ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DATE OF DECISION: July 27, 2012
FINDINGS DATE: August 1, 2012

ASSISTANT CHIEF: Martha J. Frisone
CHIEF: Craig R. Smith

PROJECT I.D. NUMBER: #J-8823-12 / Wake Endoscopy Center, LLC / Develop one additional gastrointestinal endoscopy room in an existing licensed ambulatory surgical facility/ 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 facility or ambulatory surgery center (ASC) with three gastrointestinal endoscopy rooms (GI endoscopy rooms) at 2601 Lake Drive, Suite 201 in Raleigh. The building is owned by Five GIS Rex Properties, LLC. Raleigh Medical Group, PA, leases the entire second floor, and subleases the space for the existing ASC to WEC.

The applicant proposes to add one GI endoscopy room to the existing facility for a total of four GI endoscopy rooms. There are no policies or need determinations in the 2012 State Medical Facilities Plan 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(2) Repealed effective July 1, 1987.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

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Population to be Served

In Sections III.7 and III.6, pages 53-54, the applicant provides the current and projected patient origin for WEC, as illustrated in the following table.

COUNTY	CURRENT (CY 2011)	PROJECTED	
		YEAR ONE (CY 2013)	YEAR TWO (CY 2014)
Wake	86.4%	86.4%	89.3%
Johnston	10.1%	10.1%	10.1%
Franklin	2.8%	2.8%	0.0%
Harnett	0.5%	0.5%	0.5%
Alamance	0.1%	0.1%	0.1%
Total	**100.0%**	**100.0%**	**100.0%**

On page 53, the applicant states that projected patient origin is based on its historical experience. The major change projected by the applicant is a reduction in the number of patients from Franklin County to zero. The applicant assumes that Wake County residents will represent a larger percentage of the total if no Franklin County residents are served at the Raleigh facility in Year Two of the project. The applicant adequately explains that this is based on an assumption that its application to develop a new ASC with two GI endoscopy rooms in Wake Forest will be approved. That application (Project I.D. #J-8822-12) is still under review as of the date of this decision. The applicant adequately demonstrates that it is reasonable to assume that the residents of Franklin County currently utilizing the Raleigh facility (which is located near the State Fairgrounds) would shift to the proposed Wake Forest facility because the Wake Forest facility would be more conveniently located. If the proposed facility in Wake Forest was not approved, then the Franklin County residents currently utilizing WEC would presumably continue to utilize the Raleigh facility. The applicant adequately identifies the population proposed to be served.

Need for the Proposal

In Section III.1, page 31, the applicant states the following factors support the need to develop one additional GI endoscopy room at WEC:

- "*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 disproportionally 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 31-38, the applicant describes the three primary types of GI endoscopy procedures, which are 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. Finally, 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 pages 38-39, the applicant states that the American Cancer Society has made promoting colorectal cancer screening a high priority.

On page 38, 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.

On pages 39-42, the applicant provides demographic data for Wake County, which is summarized in the table below.

	WAKE COUNTY	
	TOTAL POPULATION	POPULATION AGE 55+
2012	946,278	167,384
2013	971,025	178,254
2014	995,773	189,125
2015	1,020,520	199,995
2016	1,045,268	210,866
2017	1,070,015	221,736
5-year CAGR*	2.5%	5.8%

*Compound annual growth rate
Applicant's source: Claritas

As shown in the above table, between 2012 and 2017, the population aged 55+ is projected to increase 5.8% per year.

The applicant also provides the following information regarding colorectal cancer rates for Wake County

Population	Cancer Incidence Rate per 100,000 population
All Ages	41.7
Age 65+	216.4

As shown in the table above, the incidence of cancer increases substantially with age.

Finally, the applicant provides information regarding the African-American population and other minorities. The applicant states that African-Americans represent 20.7% of Wake County's population, which is similar to the percentage for the state as a whole (21.5%). However, the colorectal cancer rate for African-Americans in Wake County is higher than that for the population of Wake County as a whole. The applicant also provides statewide colorectal cancer rates for other minority groups. See page 42 for the applicant's tables.

Regarding utilization of the existing GI endoscopy rooms at WEC, on page 43, the applicant states that utilization has increased 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% of capacity [2,693.7 / 1,500 = 1.7958].

On pages 44-46, the applicant provides information regarding the existing and approved GI endoscopy rooms in Wake County, as shown in the following table.

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 Capacity		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 Capacity		129.3%
Total Wake County	**42**	**62,445**
# of Procedures / 1,500		**41.63**
# of Procedures / # of Rooms		**1,486.8**
% of Capacity		**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. They have been excluded in the table above.

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

On page 44, the applicant states *"freestanding outpatient facilities provide a high quality, more affordable healthcare service option for patients compared to a hospital-based provider. A patient's out-of-pocket expenses are markedly lower when GI endoscopy services are rendered in a freestanding outpatient facility. As a result, freestanding outpatient facilities are highly utilized."* The applicant notes that 77% of all GI endoscopy procedures are performed in freestanding outpatient facilities. See also the applicant's discussion on page 38 of the application.

As shown in the table above, the hospital based GI endoscopy rooms are not utilized to the same extent as the freestanding non-hospital based GI endoscopy rooms. There

are 17 hospital based GI endoscopy rooms but assuming each room performs 1,500 procedures per year, only 9 are needed. However, that assumption does not take into account that 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 capacity. In contrast, there are 25 freestanding non-hospital based GI endoscopy rooms and assuming each room performs 1,500 procedures per year, 32 are needed. Moreover, when all GI rooms are combined (hospital based and non-hospital based), there are 42 existing and approved rooms and 42 rooms are needed based on the level of utilization in FFY 2011. Given that the population age 55 and older 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.

Exhibit 17 contains letters from physicians supporting this proposal to add one GI endoscopy room at WEC in order to meet current and projected demand for GI endoscopy procedures. Furthermore the physicians state their intent to continue performing GI endoscopy procedures at WEC.

Historical and Projected Utilization

The following table illustrates historical and projected utilization of the existing and proposed GI endoscopy rooms at WEC, as reported by the applicant in Sections IV.1 and IV.2, pages 58-59.

YEAR	A TOTAL # OF GI ENDOSCOPY PROCEDURES	B # OF LICENSED GI ENDOSCOPY ROOMS	C (A / B) AVERAGE # OF PROCEDURES PER ROOM	D (C / 1,500) % OF CAPACITY
CY 2010 (actual)	7,465	3	2,488.3	165.9%
CY 2011 (actual)	8,081	3	2,693.7	179.6%
CY 2012 (projected)	8,389	3	2,796.3	186.4%
CY 2013 (projected) (Year 1)	7,708	4	1,927.0	128.5%
CY 2014 (projected) (Year 2)	6,040	4	1,510.0	100.7%
CY 2015 (projected) (Year 3)	6,384	4	1,596.0	106.4%

As shown in the above table, in CY 2011, WEC performed 8,081 GI endoscopy procedures in three rooms, which is an average of 2,693.9 procedures per room or 179.6% of capacity. If the facility had had four GI endoscopy rooms in CY 2011, it would have averaged 2,020.3 GI endoscopy procedures per room [8,081 procedures / 4 rooms = 2,020.3 procedures per room], which exceeds the minimal threshold of 1,500 procedures per room. Furthermore, it would have operated at 134.7% of capacity [2,020.3 / 1,500 = 134.7%].

The applicant's assumptions and methodology used to project utilization are provided in Section III.1, pages 46-49, and are summarized below.

Step 1: The applicant states that it reviewed historical utilization at WEC from CY 2008 through CY 2011, which is illustrated in the following table.

Year	# of GI Endoscopy Procedures
CY 2008	6,484
CY 2009	7,106
CY 2010	7,465
CY 2011	8,081
3-Year CAGR	7.6%

On page 46, the applicant notes that the one-year growth rate between CY 2010 and CY 2011 was 8.3%. The applicant documents that the facility is well utilized and that utilization has been increasing.

Step 2: The applicant states that it assumed that volume would increase 3.8% per year, which is half the 3-year CAGR [7.6% / 2 = 3.8%]. The applicant states that it believes that a growth rate of 3.8% is reasonable based on physicians who have wanted to perform GI endoscopy procedures at WEC but were not able to schedule their procedures there due to current capacity constraints. The applicant states that Mamun Shahrier, MD used to perform his GI endoscopy procedures at WEC but started utilizing another facility due to scheduling difficulties at WEC. Dr. Sharier has indicated that he would start utilizing WEC once the facility has additional capacity. See Exhibit 17 for a letter from Dr. Sharier. The applicant states that another unidentified physician has also indicated an intention of utilizing WEC once it has additional capacity. The applicant states that this physician cannot be identified because he or she was still obligated to another practice when the application was submitted. The applicant adequately demonstrates that it is reasonable to assume that utilization at WEC will increase 3.8% per year, given that it increased 7.8% per year between CY 2008 and CY 2011. Moreover, at least one additional physician is expected to utilize the facility if capacity is increased.

Step 3: A separate certificate of need application was filed in the same review cycle as this application. That application, Project I.D. #J-8822-12 is still under review as of the date of the decision on this application. Assuming that application is approved, the applicant assumed that some of its existing patients would shift to the proposed facility in Wake Forest.

The applicant determined the number of patients that would shift as follows:

- The applicant identified the physicians that are expected to utilize the proposed facility in Wake Forest. They are Christopher Schwarz, MD, Michael Battaglino, MD and Neeraj Sachdeva, MD.
- The applicant estimated the number of GI endoscopy procedures that each of these physicians would perform at the proposed Wake Forest facility, as shown in the table below.

Physician	**# of GI Endoscopy Procedures to be Performed at the Proposed Wake Forest Facility**
Christopher Schwarz, MD	750
Michael Battaglino, MD	750
Neeraj Sachdeva, MD	1,500
Total	**3,000**

- Finally, the applicant subtracted the number of GI endoscopy procedures expected to shift to the proposed Wake Forest facility from the number of procedures calculated in Step 2, as shown in the table below.

	CY 2013 Year 1	**CY 2014 Year 2**	**CY 2015 Year 3**
# of GI Endoscopy Procedures from Step 2	8,708	9,040	9,384
# of Procedures Expected to Shift to the Proposed Wake Forest Facility	1,000	3,000	3,000
Total at Lake Drive	7,708	6,040	6,384

On page 49, the applicant states that the proposed Wake Forest facility is expected to begin operations in September of 2013. Thus, only one third of the 3,000 procedures are expected to shift during CY 2013.

The applicant adequately demonstrates that it is reasonable to assume that it will perform 6,040 GI endoscopy procedures in the four GI endoscopy rooms in the second operating year, which is an average of 1,510 procedures per room [6,040 procedures / 4 rooms = 1,510 procedures per room]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room as required by 10A NCAC 14C .3903(b).

If the proposed Wake Forest facility is not approved, GI endoscopy procedures would not shift from WEC to the proposed Wake Forest facility. Therefore, WEC would perform 9,040 GI endoscopy procedures in Year 2, not 6,040, which is an average of 2,260 procedures per room [9,040 / 4 = 2,260]. The applicant adequately demonstrates that it would be reasonable to expect that WEC would perform that many procedures based on historical growth at WEC (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). The applicant assumed that volume would increase 3.8% per year, a rate lower than either the historical growth rate at WEC and than the growth rate for the population age 55 and older.

Regardless of whether or not the proposed Wake Forest facility is approved, the applicant adequately demonstrates the need to add one GI endoscopy room to WEC.

In summary, the applicant adequately identified the population to be served and demonstrated the need the population proposed to be served has for one additional GI endoscopy room at WEC. 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. See Criteria (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .3900.

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 shall materially comply with all representations made in the certificate of need application.**

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

3. **Wake Endoscopy Center, LLC shall develop no more than one additional gastrointestinal endoscopy room and shall be licensed for a total of no more than four gastrointestinal endoscopy rooms upon completion of the project.**

4. **The facility fee charged by Wake Endoscopy Center, LLC shall be no more than $1,571 during a three year period beginning January 1, 2013.**

5. **Wake Endoscopy Center, LLC shall prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay.**

6. **Wake Endoscopy Center, LLC shall accept patient referrals from Project Access as described on page 69 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.**

(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 84, the applicant projects that the total capital cost will be $306,966, including $10,250 for renovation costs, $273,860 for equipment and furniture, $21,000 for consultant fees and $1,856 for freight costs. In Section IX.1,

page 89, the applicant projects there will be no start-up or initial operating expenses. In Section VIII.2, page 86, the applicant states that it will provide $31,250 in owner's equity. The applicant will finance the remainder of the capital cost through a Capital Master Equipment Lease with Olympus. Exhibit 18 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 expansion of our GI endoscopy center on Lake Drive in Raleigh. 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 $31,250 owner's equity (i.e., accumulated reserves) contribution. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

In the assumptions following the pro formas, the applicant states the average charge per procedure during each of the first three operating years will be $1,262, which includes the professional fee for the gastroenterologist. It does not include the charges for anesthesia, pathology or radiology. Those fees are billed by other providers. 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, which includes the professional fee for the gastroenterologist. The assumptions used by the applicant in preparation of the pro formas are reasonable, including projected utilization, costs and charges, including professional fees. See the Financials Tab for the pro formas and assumptions. See Criterion (3) for discussion of utilization projections. 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

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On pages 44-46, the applicant provides information regarding the existing and approved GI endoscopy rooms in Wake County, as shown in the following table.

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# of Procedures / 1,500		**41.63**
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% of Capacity		**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. They have been excluded in the table above.

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

On page 44, the applicant states *"freestanding outpatient facilities provide a high quality, more affordable healthcare service option for patients compared to a hospital-based provider. A patient's out-of-pocket expenses are markedly lower when GI endoscopy services are rendered in a freestanding outpatient facility. As a result, freestanding outpatient facilities are highly utilized."* The applicant notes that 77% of all GI endoscopy procedures are performed in freestanding outpatient facilities. See also the applicant's discussion on page 38 of the application.

As shown in the table above, the hospital based GI endoscopy rooms are not utilized to the same extent as the freestanding non-hospital based GI endoscopy rooms. There are 17 hospital based GI endoscopy rooms but assuming each room performs 1,500 procedures per year, only 9 are needed. However, that assumption does not take into account that 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 capacity. In contrast, there are 25 freestanding non-hospital based GI endoscopy rooms and assuming each room performs 1,500 procedures per year, 32 are needed. Moreover, when all GI rooms are combined (hospital based and non-hospital based), there are 42 existing and approved rooms and 42 rooms are needed based on the level of utilization in FFY 2011. Given that the population age 55 and older 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 one additional GI endoscopy room at WEC would improve access to freestanding non-hospital based GI endoscopy services which are more cost effective for the patient. The data provided by the applicant shows that additional freestanding non-hospital based GI endoscopy rooms are needed in Wake County based on the level of utilization in FFY 2011.

Furthermore, the applicant adequately demonstrates that one additional GI endoscopy room is needed at WEC based on current utilization as well as projected utilization. In CY 2011, WEC operated at 179.6% of capacity [8,081 procedures / 3 rooms / 1,500 procedures per room per year = 1.7957]. In Year 2, the facility is projected to operate at 100.7% of capacity assuming 3,000 procedures are shifted to the proposed Wake Forest facility [6,040 procedures / 4 rooms / 1,500 procedures per room per year = 1.0066]. If the proposed Wake Forest facility is not approved, WEC is projected to operate at 150.7% of capacity [9,040 procedures / 4 rooms / 1,500 procedures per room per year = 1.5066].

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

The following table illustrates the current and projected staffing at WEC during the second operating year, as reported by the applicant in Sections VII.1 and VII.2, pages 76-77.

POSITION	# OF FULL-TIME EQUIVALENT POSITIONS (FTEs)	
	CURRENT STAFF CY 2012	PROJECTED STAFF YEAR 2 CY 2014
Administrator	0.50	0.5
Nurse Supervisor	1.00	1.0
Registered Nurses (RNs)	5.00	6.5
Licensed Practical Nurses (LPNs)	2.00	2.0
BSN	0.75	1.0
Endoscopy Technicians	2.00	3.0
Clerical/Scheduling	1.00	1.0
Total	12.25	15.0

The following table illustrates the projected staffing at WEC by functional area, as reported by the applicant in Section VII.7, page 79.

FUNCTIONAL AREA	TYPE	# OF FTE POSITIONS
Administration	Administrator	0.5
Preoperative	RNs LPNs	3.0
Postoperative	RNs BSN	2.5
GI Endoscopy Rooms	Nurse Supervisor RNs Endoscopy Technicians	8.0
Equipment cleaning, safety & maintenance [(1)]		
Other	Clerical / Scheduling	1.0

[(1)] The table in Section VII.7, page 79, does not have a column labeled "Equipment cleaning, safety and maintenance." The applicant includes the 3.0 FTE endoscopy technician positions in the GI Endoscopy Room column. A review of the job description for the endoscopy technician position provided in Exhibit 9 documents that the primary responsibility of the endoscopy technician is equipment cleaning, safety and maintenance.

In Section VII.7(b), page 80, the applicant states it anticipates no difficulty in recruiting the additional FTEs.

The applicant projects sufficient RNs so that there will be at least one RN in each of the four GI endoscopy rooms during a procedure and one each in the Preoperative and Postoperative areas. Exhibit 4 contains a letter signed by Neeraj Sachdeva, M.D., and a curriculum vitae which document that the physician is board-certified in both

internal medicine and gastroenterology and has agreed to continue to serve as Medical Director for WEC. The applicant adequately documented the availability of sufficient health manpower and management personnel to provide the proposed GI endoscopy services. Therefore, the application is conforming to this criterion.

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

C

The applicant identifies the necessary ancillary and support services in Section II.2, pages 9-10. The applicant discusses coordination with the existing health care system in Sections V.2 - V.6, pages 60-63. The applicant provides supporting documentation in Exhibits 8, 10, 11, 13, 16 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.

NA

The applicant proposes to renovate an existing office for the fourth GI endoscopy room for a total cost of $10,250 for labor and materials. Therefore, this criterion is not applicable to this review.

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

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

C

The following table illustrates the current payor mix for WEC, as reported by the applicant in Section VI.12, page 73.

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

In Section VI.4, page 67, the applicant states *"All services offered by WEC at the Lake Drive facility are 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."*

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 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 July 27, 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.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar

information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

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 applicants' 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.

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 72, the applicant states *"WEC is not obligated under public regulations to provide uncompensated care, community service, or access by minorities and handicapped persons. However, ... WEC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay."* In Section VI.10, page 72, 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 74.

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

In Section VI.4, page 67, the applicant states *"All services offered by WEC at the Lake Drive facility are 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

See Section VI.9 for documentation of the range of means by which patients have access to the services provided at WEC. The information provided 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 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 VI.7, pages 63-64, 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 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 add one GI endoscopy room to the existing ASC based on current and projected utilization (see Section III of the application);
- The applicant adequately demonstrates the need in Wake County for an additional GI endoscopy room 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 and will continue to provide quality services (see Sections II and VII of the application);
- The applicant has and will continue to 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 services 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.

C

WEC is accredited by the Accreditation Association for Ambulatory Health Care and is certified for Medicare and Medicaid participation. According to the records in the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, no incidents have occurred at the facility within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

CA

The proposal submitted by WEC is conforming or conditionally conforming with 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 53, the applicant identified the service area in Year 2 as: Wake; Johnston; Harnett; and Alamance counties. In Year 1, the applicant projects a small percentage of patients from Franklin County based on historical patient origin for the existing facility. The applicant assumes these patients will shift to the proposed Wake Forest facility if that application is approved.

.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 is currently licensed with three GI endoscopy rooms. The applicant proposes to develop one additional GI endoscopy room for a total of four.

.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."*

-NA- Neither the applicant nor a related entity has another licensed health service facility in the proposed service area.

.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 endoscopy rooms between March 1, 2011 and February 29, 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 applicant's licensed endoscopy rooms 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 no procedures other than GI endoscopy procedures were performed in the GI endoscopy rooms 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 GI endoscopy rooms in the first three years of operation.

.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 1, 2011 and February 29, 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 6,898 patients will be served in Year 1, 5,405 patients in Year 2 and 5,713 patients in Year 3.

.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 and does not propose to develop 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 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 facility charges by CPT code during CY 2011 for the seven procedures performed most often at WEC. The applicant explains that all other codes are "incidental" and considered "add on" codes which are billed in addition to one of the seven primary codes.

.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 projected facility charges by CPT code during the first three operating years for the seven procedures performed most often at WEC. The applicant explains that all other codes are "incidental" and considered "add on" codes which are billed in addition to the seven primary codes.

.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 at WEC are 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 are billed separately by the anesthesiologist. If a tissue biopsy is required, pathology fees are billed separately by the physician .... Also if any radiology services are required there is 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. The applicant explains that all other procedures are "incidental" and considered "add on" procedures which are billed in addition to one of the seven primary procedures.

.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 in the facility. The applicant explains that all other procedures are "incidental" and considered "add on" procedures which are billed in addition to one of the seven primary procedures.

.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; (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; (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; (4) a written description 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; (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."*

-NA- WEC is an existing licensed ASC.

.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 48, and Section IV.1, page 59, the applicant projects to perform 6,040 GI endoscopy procedures during Year 2, which is an average of 1,510 procedures per room (6,040 procedures / 4 procedure rooms = 1,510 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 continue to provide upper endoscopy, esophagoscopy and colonoscopy procedures at WEC.

.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- The applicant provides all assumptions and the methodology used to project GI endoscopy procedures in Section III.1, pages 31-50. 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 Exhibit 11, the applicant documents that it has an 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- See Exhibit 5 for 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- See Exhibit 5 for copies of WEC's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room 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 that utilize WEC have active medical staff privileges at Wake County hospitals. See Exhibit 4 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.

.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. See also WEC's 2012 LRA in Exhibit 2 which states that the facility has a transfer agreement with Rex Hospital. However, the applicant did not provide documentation of an agreement to accept referrals <u>from a hospital</u> where the physicians utilizing WEC have privileges. Therefore, the application is conforming to this Rule subject to the following condition.

Prior to issuance of the certificate of need, Wake Endoscopy Center, LLC 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 letter from Rex Hospital stating that it will accept patients transferred from WEC. See also WEC's 2012 LRA in Exhibit 2 which states that the facility has a transfer agreement with Rex Hospital.

.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 response to this rule, in Section II.II, page 26, the applicant states *"Please refer to Section VII for staffing details for the proposed GI endoscopy expansion project."* The following table illustrates the projected staffing at WEC by functional area, as reported by the applicant in Section VII.6, page 79.

FUNCTIONAL AREA	TYPE	# OF FTE POSITIONS
Administration	Administrator	0.5
Preoperative	RNs LPNs	3.0
Postoperative	RNs BSN	2.5
GI Endoscopy Rooms	Nurse Supervisor RNs Endoscopy Technicians	8.0
Equipment cleaning, safety & maintenance [(1)]		
Other	Clerical / Scheduling	1.0

[(1)] The table in Section VII.7, page 79, does not have a column labeled "Equipment cleaning, safety and maintenance." The applicant includes the 3.0 FTE endoscopy technician positions in the GI Endoscopy Room column. A review of the job description for the endoscopy technician position provided in Exhibit 9 documents that the primary responsibility of the endoscopy technician is equipment cleaning, safety and maintenance.

.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 26, the applicant states there are 11 physicians that currently perform GI endoscopy procedures at WEC. All 11 are board-certified. They are expected to continue using WEC. See Exhibit 4 for the curriculum vitae for the Medical Director, who is one of the 11 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 physicians utilizing WEC must be board-eligible or board-certified and active members in good standing at at least one Wake County hospital. See Exhibit 16 for the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the 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; (2)all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery; (3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area; (4) at least one registered nurse shall be employed per procedure room; (5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and, (6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified."*

-NA- WEC is accredited by the Accreditation Association for Ambulatory Health Care. See Exhibit 6.

.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 is an existing licensed ASC and it is not 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- See Exhibit 6 for a copy of the accreditation certificate from The Accreditation Association for Ambulatory Health Care for WEC.

.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. (2) provide a floor plan of the proposed facility identifying the following areas: (A) receiving/registering area; (B) waiting area; (C) pre-operative area; (D) procedure room by type; and (E) recovery area. (3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and, (4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located."*

-NA- WEC is an existing facility accredited by The Accreditation Association for Ambulatory Health Care. See Exhibit 6.