

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: September 27, 2012
FINDINGS DATE: October 4, 2012
PROJECT ANALYST: Tanya S. Rupp
CON CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: J-8822-12 / Wake Endoscopy Center LLC d/b/a Wake Endoscopy Center Wake Forest / Develop a new licensed ambulatory surgery center with two GI Endoscopy rooms / Wake County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Wake Endoscopy Center, LLC (WEC) owns and operates an existing licensed and accredited ambulatory surgical center (ASC) with three gastrointestinal endoscopy rooms (GI endoscopy rooms) at 2601 Lake Drive, Suite 201 in Raleigh. Pursuant to Project ID Number J-8823-12, WEC was approved to add one licensed GI endoscopy room to its existing facility, for a total of four GI endoscopy rooms.

In this application, the applicant proposes to develop Wake Forest Endoscopy Center Wake Forest (WECWF), a new ASC with two new GI endoscopy rooms, to be located at 11211 Galleria Avenue in Wake Forest, approximately 17 miles from the existing facility. The total projected capital cost for the proposal is less than two million dollars; therefore, Policy GEN-4 in the 2012 State Medical Facilities Plan (SMFP) is not applicable to this review.

Additionally, N.C.G.S. 131E-178(a) states in part:

“...The annual State Medical Facilities Plan shall not include policies or need determinations that limit the number of gastrointestinal endoscopy rooms that may be approved.”

N.C.G.S. 131E-182(a) states in part:

“An applicant for a certificate of need to establish a licensed gastrointestinal endoscopy room shall show that it is performing or reasonably projects to perform at least 1,500 gastrointestinal endoscopy procedures per gastrointestinal endoscopy room per year.”

Furthermore, there are no other policies or need determinations in the 2012 SMFP applicable to the review of applications for GI endoscopy rooms. Therefore, this criterion is not applicable in this review.

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

C

Wake Endoscopy Center, LLC (WEC) owns and operates an existing licensed and accredited ambulatory surgical center (ASC) with three gastrointestinal endoscopy rooms (GI endoscopy rooms) at 2601 Lake Drive, Suite 201 in Raleigh. Pursuant to Project ID Number J-8823-12, WEC was approved to add one licensed GI endoscopy room to its existing facility, for a total of four GI endoscopy rooms. In this application, the applicant proposes to develop a new ASC in Wake Forest, with two new GI endoscopy rooms.

Population to be Served

In Section III.7, page 58, the applicant provides current patient origin for its Lake Drive facility, also in Wake County, as shown in the table below:

COUNTY	NO. OF PATIENTS*	% OF TOTAL
Wake	6,132	86.4%
Johnston	716	10.1%
Franklin	202	2.8%
Harnett	35	0.5%
Alamance	10	0.1%
Total	7,095	100.0%

*The project analyst looked the numbers up on WEC’s 2012 License Renewal Application

In Section III.6, page 57, the applicant provides projected patient origin for the proposed facility in West Lake, as shown in the table below:

COUNTY	% OF TOTAL
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Wake	96.0%
Franklin	4.0%
Total	100.0%

On page 57, the applicant states its projected patient origin is based on its historical experience providing GI endoscopy procedures at the Lake Drive facility. Additionally, the applicant states three of WEC's physicians practice in Wake Forest and have a large patient base from Wake Forest that currently receives GI endoscopy services in the Lake Drive facility in Raleigh. The applicant states:

“WEC projects that the Wake Forest GI endoscopy procedures will shift from its existing Lake Drive facility to the proposed new facility. WEC also received letters from two additional physicians with a large patient base in Wake Forest that will utilize the proposed facility. Therefore, WEC’s projected patient origin is based on its large base of patients that reside in the Wake Forest and surrounding areas, and that will shift to the proposed new facility. Historically, WEC has also served a small portion of patients from Franklin County. WEC projects these patients will utilize the proposed Wake Forest location due to its improved proximity to Franklin County.”

The applicant adequately identifies the population proposed to be served at the proposed West Lake facility.

Demonstration of Need

In Section III.1, pages 34 – 53, the applicant describes the need for two new GI endoscopy procedure rooms in the Wake Forest area, and presents the methodology and assumptions it used to support the need. In Section III.1, page 32, the applicant summarizes its need:

- *“Historical utilization has increased rapidly for WEC’s three existing GI endoscopy rooms,*
- *Wake County population is increasing rapidly,*
- *Wake County residents age 55 and older are projected to increase an average 5.8% annually during the next five years,*
- *As the average age of the Wake County population increases, the increase of cancer will increase as well,*
- *Wake County has a large percentage of minority population who are disproportionately affected by colon / rectum cancer,*
- *Third-party payers have been exerting pressure on their subscribers to choose lower-cost options for outpatient care.”*

In Section III.1, pages 33 - 36, the applicant describes the types of GI endoscopy procedures it most commonly performs, which include upper GI endoscopy, colonoscopy and sigmoidoscopy. The applicant also describes the diseases and conditions for which GI endoscopy is used, such as: heartburn; gastroesophageal reflux disease (GERD); and colorectal cancer and screening. On pages 36 – 38, the applicant describes colonoscopy screening guidelines, which were jointly developed by a number of organizations, including

the American Cancer Society, the American College of Radiology and the US Multi-society Task Force on Colorectal Cancer. For example, all non-symptomatic persons age 50 or older are appropriate for screening every 10 years. Persons less than age 50 may be appropriate for screening if they have a higher risk for cancer.

On page 39, the applicant describes third-party payor trends. The applicant states that Medicare beneficiaries are responsible for substantially lower co-pays if they have the screening procedure done in an ASC rather than in a hospital as an outpatient. The applicant states that commercial insurance companies have similar provisions in their policies which encourage patients to use ASCs rather than have the procedure done in a hospital as an outpatient. Finally, on pages 39 – 40, the applicant states the primary focus of the American Cancer Society and other organizations is increasingly on preventative screening, which includes GI endoscopic procedures.

On pages 40 – 45, the applicant discusses Wake County demographics and the projected population growth of the groups most likely to utilize GI endoscopy services. Citing information from Claritas, an on-line demographic analysis and reporting source, the applicant states Wake County is projected to be the most populous county in North Carolina by 2013. Furthermore, the 55+ population group is projected to comprise nearly 25% of the total county population. See the following table, prepared by the analyst from information on page 42:

	2012	2013	2014	2015	2016	2017	CAGR
Total Population	946,278	971,025	995,773	1,020,520	1,045,268	1,070,015	2.5%
Population 55+	167,384	178,254	189,125	199,995	210,866	221,736	5.8%
55+ as % of Total Population	17.69%	18.36%	18.99%	19.60%	20.17%	20.72%	

Thus, the data shows that the over 55 age group is projected to grow at over two times the projected growth rate of the general population in Wake County through 2017.

On pages 42 – 43, again utilizing data obtained from Claritas, the applicant shows projected growth of the age 55+ population group within each of 20 townships in Wake County for the years 2012 – 2017. See the following table, from page 43:

TOWNSHIP	2012 55+ POP.	2017 55+ POP.	5-YEAR CAGR
Cedar Fork Township	7,694	11,566	8.5%

White Oak Township	11,071	16,211	7.9%
Holly Springs Township	5,391	7,713	7.4%
Wake Forest Township	11,892	16,894	7.3%
Leesville Township	7,377	10,445	7.2%
Middle Creek Township	8,407	11,608	6.7%
Neuse Township	12,089	16,530	6.5%
Panther Branch Township	4,454	6,074	6.4%
New Light Township	1,577	2,140	6.3%
Buckhorn Township	508	689	6.3%
St. Matthews Township	11,623	15,799	6.3%
Swift Creek Township	9,140	12,388	6.3%
Marks Creek Township	4,039	5,325	5.7%
Bartons Creek Township	5,031	6,564	5.5%
Cary Township	13,660	17,423	5.0%
St. Mary's Township	13,024	16,628	5.0%
House Creek Township	11,661	14,392	4.3%
Little River Township	2,763	3,295	3.6%
Meredith Township	3,316	3,936	3.5%
Raleigh Township	22,667	26,116	2.9%
Total Wake County	167,384	221,736	5.8%

The data shows that the Wake Forest Township is projected to grow at a CAGR of 7.3% during that time period, which is the fourth fastest growth rate among the 20 townships. In addition, the project analyst created a table to show just the Wake County 55+ age group population within the northern townships of Wake County (the proposed location of the facility).

NORTHERN TOWNSHIPS	2012		2017	
	55+ POPULATION	WAKE COUNTY 55+ POPULATION	55+ POPULATION	WAKE COUNTY 55+ POPULATION
Wake Forest Township	11,892	167,384	16,894	221,736
Neuse Township	12,089		16,530	
New Light Township	1,577		2,140	
St. Matthews Township	11,623		15,799	
Marks Creek Township	4,039		5,325	
Bartons Creek Township	5,031		6,564	
Little River Township	2,763		3,295	
Total	49,014		66,547	
Percent of Total			29.3%	

Thus, within the northern townships of Wake County, which are in the portion of the service area most closely situated to the proposed location of the GI endoscopy center, the 55+ age group is projected to grow between 2012 and 2017. Furthermore, the age 55+ group as a percentage of the total Wake County population is likewise projected to grow during the years 2012 to 2017.

It is important to note that the townships are proximate, and that the proposed location of the GI endoscopy center is actually within the Neuse Township, which is still within the Wake Forest area of Raleigh, in northern Wake County.

In addition, on page 44, the applicant cites data from the North Carolina Central Cancer Registry to show that as age increases, so does the incidence of cancer. In fact, on page 44, the applicant states the incidence of colorectal cancer for persons age 65 and over is “*more than five times greater than the overall population.*” See the following table from page 44:

AGE GROUP	CANCER INCIDENCE
All Ages	41.7
Age 65+	216.4

On pages 44 – 45, the applicant provides information regarding the African-American population and other minorities. The applicant states the incidence rate for colon/rectum cancer for African Americans in Wake County is 33% higher than for other races; furthermore, the mortality rate for African Americans in Wake County from colon/rectum cancer is 51% higher than that for white or other races.

Utilization

On pages 46 – 49, the applicant discusses historical utilization of the existing GI endoscopy rooms at WEC Lake Drive. On page 46, the applicant states that utilization has increased 7.6% per year (CAGR) between CY 2008 and CY 2011. In addition, the applicant states it has accommodated the increase in demand by adding hours of operation on Saturdays. Furthermore, on page 46, the applicant states there are several physicians who have expressed an interest in obtaining privileges to utilize WEC, but these physicians have been denied privileges due to capacity constraints. In CY 2011, 8,081 procedures were performed in the 3 existing GI endoscopy rooms, which is an average of 2,693.7 procedures per room [8,081 / 3 = 2,693.66]. Based on the performance standard promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility is currently operating at 179.6% of capacity [2,693.7 / 1,500 = 1.7958], and could develop two (rather than one) additional GI endoscopy room [8,081 / 1,500 = 5.387].

In July 2012, WEC was approved to add a fourth GI endoscopy room at its Lake Drive facility [see Project ID #J-8823-12]. On pages 46 - 47, the applicant states:

“Despite the proposed addition of one more procedure room, WEC’s Lake Drive facility would continue to operate far beyond practical capacity. For example, WEC’s effective capacity for CY2011 if it had four procedure rooms would be 134.7 percent. WEC’s utilization during the first three months of CY2012 has already out-paced CY2011, thus capacity will continue to be exacerbated even with the addition of a fourth room at Lake Drive. Additionally, based on the current capacity of freestanding GI endoscopy rooms in Wake County, there is a need for seven additional GI endoscopy rooms located in freestanding facilities (48,503/1,500 = 32 rooms needed - 25 existing and approved rooms = 7 additional rooms needed).”

The applicant’s existing GI endoscopy rooms are currently utilized in excess of the minimum threshold standard defined in 10A NCAC 14C .3903(b). Even if the applicant had the two rooms requested in this application and the one additional room previously approved in Project ID#J-8823-12, the CY 2011 utilization would have been 90% of the minimum threshold set forth in the Rule [3 existing rooms + 1 added pursuant to Project ID#J-8823-12 + 2 proposed here = 6 GI endoscopy rooms. 8,081 procedures performed in CY 2011 / 6 rooms = 1,347 / 1,500 = 0.898]. It is reasonable to project that the utilization would increase, particularly with the addition of new physicians as indicated by the applicant on page 46, to reach the minimum required standard of 1,500 procedures per room.

The following table shows historical utilization of the existing GI endoscopy rooms at WEC’s Lake Drive facility, as reported by the applicant on page 49:

	CY 2008	CY 2009	CY 2010	CY 2011	3 Yr CAGR
GI Endoscopy Procedures	6,484	7,106	7,465	8,081	7.6%
# Rooms based on 1,500 procedures per room	4.3	4.7	4.9	5.3	

To project future utilization at the WEC Wake Forest location, the applicant presents a three-step methodology on pages 49 – 52. In Step One, the applicant examines historical utilization of the WEC GI endoscopy procedures performed in its existing facility on Lake Drive, as shown in the table above.

In Step Two, the applicant projects utilization for the existing WEC Lake Drive facility, using one-half of the actual historical CAGR calculated in Step One. See the following table, from page 50 of the application:

	CY 2011	X	½ CAGR 2008 - 2011	=	CY 2012	CY 2013	CY 2014	CY 2015	CY 2016
GI Endoscopy Procedures	8,081		3.8%		8,389	8,708	9,040	9,384	9,741

On page 50, the applicant states the growth rate used to project utilization at the Wake Forest facility is not only one-half of the three year CAGR from 2008 - 2012 at the Lake Drive facility, but also is less than one-half of the most recent one year annual increase of 8.3% from CY 2010 to CY 2011 [(8,081 / 7,465) – 1 = 0.082]. In addition, according to the applicant on page 50:

“... physicians have approached WEC requesting to utilize the facility; however, WEC has been unable to accommodate them because of its limited capacity. One of the physicians is Dr. Mamun Shahrier. Dr. Shahrier previously performed procedures at WEC, but lack of available scheduling time has forced him to find an alternative solution for his patients. Once WEC has additional capacity, Dr. Shahrier will once again be able to utilize the facility.”

In Exhibit 17 the applicant provides 16 letters of support from 16 area physicians, some of whom are gastroenterologists currently practicing at WEC's Lake Drive facility. Five of the 16 physician support letters together project 4,500 referrals to the Wake Forest facility.

Two of those five letters, totaling 1,500 referrals, are signed by physicians who are members of Carolina GI Associates, PC (CGI) in Henderson, in Vance County. CGI consists of the two named physicians and one nurse practitioner. According to the North Carolina Medical Licensing Board, both physicians have practice privileges at Granville Medical Center in Granville County, and Maria Parham Medical Center, in Vance County. According to Mapquest[®], the distance from the physicians' practice to the proposed location of WEC WF is approximately 31 miles, with an estimated drive time of 43 minutes traveling south on US 1. Maria Parham Medical Center and Granville Medical Center are much closer to the CGI practice than to WEC WF proposed location. Furthermore, Maria Parham Medical Center and Granville Medical Center have GI endoscopy procedure rooms and both facilities performed outpatient procedures in FY 2010, as reflected on the 2012 License Renewal Applications.

If the project analyst were to discount the two letters signed by the Vance County physicians, then the projected number of patient referrals would be 3,000 [$4,500 - 1,500 = 3,000$], or 1,500 fewer possible referrals to WEC WF for GI endoscopy procedures following project completion. The applicant, WEC Lake Drive, performed 8,081 GI endoscopy procedures on 7,045 patients in FY 2011, an average of 1.14 procedures per patient [$8,081 / 7,045 = 1.14$]. Thus, 3,000 referrals should result in 3,420 GI endoscopy procedures [$3,000 \times 1.14 = 3,420$]. Therefore, if the analyst were to discount those Vance County physician referrals, it would not be adverse to the applicant's projections. Furthermore, the applicant does not rely exclusively on the number of procedures projected through referral letters to be performed at the proposed facility to support its proposal for two additional GI endoscopy procedure rooms to be located at WEC WF.

The location of the referring physicians, hospitals where they practice and projected number of referrals notwithstanding, the number of GI endoscopy procedures performed at WEC Lake Drive in Wake County, combined with the projected population growth (particularly of the older age cohorts, those more likely to utilize GI endoscopy services) support the need for two additional GI endoscopy rooms in the Wake Forest area of Wake County.

In Step three, the applicant shows how it relies on past utilization and demographic information to support projections of future GI endoscopy procedure utilization. The applicant projects the number of GI endoscopy procedures to be performed at the Lake Drive facility, and then projects a shift in patients from the Lake Drive facility to the Wake Forest facility.

On page 52, the applicant states:

"The proposed Wake Forest facility will be operational in September 2013. WEC projects that the projected Wake Forest GI endoscopy procedures will shift from its existing Lake Drive facility to the proposed new facility upon completion of the

proposed project. Therefore, WEC subtracted the procedure totals from its projected utilization for the proposed project.”

See the following table, from page 52 of the application:

	CY 2013	CY 2014	CY 2015	CY 2016
WEC GI Endo Procedures	8,708	9,040	9,384	9,741
WEC Wake Forest Shift	1,000	3,000	3,000	3,000
Total WEC Lake Drive Procedures	7,708	6,040	6,348	6,741

The applicant’s projections of procedures to be performed at WEC locations is reasonable because it is based on historical utilization, growth projections based on one-half of the actual historical CAGR, and an analysis of past utilization of all the existing GI endoscopy procedure rooms in Wake County. The physician letters in Exhibit 17 also help to substantiate the projected growth in GI endoscopy procedures to be performed. See the following table, from page 53 of the application:

	INTERIM YEAR CY 2013	PROJECT YEAR 1 CY 2014	PROJECT YEAR 2 CY 2015	PROJECT YEAR 3 CY 2016
WEC GI Endo MDs	1,000	3,000	3,000	3,000
Non-WEC GI Endo MDs	750	1,500	1,500	1,500
Total WEC Lake Drive Procedures*	750	4,500	4,500	4,500

*There is a typographical error on the table on page 53, in which the applicant labels the third row as “Total WEC Lake Drive Procedures”; however, the analyst assumes this to be an error and assumes the reference is to the Wake Forest facility.

Regardless of whether the physician letters in Exhibit 17 are conclusive with regard to the number of patients projected to be referred to the proposed facility, they are evidence of continuing need in Wake County for additional GI endoscopy services. Furthermore, the historical utilization of the WEC Lake Drive facility confirms an increasing demand for GI endoscopy services.

There is another GI endoscopy facility in the Wake Forest area of Wake County, Wake Forest Endoscopy Center (WFE), located at 10540 Ligon Mill Road; approximately 1.5 miles from the location of the facility proposed in this application. However, proximity of the two facilities is immaterial to the fact that there is a need in Wake County for additional GI endoscopy procedure rooms. WEC Wake Forest projects to perform 6,040 GI endoscopy procedures in Year 2, which is an average of 1,510 procedures per room [6,040 / 4 = 1,510]. The applicant’s projections of the number of procedures to be performed at WEC Wake Forest are based on the historical growth in the number of procedures performed at WEC Lake Drive (7.6% CAGR between CY 2008 and CY 2011) and projected population growth, particularly the population age 55 and older (5.8% CAGR between 2012 and 2017). Therefore, the applicant’s projections are based on reasonable and credible evidence. Furthermore, the applicant projects that the number of procedures performed will increase

3.8% per year, a rate lower than either the historical growth rate at WEC or the projected growth rate for the population age 55 and older.

In summary, the applicant adequately identified the population to be served and adequately demonstrated the need the population proposed to be served has for an ambulatory surgical facility with two GI endoscopy rooms at WEC Wake Forest. 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 54-55, the applicant describes the alternatives considered, which include: 1) maintain the status quo; 2) utilize hospital based GI endoscopy rooms; 3) develop a new facility in Wake County; and 4) pursue a joint venture. The applicant states that maintaining the status quo is not an effective alternative because volumes have increased steadily and the facility has exceeded its practical capacity. The additional GI endoscopy room is needed to *“decompress capacity constraints and to increase access to convenient, cost effective gastrointestinal endoscopy services.”* The applicant states that utilizing hospital based GI endoscopy rooms *“is not cost effective for patients.”* Third party payors require higher deductibles and co-pays for GI endoscopy procedures performed in hospital based GI endoscopy rooms on an outpatient basis. Regarding developing a new facility in Wake County, the applicant states that it has submitted a proposal to develop another facility in Wake Forest. However, the applicant states that both the proposed new facility and expansion of the existing facility is needed. Regarding a joint venture, the applicant states it is not a *“realistic option”* to meet the need for additional capacity at WEC.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria. The applicant adequately demonstrates that the proposal to add one GI endoscopy room to the existing facility is the most effective or least costly alternative to meet the need for additional capacity at WEC now and in the near future. Consequently, the application is conforming to this criterion, and is approved subject to the following conditions:

- 1. Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall materially comply with all representations made in the certificate of need application.**
 - 2. Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest 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 or that would otherwise require a certificate of need.**
 - 3. Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall develop no more than one ambulatory surgical facility with not 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.**
 - 4. The facility fee charged by Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall be no more than \$1,571 during a three year period beginning January 1, 2013.**
 - 5. Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.**
 - 6. Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall accept patient referrals from Project Access as described on page 73 of the application.**
 - 7. Wake Endoscopy Center, LLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**
 - 8. Prior to the issuance of the certificate of need, Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall provide the CON Section with at least one letter addressed to an area hospital which documents that Wake Endoscopy Center, LLC will accept referrals of GI endoscopy patients from that hospital.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

In Section VIII.1, page 87, the applicant projects that the total capital cost will be \$1,000,352, including \$537,438 for construction costs, \$324,316 for fixed equipment,

\$70,910 for movable equipment, \$64,615 for consultant fees and \$3,073 for freight costs. In Section IX.1, page 93, the applicant projects start-up costs in the amount of \$35,123, and initial operating expenses in the amount of \$220,000, for a total working capital requirement of \$255,123. In Section VIII.3, page 89, the applicant states that it will provide \$21,000 in accumulated reserves, and \$440,283 will be financed with a line of credit from SunTrust Bank. The applicant will finance \$398,299 through a Capital Master Equipment Lease with Olympus, and the remainder of the capital cost (\$140,770) through a landlord lease allowance incorporated as part of the lease agreement. Exhibit 18 contains an April 10, 2012 letter signed by Scott A. Bacon, First Vice President of SunTrust Bank, which states:

“...the bank has examined the financial position of Wake Endoscopy Center and found it to be adequate to support the proposal based on financial information provided to the bank. SunTrust would be willing to consider financing in the amount of \$750,000, which would be available to fund the capital costs and working capital for the proposed Wake Forest GI Endoscopy Center project.

SunTrust is aware of the lengthy CON process and its effect on cost and financing dates. Accordingly, SunTrust is prepared to address changes as they may occur.”

Exhibit 18 also contains a March 26, 2012 letter signed by Neeraj Sachdeva, MD, 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 Wake Forest. WEC anticipates funding the project capital cost with its accumulated reserves. The audited 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 proposal from Olympus for a Capital Master Lease Agreement. Exhibit 19 contains financial statements for WEC which show that, as of December 31, 2011, WEC had enough in total equity (i.e., net assets) (\$108,196) and a positive net income (\$1,169,337) sufficient to cover the \$21,000 accumulated reserves contribution. In Exhibit 14, the applicant provides a copy of the lease agreement, Section 1.1 of which describes the terms of the landlord lease allowance of \$35.00 per rentable square foot for tenant improvements. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Below is a table that shows the facility’s charges for the 7 most commonly performed GI endoscopy procedures for the first three project years, as reported by the applicant on page 19.

CPT CODE	PROCEDURE	CY 2014	CY 2015	CY 2016
43235	Upper GI endoscopy, includes esophagus	\$908	\$908	\$908
43239	Upper GI endoscopy, biopsy	\$1,078	\$1,078	\$1,078

45330	Sigmoidoscopy, flexible; diagnostic	\$550	\$550	\$550
45331	Sigmoidoscopy, flexible; with biopsy	\$698	\$698	\$698
45378	Diagnostic colonoscopy	\$1,252	\$1,252	\$1,252
45380	Colonoscopy and biopsy	\$1,346	\$1,346	\$1,346
45385	Lesion removal colonoscopy	\$1,571	\$1,571	\$1,571

The applicant states on page 19 that the charges reflect the applicant’s historical charges at its WEC Lake Drive facility. The applicant also states that the charges will include “*professional and technical fees, nursing time, administrative time, linens, medications, billable medical supplies, equipment use, and other miscellaneous fees;*” however, anesthesiology and pathology fees will be billed separately by the physician.

In the projected revenue and expense statement, the applicant projects that revenues will exceed operating costs in each of the first three operating years based on an average charge of \$1,262 per procedure.

Below is a table prepared by the project analyst which illustrates the projected revenue and expenses for the facility for each of the first three project years, as reported by the applicant in the pro forma section of the application.

	CY 2014	CY 2015	CY 2016
Net Revenue	\$2,621,361	\$2,621,361	\$2,621,361
Expenses	\$1,988,102	\$2,030,152	\$2,081,324
Profit	\$ 633,259	\$ 591,209	\$ 540,037

The assumptions used by the applicant in preparation of the pro formas for projected utilization, costs and charges are based on the applicant’s experience operating a similar facility in Raleigh. See the Financials Tab of the application for the pro formas and assumptions. Therefore, the applicant’s utilization projections are reasonable. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and revenues. 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

WEC owns and operates an existing licensed and accredited ASC with three GI endoscopy rooms at 2601 Lake Drive, Suite 201 in Raleigh. Pursuant to Project ID #J-8823-12, WEC was approved to develop one additional GI endoscopy room in the Lake Drive facility, for a total of four GI endoscopy procedure rooms. In this application, the applicant proposes to develop one ASC near Wake Forest with two GI endoscopy rooms. The proposed site is 11211 Galleria Avenue, near Rex Wakefield. Following completion of this project, WEC will have a total of six GI endoscopy procedure rooms in Wake County.

Regarding utilization of the existing GI endoscopy rooms at WEC Lake Drive, the applicant states that historical utilization increased by a 7.6% per year CAGR between CY 2008 and CY 2011. In CY 2011, 8,081 procedures were performed in the 3 existing GI endoscopy rooms, which is an average of 2,693.7 procedures per room $[8,081 / 3 = 2,693.66]$. Based on the performance standard promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility is currently operating at 179.6% $[2,693.7 / 1,500 = 1.7958]$. If the additional approved GI endoscopy room were in use during CY 2011, then utilization would still be over 100% of the minimum performance standard in G.S. 131E-182(a) and 10A NCAC 13C .3903(b), at 107% $[(8,081 \text{ procedures} / 5 \text{ rooms} = 1,616) / 1,500 = 1.0775]$.

On pages 47 - 49, the applicant states that there are currently 13 providers of GI endoscopy services in Wake County, including four hospital based and nine free standing, non-hospital based providers. In addition, the applicant provides a table that illustrates the 2011 utilization at all thirteen facilities. See the following table showing that utilization, from page 47:

HOSPITAL BASED	# OF GI ENDOSCOPY ROOMS	GI ENDOSCOPY PROCEDURES PERFORMED DURING FFY 2011*
Duke Raleigh Hospital	3	2,980
Rex Hospital **	4	3,991

WakeMed **	6	4,073
WakeMed Cary Hospital	4	2,898
Subtotal	17	13,942
# of Procedures / 1,500	9.3	
# of Procedures / # of Rooms	820.1	
% of Regulatory Performance Std.	54.7%	
FREESTANDING, NON-HOSPITAL BASED		
Cary Endoscopy Center	3	2,806
Duke GI at Brier Creek	2	2,861
Gastrointestinal Healthcare, PA	2	2,177
Raleigh Endoscopy Center	4	10,817
Raleigh Endoscopy Center – Cary	4	9,269
Raleigh Endoscopy Center – North	3	7,692
Triangle Gastroenterology	2	4,867
Wake Endoscopy Center	3	8,014
Wake Forest Endoscopy ***	2	NA
Subtotal	25	48,503
# of Procedures / 1,500	32.4	
# of Procedures / # of Rooms	1,940.1	
% of Regulatory Performance Std.	129.3%	
# of Procedures / 1,500	41.63	
# of Procedures / # of Rooms	1,486.8	
% of Regulatory Performance Std.	99.1%	

* From 2012 License Renewal Applications. Note: the application states the data is from the 2012 SMFP; however, the data in the 2012 SMFP is for FFY 2010, not FFY 2011.

The analyst verified that the data is from the 2012 LRAs.

**The applicant did not exclude the non-GI endoscopy procedures. The analyst excluded them from the data in the table for a more accurate comparison.

***This facility has been approved but was not operational during FFY 2011.

If the analyst were to add the one additional GI endoscopy room that was approved pursuant to Project ID #J-8823-12, and the two GI endoscopy rooms requested in this application to the existing inventory of GI endoscopy rooms, the total number of GI endoscopy rooms in freestanding outpatient facilities would increase to 28, and the total number of rooms in Wake County would increase to 45. The utilization in freestanding, non-hospital based GI endoscopy rooms, based on FFY 2011 numbers and projected total rooms of 28, would still be in excess of the minimum standard of 1,500 GI endoscopy procedures per room, the minimum standard established by 10A NCAC 14C .3903(b). See the following table:

Wake County GI Endoscopy Procedure Room Utilization, FFY 2011
 Hospital and Non-Hospital Based

TYPE OF ROOM	CURRENT NUMBER	APPLIED/ APPROVED	REVISED TOTAL	NO. PROCEDURES FFY 2011	PROCEDURES PER ROOM	UTILIZATION
Freestanding, Non hospital-based	25	3	28	48,503	48,503 / 28 = 1,732.5	1,732 / 1,500 = 1.1547 (115%)
Hospital-based	17	--	17	13,942	13,942 / 17 =	820.11 / 1,500

					820.11	= 0.546 (55%)
Total Wake County	42	3	45	62,445	1,357.66	0.925 (92%)

The above table makes no projections regarding the number of procedures projected to be performed.

As shown in the tables above, the hospital based GI endoscopy rooms in Wake County are not utilized to the same extent as the freestanding non-hospital based GI endoscopy rooms. However, the hospital based GI endoscopy rooms are used by inpatients and high-risk patients. These procedures may take longer, and thus, hospital based GI endoscopy rooms could have a lower practical utilization. In contrast, there are 25 freestanding non-hospital based GI endoscopy rooms in Wake County. Assuming each room performs 1,500 procedures per year, 32 rooms are needed [48,503 procedures in FFY 2011 / 1,500 = 32.3]. Given that the population age 55 and older (the age group most likely to utilize GI endoscopy services) is projected to increase 5.8% per year between 2012 and 2017, it is reasonable to assume additional GI endoscopy rooms will be needed in Wake County, particularly in freestanding non-hospital based facilities such as WEC.

The applicant adequately demonstrates that developing an ambulatory surgery facility with two new GI endoscopy rooms in Wake Forest would improve access to freestanding non-hospital based GI endoscopy services, which are more cost effective for the patient. Furthermore, the applicant adequately demonstrates that two additional GI endoscopy rooms are needed at WEC Wake Forest, based on current and projected utilization of the existing Lake Drive facility and the proposed Wake Forest facility. In CY 2011, WEC Lake Drive operated at 179.6% of the statutory performance standard [8,081 procedures / 3 rooms / 1,500 procedures per room per year = 1.7957].

In summary, the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy rooms in Wake County. Therefore, the application is conforming to this criterion.

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

C

In Section VII.2, page 79, and in Section VII.6, page 82, the applicant provides tables to illustrate projected staffing for the proposed GI endoscopy center. See the following table, prepared by the analyst from information provided by the applicant:

FUNCTIONAL AREA	# FTE POSITIONS
Professional	
Administrator	0.5
Clerical Personnel	
Nurse Supervisor	1.0
Registered Nurses	3.0
LPN – Pre-Op	1.0
BSN – Post-Op	1.0

Endo Technicians	2.0
Support Personnel	
Clerical/Scheduling	1.0
Total:	9.5

The applicant projects sufficient RNs 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. In Exhibit 4 the applicant provides a letter signed by Neeraj Sachdeva, 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. Sachdeva's curriculum vitae which documents that the physician is board-certified in both internal medicine and gastroenterology.

In Section VII.3, page 80, the applicant states it anticipates no difficulty in recruiting the additional FTEs, since it operates a similar practice in Wake County. In addition, in Section VII.7, page 83, the applicant states the physicians of Wake Endoscopy Center will also serve as physicians of the proposed Wake Forest GI endoscopy center. Additionally, in Section VII.8, page 83, the applicant projects that five of the WEC physicians will initially use the Wake Forest facility, and that as the practice grows, additional physicians will join the staff. The applicant adequately documents the availability of sufficient health manpower and management personnel to provide the proposed Wake Forest GI endoscopy services. Therefore, the application is conforming to this criterion.

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant identifies the necessary ancillary and support services in Section II.2, pages 9-10, which include the following:

- Preoperative and recovery care
- Sterilization
- Medical Records
- Billing/Insurance
- Administration
- Patient education
- Anesthesia and Pathology
- Housekeeping and Linens

On page 9 the applicant states pathology services will be provided by WakeMed pathology. In Exhibit 11 the applicant provides a copy of an agreement with WakeMed Pathology. The remaining services will be provided by WEC staff. The applicant discusses coordination with the existing health care system in Sections V.2 - V.6, pages 64 - 67. The applicant provides supporting documentation in Exhibits 10, 13, and 17. The information provided in

those sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

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

NA

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

NA

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

C

The applicant proposes to lease space properly zoned for construction of an ambulatory surgical facility from an unrelated third-party developer. In Section XI.6(a), page 102, the applicant states the proposed ambulatory surgical facility will be constructed in 4,022 square feet of leased space on Galleria Avenue in Wake Forest. In Exhibit 15 the applicant provides a copy of a construction cost estimate prepared by GMK Associates, Inc. that is consistent with the construction cost projected in Section VIII of the application. In Section XI.8, pages 103 – 104, the applicant states:

“The proposed facility will use modern energy conservation practices and methods, featuring energy efficiency and water conservation.

The facility HVAC and electrical systems will be designed to meet all requirements of the latest energy code adopted by the State, as well as the latest edition of ASHRAE 90.1 ... the industry standard to energy efficient buildings. All lighting systems will be designed to meet the requirements of ASHRAE 90.1, and the adopted State energy code.”

In summary, the applicant adequately demonstrates that the cost, design and means of construction represent a reasonable alternative for the development of a licensed ambulatory surgical facility. Consequently, the application is conforming to this criterion.

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

C

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages as of June 2010 and CY 2008-2009, respectively. The data in the table was obtained on September 13, 2012. More current data, particularly with regard to the estimated uninsured percentages, was not available.

	TOTAL # OF MEDICAID ELIGIBLES AS % OF TOTAL POPULATION	TOTAL # OF MEDICAID ELIGIBLES AGE 21 AND OLDER AS % OF TOTAL POPULATION	% UNINSURED CY 2008-2009 (ESTIMATE BY CECIL G. SHEPS CENTER)
Wake County	10.0%	3.3%	18.4%
Statewide	17.0%	6.7%	19.7%

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

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

The project analyst prepared a table from data collected from the 2012 License Renewal Applications for eight free-standing, non hospital-based GI endoscopy facilities in Wake County.

Wake County Free Standing GI Endoscopy Facility Payor Mix, FY 2010

FACILITY	PERCENT OF TOTAL			
	SELF PAY / INDIGENT	COMMERCIAL INSURANCE	MANAGED CARE	MEDICARE / MEDICARE MANAGED CARE / MEDICAID
Wake Endoscopy Center – Lake Drive	2%	5%	71%	31%
Raleigh Endoscopy Center	2%	3%	65%	30%
Raleigh Endoscopy Center – North	1%	3%	74%	23%
Raleigh Endoscopy Center – Cary	1%	5%	78%	17%
Duke GI at Brier Creek	1%	2%	80%	18%
Gastrointestinal Healthcare, PA	1%	5%	80%	14%
Center for Digestive Diseases & Cary Endoscopy Center	1%	79%	0%	20%
Triangle Gastroenterology	16%	43%	2%	39%

*Source: 2012 License Renewal Applications

This application is for a proposed facility, and thus the applicant has no payor history for this facility to report. However, the applicant has an existing GI endoscopy facility in Raleigh. The following table illustrates the current payor mix for the Wake Endoscopy Center's existing location on Lake Drive in Raleigh, as reported by the applicant in Section VI.14, page 77.

PAYOR CATEGORY	PERCENT OF TOTAL
Self Pay / Indigent / Charity	2%
Medicare	24%
Medicaid	1%
Commercial / PPO	25%
Blue Cross / Blue Shield	48%
Total	100%

*The applicant states on page 78 that this table reflects current outpatient payor mix at the Lake Drive facility in Raleigh.

In Section VI.2, page 66, the applicant states that, during CY 2011:

- 55% of WEC’s patients were women. Women comprised 51.3% of the Wake County population.
- 21% of WEC’s patients were 65 and older. Only 8.1% of the Wake County population was 65 and older.
- 3% of WEC’s patients were self pay, indigent, charity care or Medicaid recipients. Ten percent of Wake County’s population was Medicaid eligible. However, most of those Medicaid eligible residents were under the age of 21 and not likely to utilize the GI endoscopy services offered by WEC.
- WEC does not track the number of minority or handicapped patients it serves.

The applicant demonstrates that medically underserved populations currently have adequate access to its existing services. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.11, page 76, the applicant states “WEC is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, continuing its current business practice, WEC will not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay.” In Section VI.10, page 76, the applicant states that no civil rights access complaints have been filed against the facility in the last five years. The application is conforming to this criterion.

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

C

The following table illustrates the projected payor mix during the second operating year, as reported by the applicant in Section VI.14, page 77.

SECOND FULL PROJECT FISCAL YEAR PROJECTED PROCEDURES AS % OF TOTAL	
Self Pay / Indigent / Charity	2.0%
Medicare	24.0%
Medicaid	1.0%
Commercial / PPO	25.0%
Blue Cross / Blue Shield	48.0%

Total	100.0%
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In Section VI.4, page 71, the applicant states “*All services offered by WEC at the Wake Forest facility will be available to all persons who present themselves for services, regardless of their ability to pay.*” Exhibit 8 contains a copy of the 2012 Project Access Physician Participation Pledge Form for Raleigh Medical Group, PA. In Section VI.2, page 65, the applicant states that Project Access is “*a community initiative ... to make health services more accessible to medically indigent residents of Wake County.*”

The applicant demonstrates that medically underserved populations will continue to have adequate access to the facility’s services and the application is conforming to this criterion.

- (d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Section VI.9, page 75, the applicant states access to the proposed outpatient 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 and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

See Section V.1, page 64 and referenced exhibits for documentation that WEC currently accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. 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

See Sections II, III, V, VI and VII. In particular, see Section V.7, pages 67-68, in which the applicant specifically discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. The information provided by the applicant in each of those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition include a positive impact on cost-effectiveness, quality and access to GI endoscopy services in the Wake Forest area of Wake County.

The following conclusions are based on a review of the information in the sections of the application referenced above:

- The applicant adequately demonstrates the need to develop an ambulatory surgery center with two GI endoscopy rooms based on current and projected utilization (see Section III of the application);
- The applicant adequately demonstrates the need in Wake County for two additional GI endoscopy rooms in a freestanding non-hospital based facility based on current and projected utilization (see Section III of the application);
- The applicant adequately demonstrates that the proposal is a cost-effective alternative to meet the need (see Section III of the application);
- The applicant has provided quality services in its other facilities and will continue to provide quality services (see Sections II and VII of the application);
- The applicant will provide adequate access to medically underserved populations (see Sections III and VI of the application); and
- The proposal will have a positive impact on competition by providing patients with increased access to quality GI endoscopy services in Wake Forest at a lower cost to the patient than a hospital based provider (see Sections II and V of the application).

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.

CA

The proposal submitted by WEC is conforming or conditionally 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

.3902(a)(1) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: (1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906.”*

-C- In Section III.6, page 57, the applicant identifies the service area in Year 2 as Wake and Franklin counties. The applicant projects that 96% of the patients to be served will reside in Wake County, and 4% will reside in Franklin County.

.3902(a)(2)(A) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: (A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located.”*

-C- WEC proposes to develop one ambulatory surgery facility in Wake Forest with two GI procedure rooms.

.3902(a)(2)(B) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (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.”*

-C- WEC is currently licensed to operate three GI endoscopy rooms in its facility on Lake Drive in Raleigh. In addition, pursuant to Project ID #J-8823-12, the applicant was approved to add one GI endoscopy room to the existing facility, for a total of four GI endoscopy procedure rooms at the Lake Drive facility.

- .3902(a)(2)(C) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months.”*
- C- In Section II.11, page 16, the applicant provides the number of GI endoscopy procedures (8,305), identified by CPT code, performed in the applicant's GI endoscopy rooms at its Lake Drive facility between March 2011 and February 2012.
- .3902(a)(2)(D) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (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 16, the applicant provides the number of GI endoscopy procedures, identified by CPT code, projected to be performed in the proposed Wake Forest facility in each of the first three operating years of the project. See Criterion (3) for discussion of the reasonableness of projections which is hereby incorporated by reference as if fully set forth herein.
- .3902(a)(2)(E) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months.”*
- NA- In Section II.11, page 17, the applicant states that WEC has performed only GI endoscopy procedures in the GI endoscopy rooms in its existing Lake Drive facility in the last 12 months.
- .3902(a)(2)(F) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (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 17, the applicant states that no procedures other than GI endoscopy procedures will be performed in the existing or proposed GI endoscopy rooms.
- .3902(a)(2)(G) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months.”*

-C- In Section II.11, page 17, the applicant states that 7,415 patients were served in the three GI endoscopy rooms between March 2011 and February 2012.

.3902(a)(2)(H) This rule states “An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2): ... (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 17, the applicant projects 4,027 patients will be served in the proposed GI endoscopy rooms in each of the first three project years.

.3902(a)(3) This rule states “An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (3) with regard to services provided in the applicant's operating rooms identify: (A) the number of existing operating rooms in the facility; (B) the number of procedures by type performed in the operating rooms in the last 12 months; and (C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project.”

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

.3902(a)(4) This rule states “An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located.”

-C- In Section II.11, page 18, the applicant states that the facility will be operated Monday through Friday from 7:30 AM to 4:00 PM, 52 weeks per year, excluding holidays.

.3902(a)(5) This rule states “An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.”

-C- In Section II.11, page 18, the applicant provides the type and average facility charges by CPT code during CY 2011 for the seven procedures performed most often at WEC Lake Drive. See the following table, from page 18:

CPT CODE	DESCRIPTION	CHARGE CY 2011
43235	Upper GI endoscopy, includes esophagus	\$ 908
43239	Upper GI endoscopy, biopsy	\$1,078
45330	Sigmoidoscopy, flexible; diagnostic	\$ 550
45331	Sigmoidoscopy, flexible; with biopsy	\$ 698
45378	Diagnostic colonoscopy	\$1,252

45380	Colonoscopy and biopsy	\$1,346
45385	Lesion Removal colonoscopy	\$1,571

- .3902(a)(6) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility.”*
- C- In Section II.11, page 19, the applicant provides the type and average facility charges by CPT code projected during the first three operating years for the seven procedures projected to be performed most often at WEC Wake Forest.
- .3902(a)(7) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge.”*
- C- In Section II.11, page 19, the applicant states *“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.”*
- .3902(a)(8) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility’s charges.”*
- C- In Section II.11, page 19, the applicant states *“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 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.”*
- .3902(a)(9) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.”*
- C- In Section II.11, page 20, the applicant provides the average reimbursement received per procedure during CY 2011 for the seven procedures performed most often at WEC Lake Drive.

- .3902(a)(10) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (10) the average reimbursement projected to be received for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.”*
- C- In Section II.11, page 20, the applicant provides the average reimbursement projected to be received for the seven GI endoscopy procedures which the applicant projects will be performed most frequently in the facility for the first three project years.
- .3902(b) This rule states *“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 applicant provides 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 applicant provides a February 24, 2012 letter signed by Dr. Sachdeva that documents WEC Wake Forest’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 applicant provides 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 21, and Section VI, the applicant states *“all persons will have access to the proposed GI endoscopy services ... regardless of ... ability to pay.”*
- (4) a written description of patient selection criteria including referral arrangements for high-risk patients;*
- C- In Exhibit 7 the applicant provides copies of patient selection criteria, including referral arrangements for high-risk patients.
- (5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;*

-C- In Section II.11, page 22, the applicant provides the number of GI endoscopy procedures performed by the applicant in its WEC Lake Drive facility in each of the last 12 months.

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

-C- In Section II.11, page 22, and Section III.1, pages 47 – 53, the applicant describes a projected “*shift*” in patient patterns and procedures from its Lake Drive facility to the Wake Forest facility, without a reduction in the total number of patients projected to be served.

.3903 PERFORMANCE STANDARDS

.3903(a) This rule states “*In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*”

-NA- The applicant does not have operating rooms.

.3903(b) This rule states “*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 53, and Section IV, page 63, the applicant projects to perform 4,500 GI endoscopy procedures during all three project years, which is an average of 2,250 procedures per room (4,500 procedures / 2 procedure rooms = 2,250 procedures per room). See Criterion (3) for a detailed analysis of the applicant’s projected utilization which is hereby incorporated by reference as if fully set forth herein.

.3903(c) This rule states “*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 23, the applicant states it will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at WEC Wake Forest.

.3903(d) This rule states “*If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the*

applicant shall meet one of the following criteria: (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.”

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

.3903(e) This rule states *“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 32 - 53, the applicant provides all assumptions and methodology it used to project GI endoscopy procedures. See Criterion (3) for a detailed analysis of the applicant’s projected utilization which is hereby incorporated by reference as if fully set forth herein.

.3904 SUPPORT SERVICES

.3904(a) This rule states *“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.1, pages 24 – 25, the applicant states pathology services are currently provided by WakeMed for WEC Lake Drive, and WakeMed will continue to provide pathology services to WEC’s Lake Drive and Wake Forest locations following project completion. In addition, in Exhibit 11, the applicant provides a copy of the existing agreement with WakeMed for pathology services.

.3904(b) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.”*

-C- In Exhibit 5 the applicant provides a copy of WEC’s conscious sedation policy.

- .3904(c) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.”*
- C- In Exhibit 5 the applicant provides a copy of WEC’s policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases.

- .3904(d)(1) This rule states *“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 25, the applicant states that the physicians who will utilize WEC Wake Forest have active medical staff privileges at existing Wake County hospitals. See Exhibit 22 for the curriculum vitae for the Medical Director for WEC, which states that he is affiliated with Duke Raleigh Hospital, Rex Hospital and WakeMed. According to his profile on the NC Board of Medical Examiners website, he has admitting privileges at Duke Raleigh Hospital, Rex Hospital and WakeMed Cary. In addition, the NC Board of Medical Examiners website confirms the six additional physicians listed in Exhibit 22 who will practice at WEC Wake Forest have admitting privileges at the same hospitals in Wake County.

- .3904(d)(2) This rule states *“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: ... (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.”*

- CA- See Exhibit 13 for a letter from Rex Hospital stating that it will accept patients transferred from WEC. However, the applicant did not provide documentation of an agreement to accept referrals from a hospital where the physicians who will utilize WEC Wake Forest have privileges. Therefore, the application is conforming to this Rule subject to the following condition.

Prior to the issuance of the certificate of need, Wake Endoscopy Center, LLC d/b/a Wake Endoscopy Center Wake Forest shall provide the CON Section with at least one letter addressed to an area hospital which documents that Wake Endoscopy Center, LLC will accept referrals of GI endoscopy patients from that hospital.

- .3904(d)(3) This rule states *“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: ... (3) documentation of a transfer agreement with a hospital in case of an emergency.”

- C- See Exhibit 13 for a March 23, 2012 letter from Rex Hospital stating that it will accept patients transferred from WEC.

.3905 STAFFING AND STAFF TRAINING

.3905(a) This rule states *“An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas: (1) administration; (2) pre-operative; (3) post-operative; (4) procedure rooms; (5) equipment cleaning, safety, and maintenance; and (6) other.”*

- C- In Section II.11, page 26, the applicant states the proposed facility will have sufficient staff in the areas identified in this rule. The following table illustrates the projected staffing at WEC Wake Forest, as reported by the applicant in Section VII.6, page 82.

EMPLOYEE CATEGORY	ADMIN.	PRE-OP	POST-OP	OPERATING ROOM	OTHER (CLERICAL)	TOTAL
Prof. Healthcare Administrator	0.5					0.5
Registered Nurses		0.5	0.5	2.0		3.0
Licensed Practical Nurses		1.0				1.0
BSN			1.0			1.0
Endoscopy Technician				2.0		2.0
Nurse Supervisor				1.0		1.0
Non-health professionals					1.0	1.0
Total	0.5	1.5	1.5	5.0	1.0	9.5

.3905(b) This rule states *“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 27, the applicant lists the name and board certification area of five physicians who will perform GI endoscopy procedures at WEC Wake Forest. In Exhibit 4 the applicant provides the curriculum vitae for the Medical Director, who is one of the five physicians.

- .3905(c) This rule states *“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 27, the applicant states that all physicians who will utilize WEC Wake Forest 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. In Exhibit 16 the applicant provides 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.
- .3905(d) This rule states *“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 27, the applicant states that all physicians who will utilize WEC Wake Forest 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. In Exhibit 16 the applicant provides 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.
- (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- In Exhibit 16, the applicant provides a copy of WEC’s credentialing policy, 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 28, the applicant states that all physicians with practice privileges at WEC Wake Forest will be active members in good standing at a general acute care hospital within the proposed service area. The project analyst looked at the North Carolina Board of Medical Examiners’ website and confirmed that each of the listed physicians who will practice at WEC Wake Forest are active members in

good standing at several general acute care hospitals in the area, including Duke Raleigh Hospital, Rex Healthcare, and WakeMed Cary Hospital.

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

- C- In Section II.11, page 28, the applicant states that at least one registered nurse will be employed per procedure room at WEC Wake Forest. In Section VII.2, page 79, the applicant provides a staffing chart that illustrates proposed staffing for WEC Wake Forest.

(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 28, the applicant states that additional staff or patient care technicians will be employed to provide assistance in the procedure rooms at WEC Wake Forest. In Section VII.2, page 79, the applicant provides a staffing chart that illustrates proposed staffing for WEC Wake Forest.

(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 28, the applicant states 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. In Exhibit 9 the applicant provides copies of job descriptions for registered nurses which confirm that the nurses will be certified consistent with the requirements in this rule.

.3906 FACILITY

.3906(a) This rule states *“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- WEC Wake Forest is not proposed to be located in a physician office or a general acute care hospital.

.3906(b) This rule states *“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 29, the applicant states WEC will pursue accreditation from the Accreditation Association for Ambulatory Health Care within one year of completion of the proposed project.

- .3906(c) This rule states *“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 29, the applicant states the physical environment of the facility 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- In Exhibit 15, the applicant provides 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- In Exhibit 15, the applicant provides a floor plan that demonstrates that the procedure room is 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- In Exhibit 14 the applicant provides a copy of the lease between an unrelated third party landlord and WEC as tenant.