contains a floor plan that demonstrates that the procedure rooms are separate and physically segregated from the general office area.

(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- Exhibit 14 contains a copy of a letter stating that the Receiver for the property has received an offer to purchase the land from Five GIS. The Receiver states the proposed purchase price is fair and reasonable and has recommended that Plaintiff (PNC Bank) accept the offer. The Asset Manager of PNC Bank is reported to have agreed with the Receiver. Exhibit 14 also contains a proposed lease for Five GIS to lease the facility space to WEC.