RALEIGHENDOSCOPYCENTER NORTH

May 31, 2012

Mr. Craig Smith, Chief
Ms. Tanya Rupp, Analyst
Certificate of Need Section
Division of Health Service Regulation
2704 Mail Service Center
Raleigh, NC 27699-2704

RE: Comments on Certificate of Need application filed by Wake Endoscopy Center, LLC to develop an ambulatory surgical center with two gastrointestinal procedure rooms / Wake County / Project ID # J-8822-12

Dear Mr. Smith and Ms. Rupp:

On behalf of Raleigh Endoscopy Center, LLC (hereinafter "Raleigh Endoscopy"), thank you for the opportunity to comment on the above referenced application by Wake Endoscopy Center, LLC (hereinafter "WEC") for a Certificate of Need for a new licensed ambulatory surgical center with two gastrointestinal procedure rooms. Raleigh Endoscopy's comments are attached to this letter.

Raleigh Endoscopy is an existing provider with 11 endoscopy rooms in 3 facilities in Wake County and is therefore an affected person per N.C.G.S. §131E-188(c). As an affected person, Raleigh Endoscopy requests a public hearing pursuant to N.C.G.S. §131E-185 (a1)(2), which ensures that a public hearing will take place if "a written request for a public hearing is received before the end of the written comment period from an affected party".

Given Raleigh Endoscopy's concerns and the number of flaws in the application, we urge the CON Section to deny WEC's request.

Thank you for your time and consideration of our comments.

Sincerely,

Morris A. Pollock, M.D.
Raleigh Endoscopy Center

Comments on Wake Endoscopy Center CON Application
for Two Endoscopy Rooms in Wake Forest, NC
CON Project ID # J-8822-12
Submitted by Raleigh Endoscopy Center

COMPLIANCE WITH CON REVIEW CRITERIA

This document discusses Wake Endoscopy Center, LLC's (WEC) Certificate of Need (CON) application within the framework of the State's CON Review Criteria (NCGS 131E-183) and applicable Gastrointestinal Endoscopy Procedure Room Rules (10A NCAC 14C .3900). We have addressed only those Criteria for which we believe the information provided is nonconforming.

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.*

The applicant is nonconforming to Criterion 3 because:

- The population to be served by the proposed rooms is not clearly identified.
- The application lacks statistical evidence of a need for additional GI endoscopy rooms in Wake Forest.
- The statistical forecast of WEC utilization on page 50 in support of Section IV is based on patients from all of Wake County, not from areas near the proposed Wake Forest facility.
- An independent analysis supported by information from existing freestanding GI endoscopy providers located within a 20-minute drive time from the proposed location shows that the Wake Forest service area has and will have excess freestanding capacity for GI procedures through 2016.
- The application erroneously projects routine use of screening endoscopy procedures for persons over 75.
- Performance Standard 10A NCAC 14C .3903 (b) is used in a misleading and inconsistent manner.
- The applicant has not demonstrated that adequate access to low income groups will be provided.
- The application demonstrates need for GI services among Wake County African Americans, but shows neither evidence of outreach to this population nor history of serving this population.

Population to be Served

The application is inconsistent and confusing about the service area and does not adequately identify the population to be served.

The applicant identifies the proposed service area as Wake County (page 15), but frequently refers to the patients it proposes to serve as residents of the Wake Forest area. Letters in Exhibit 17 indicate that patients will come from Vance County, but Vance is not mentioned in the patient origin or otherwise described in the need analysis. The application indicates that the facility will be supported through WEC's existing patient base in the Wake Forest area and growth in the 55 and older population in this area (page 43). The application focuses on the Wake Forest population, citing population statistics from Wake Forest Township (page 43).

Additionally, WEC claims a "large base of patients" in the Wake Forest area (page 57). However, WEC does not provide specific evidence of this patient base through:

- Patient letters of support;
- Documentation of the number of patients currently served in the Wake Forest area by the WEC doctors currently practicing there;
- Documentation of the number of patients in need who reside in the Wake Forest area; or
- Any other means.

The application mentions "shifting" patients from a service group that includes all of Wake and some of Johnson and Harnett Counties. The population to be shifted is not identified.

The application includes, in Exhibit 17, letters from physicians who support a freestanding facility in north Raleigh and letters from five physicians who propose to bring patients to the facility. However, the letters are not clear that the patients these physicians propose to bring to the new facility are from the Wake Forest area. They separate "existing base of patients from the Wake Forest area" from patients the five physicians propose to bring. Three of these physicians have been offered the opportunity to work at Wake Forest Endoscopy. Hence, the inference in their letters that freestanding options are not available to their patients in the Wake Forest area is without foundation. One of the physicians from Vance County indicated to Wake Forest Endoscopy Center that Wake Forest is too far away.

Statistical Evidence of Need - Not Provided

Just as it does not provide clarity with regard to the population to be served, the WEC Wake Forest application also fails to adequately demonstrate the need of the population to be served for the services proposed. The applicant references utilization data at its facility on Lake Drive in Raleigh, 18 miles south and inside the Raleigh Beltway. It assumes that the number of procedures will continue to increase in future years and arbitrarily selects procedures to be "shifted" to the proposed Wake Forest facility (page 49). Not only does the application not provide statistical evidence of a sufficient number of Wake Forest patients to "shift" to the proposed facility, but the applicant does not substantiate the existence of unmet need among Wake Forest area residents or even among Wake County residents. The applicant has not demonstrated the need that the population has for this service. Thus, the application is nonconforming with Criterion (3).

No Need for Freestanding GI Rooms in Wake Forest

Absent a methodology for defining need of the population, consider the following, which demonstrates the absence of need.

Within 20 minutes drive time of the proposed Wake Forest location at 11211 Galleria Avenue are nine (9) licensed freestanding endoscopy rooms, of which only 7.49 are actually in use in 2012. See Attachment C. The Wake Forest Endoscopy Center was not doing procedures in its two rooms in FY 2011, but it is now in operation. To be very generous in counting rooms available, add both rooms to the 5.49 referenced in Table C4. In fact, the two rooms at Wake Forest Endoscopy Center are not yet fully used because the facility does not yet have a Medicaid provider number or contracts with all insurance companies. These have been delayed by the agencies, and their requirements for sequencing.

Using population data from the NC Office of State Budget and Management and Claritas, GI endoscopy procedures reported on 2012 NC Licensure Renewal Applications and verified reports of rooms in service from operators of those facilities, one can construct a picture of the need for GI endoscopy services in the Wake Forest area.

The following analysis clearly demonstrates that through 2016, no additional GI endoscopy rooms are needed, even if 100 percent of the market, every person in need in the Wake Forest area, in need of freestanding GI endoscopy services stays in the area and 10 percent more from outside the area come to the existing providers. In fact, there is excess capacity in the Wake Forest service area in proposed project year 02, and there is insufficient need to support even one additional room at the 10 NCAC 14C .3903 (b) performance standard of 1500 procedures in proposed project year 03, 2016.

Step One: Determine a reasonable population to be served by a Wake Forest facility.

The application proposes to serve the residents of Wake Forest and surrounding communities. Anecdotes from our patients indicate that it is reasonable to assume that a majority of the patients who would receive care at the proposed location will live within a 20-minute drive time. As shown in Attachments A and D, this area roughly encompasses communities that are north of the Raleigh Beltline, east of Creedmoor Road, south of Franklinton and west of the intersection of US Route 401 and NC Highway 96. According to Claritas, a respected national demographic source, over 278,000 people live within 20-minutes of the proposed WEC Wake Forest facility.

The US Preventive Services Task Force recommends colorectal cancer screening beginning at age 50 and continuing until age 75.

Based on these criteria, the population to be served are persons ages 50 to 74 residing within a 20-minute drive of the proposed facility. In 2012, Claritas estimates this subset of the population to be 61,698 individuals. (See Attachment B).

Step Two: Project the population to be served through 2016.

Table 1 – Wake Forest Area Population, Age 50-74 2013 through 2016

	2013	2014	2015	2016
Wake Forest Area Population 50-74	65,057	68,507	71,860	75,356

Source: Claritas, NCOSBM

Note:

a) Claritas provides an estimate of the population in 2012 and a projected population in 2017. Population data for intervening years are interpolated, assuming a constant growth rate.
b) Claritas provides age group population estimates for ages 45-54, 55-64 and 65-74. An estimate for the population ages 50-54 was derived using NCOSBM projected population data for Wake County. The percent of those ages 45-54 that were 50-54 years of age was determined for each year. The ratios of 50-54 year olds in the 45-54 age brackets were used to calculate the number individuals 50-54 years old in the Claritas age group.

Assumption: The ratio of 50-54 year olds in the 45-54 age group residing in the Franklin County Wake Forest area will be the same as for Wake County, because this small segment of Franklin is so close to Wake County.

Step Three: Determine the utilization rate of GI endoscopic procedures at freestanding locations in 2011 in Wake County.

Table 2 – 2011 GI Endoscopies per Person Ages 50-74 Performed at Wake County Freestanding Locations

	2011
GI Endoscopies in Freestanding GI centers	48,503
Wake County Population Ages 50-74	207,126
Freestanding Endoscopies per Person Ages 50-74	**0.23**

Sources: 2012 License Renewal Applications, NCOSBM

Assumptions: Most endoscopic procedures are performed on persons ages 50-74. Hence expressing the use in a ratio of this population is reasonable. Any use by persons outside this age group will be absorbed in this calculation.

Step Four: Project the number of endoscopies needed in the Wake Forest service area through 2016.

Table 3 – Projected GI Endoscopies in the Wake Forest Service Area 2013 through 2016

	2013	2014	2015	2016
Wake Forest Service Area Population Ages 50-74	65,057	68,507	71,860	75,356
Ratio of GI Endoscopies per Person 50-74	0.23	0.23	0.23	0.23
GI Endoscopy Procedures in the Wake Forest Service Area	15,234	16,042	16,828	17,646

Assumption: Age adjusted Wake County area freestanding GI endoscopies per person will remain constant through 2016.

The analysis is restricted to freestanding rooms to avoid over counting inpatients and other complex patients who may require hospital-based services.

Step Five: Project the number of endoscopies needed in the Wake Forest area through 2016 with an allowance for additional procedures for individuals from outside of the Wake Forest area.

Table 4 – Projected Endoscopies 2013 through 2016 Accounting for Patients Outside of the Wake Forest Area

	2013	2014	2015	2016
Endoscopy Procedures in the Wake Forest Area	15,234	16,042	16,828	17,646
Percent from Outside the Wake Forest Area	10%	10%	10%	10%
Total Endoscopy Procedures	16,757	17,646	18,511	19,411

Assumption: 10 percent more persons may come in to the service area. This is generously more than twice the 4 percent estimated by WEC. (page 57).

Step Six: Determine the number of licensed freestanding GI procedure rooms in use in the Wake Forest service area in 2011.

Table 5 – 2011 Licensed Freestanding GI Procedure Rooms in Use

	Name of Center	Licensed GI Procedures Rooms in use in 2012
a	Gastrointestinal Healthcare Endoscopy Center	1.1
b	Raleigh Endoscopy Center - North	2.39
c	Triangle Gastroenterology	2
	Total Procedure Rooms in Use	**5.49**

Source: 2012 License Renewal Applications, Raleigh Endoscopy Phone Conversation 5/23/12

Notes:

a) In 2011, had two licensed GI rooms, but operated only 22 hours per week. (22 * 2 / 40 = 1.1)

b) In 2011, Raleigh Endoscopy Center – North had three licensed GI rooms, but used the equivalent of 2.39 two rooms to maximize efficiency. Both Raleigh Endoscopy and Gastrointestinal Healthcare report reducing schedules periodically, because of lower demand.

c) Full license.

Step Seven: Determine the average number of procedures for each GI procedure room in use in the Wake Forest service area.

Table 6 –Average Procedures per Room in Use

	2011
Procedures Performed	14,736
GI Procedure Rooms in Use	5.49
Procedures per Room in use	**2,684**

Source: 2012 License Renewal Applications

The applicant reports completing 8,305 procedures in three rooms at Lake Drive in the 12 month period March 2100 through February 2012, or 2,768 procedures per room.

Step Eight: Set procedure capacity per room at the 2011 average use of freestanding rooms in use in the Wake Forest area.

Assumption: An average of 2,684 procedures per room is highly reasonable. According to the 2012 State Medical Facilities Plan (SMFP) Table 6D: Endoscopy Room Inventory, eight other endoscopy facilities averaged more than 2,684 procedures per room in FY 2011 SMFP data may understate the number of procedures per room at some facilities because they do not take into account facilities that are not using all licensed rooms, for example, GI Healthcare has two licensed rooms but reports using only 1.1 equivalent.

This is a conservative and reasonable estimate of functional capacity.

Step Nine: Determine the number of GI procedure rooms in use in 2011 that were in the Wake Forest service area.

Table 7 – 2011 GI Procedure Rooms in Use Serving the Wake Forest Service Area

		Wake Forest Area GI Procedures Rooms
a	**Procedure Rooms in Use**	5.49
b	**Rooms Used by Out of Area Patients**	1.5
c	**Rooms in Use Serving Wake Forest Area Patients**	**3.99**

Notes

a) Table 5

b) Triangle Gastroenterology is located within, but near the boundary of the 20-minute Wake Forest area. Conservatively assuming that patients at Triangle Gastroenterology equally represent the surrounding communities, this approach estimated that only 25 percent of Triangle patients would come from the Wake Forest service area. A 20-minute arc located at Triangle Gastroenterology is approximately 25 percent inside the Wake Forest 20-minute area. Triangle Gastroenterology has two GI procedure rooms (1-0.25 times 2 equals 1.5)

c) a – b

Step Ten: Determine the 2011 procedure capacity for the rooms in use serving the Wake Forest area.

Table 8 – 2011 Capacity of Rooms in Use Located in and Serving the Wake Forest Area

GI Procedure Rooms in Use	3.99
Procedures per Room	2,684
2011 Procedure Capacity	**10,709**

Step Eleven: Determine the capacity of currently licensed rooms in the Wake Forest area that were unused, underutilized or not yet operational in 2011.

Table 9 –Procedure Capacity Available in Unused GI Procedure Rooms 2012

	Wake Forest Endoscopy (a)	Raleigh Endoscopy – North (b)	GI Healthcare (c)
Available Rooms	2	0.61	0.9
Avg. Procedures Per Room	2,684	2,684	2,684
Unused Procedure Capacity	**5,368**	**1,637**	**2,416**

a) Not licensed
b) Reduced hours reflecting reduced demand.
c) Reduced hours; not functioning full day per 2012 License Renewal

Step Twelve: Determine the total Wake Forest service area procedure capacity for in-area patients by adding back the capacity for rooms that were out of service.

Table 10 – Procedure Capacity in the Wake Forest Service Area

	Procedures
2011 Procedure Capacity	10,709
Wake Forest Endoscopy	5,368
Raleigh Endoscopy Center – North	1,637
Gastrointestinal Healthcare	2,416
Total Procedure Capacity	**20,130**

Numbers may not foot due to rounding.

Step Thirteen: Project the difference between the procedures needed and the procedure capacity available through 2016.

Table 11 – Difference in Procedures Needed and Procedure Capacity

	2013	2014	2015	2016
Endoscopy Procedures Needed	17,519	18,448	19,352	20,293
Procedure Capacity	20,130	20,130	20,130	20,130
Difference (Procedures Needed less Capacity) (Surplus) / Deficit	(3,373)	(2,484)	(1,619)	(719)

Assumption: Procedure capacity will remain constant through 2016.

The area has and will have surplus capacity for freestanding GI endoscopy procedures.

There is clearly not a need for additional GI procedure rooms in the Wake Forest area. Adding more freestanding GI rooms in Wake Forest will create excess capacity of freestanding GI endoscopy rooms. On the basis of no need by the population to be served, the application is nonconforming with Criterion (3).

Patient Age

The most recent guidelines of the US Preventive Services Task Force recommend screening for colon cancer beginning at age 50 and continuing to age 75. WEC supports the application using population projections for all persons 55 and older. This is in direct conflict with the USPSTF recommendation against routine screening for colon cancer in those over 75 (page 42). Furthermore, the WEC policy "MAC Scheduling Guidelines" (WEC Exhibit 7) establishes an acceptable patient age range of 18 through 80, a limit not supported by the USPSTF. Patients over 75 are at greater risk for deadly complications from colon cancer screening. The application incorrectly identifies the population appropriate for the service. Thus the application is nonconforming with Criterion (3).

Misapplication of Performance Standard (b)

Throughout Section III, WEC relies on a misleading and inconsistent interpretation of Performance Standard (b) (10A NCAC 14C .3903). The performance standard is a measure of minimum use in the second year of operation, not a measure of capacity.

WEC attempts to demonstrate a need for endoscopy rooms in Wake County by using Performance Standard (b), a requirement for a *minimum* of 1,500 procedures per GI procedure room during the second year of operation, as the measure of room "capacity," "effective capacity," "practical capacity" and "percent occupancy." This is clearly a misuse of the standard. In Section III.1 page 48, WEC sites a need for additional free standing procedure rooms in Wake County based on an average of 129 "percent occupancy" for GI procedure rooms in 2011. However, in the same section WEC states that its own "percent occupancy" was 179.6 percent of the *minimum* standard (page 47). Clearly WEC itself has demonstrated that true capacity of a GI endoscopy room is far in excess of 1,500 procedures.

WEC does not describe or define actual capacity of GI procedure rooms. However, by its own admission on page 49, capacity in a WEC room is at least 2,694 procedures (1,500 x 179.6 percent = 2,694). This is consistent with the history of other freestanding facilities discussed earlier in these comments.

In Section III.1 page 46 the applicant states that even with a fourth GI procedure room in 2011 WEC would have operated beyond "practical capacity" at 134.7 percent of the minimum standard. However, according to the utilization projection on page 51 the proposed facility will operate at 150 percent of the minimum performance standard after the first year, an amount that WEC would find unreasonable based on previous arguments. Thus, the application itself asserts that "capacity" is substantially more than 1,500 procedures per room.

In a state concerned about budget, and a nation concerned about the impact of high spending on health care, it is inappropriate to build estimates of need on the basis of unreasonably low estimates of capacity. Because of the misapplication of Performance Standard 10 NCAC 14.3903(b), the applicant fails to adequately demonstrate need. Thus the application is nonconforming with Criterion (3).

Low Income Access

This application fails to demonstrate that sufficient access to care has been provided by the applicant, or will be provided to low income or underserved persons.

In 2011, the application reports that three (3) percent of procedures at the Lake Drive location were covered by Medicaid and self-pay/indigent/charity care patients (Section VI.2, page 70). The most recent North Carolina Department of Health and Human Services statistics estimate that 4.8 percent of Wake County residents over age 21 are Medicaid eligible.[1] Offering only three (3) percent of procedures to all low income groups combined, and only one percent to Medicaid, is evidence that low income groups are and will be clearly underrepresented at WEC's

[1] Division of Medical Assistance website. http://www.ncdhhs.gov/dma/pub/index.htm

current practice. The fact that in 2011 only 0.57 percent of WEC's revenue was for charity care highlights WEC's the lack of emphasis on providing access to the underserved (page 73). The applicant does not adequately demonstrate that low income persons will have s access to care in proportion to their representation in the service area. Thus the application is nonconforming with Criterion (3).

Ethnic Minorities

In Section III, page 44, WEC explains the elevated risk for African Americans to develop cancer and specifically colorectal cancer. Evidence is not provided to show that the current WEC facility delivers care to a representative number of patients from this vulnerable group. Although WEC recognizes the unique circumstances of this population, the application does not show evidence of outreach to African Americans to help improve their access to services. There is no reason to believe that WEC's proposed facility will increase the availability of services to African Americans. The applicant does not adequately demonstrate that minority groups are likely to have access to care. Thus, the application is nonconforming with Criterion (3).

Misleading Letters of Support and Referral

The application provides letters of support from referring physicians in Exhibit 17. However, most (11) of these 15 letters reference a north Raleigh facility, not a Wake Forest location. Three of the letters are from WEC owners. None of the letters distinguish between the patients to be referred and the patients that are actually from the Wake Forest area. The language of the letters separates patients from Wake Forest and patients who would be referred.

WEC does not mention that Dr. Sachdeva and Dr. Schwartz have been offered privileges at Wake Forest Endoscopy. Dr. Dubinski has told Wake Forest Endoscopy Center owner, Dr. Sabbagh, that he does not want to care for patients in Wake Forest because the travel distance is too far. He works instead at a more convenient center in Durham. One of the letters of support is from a Cary physician.

Third Party Payor Trends

The application contains misleading information about Medicare coinsurance on page 39. As of 2012, Medicare patients have neither copay nor deductible requirements for screening colonoscopies. This is a requirement in the Affordable Care Act.

(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.***

The application indicates that patients will be shifted to the proposed Wake Forest location from the Lake Drive location, indicating that a service will be relocated. However, there is no discussion on the impact on the remaining Lake Drive facility or specificity with regard to the population that will be shifted.

Without this information, the application is non-conforming with this criterion.

(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.***

The common justification for new freestanding GI endoscopy rooms is the absence of capacity in low charge freestanding facilities in the service area, or the absence of consumer choice among the options. Neither of these is true. Alternative capacity does exist and will through 2016.

- One new freestanding GI endoscopy provider, Wake Forest Endoscopy, was only recently licensed and has not yet received contracts with all area insurance companies. It is operating below capacity. Wake Forest Endoscopy has offered privileges to the applicant owners, who have indicated intent to bring their patients to WFE.
- One existing freestanding provider, GI Healthcare, is operating only 1.1 of its two rooms (see license renewal application).
- One existing provider in the Wake Forest service area, Raleigh Endoscopy North, has adjusted hours and notes that it has effective unreached capacity of 0.61 rooms.

Compared to what is available in the service area, WEC is not proposing low or reduced charges, or organizes access to low income or medically underserved groups.

Moreover, in this situation, the proposal to construct an entire new GI facility in Wake Forest to serve all of Wake County is far less effective than the applicants own proposed solution in project ID # J-8823-12 that would add one room to its existing Lake Drive facility.

For these reasons, the application is non-conforming to this criterion.

(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.

Financial Projections

The application did not adequately demonstrate that procedure projections were reasonable. Therefore, financial projections are unreliable. As a result, the application is nonconforming to Criterion (5).

Forecasts of utilization on page 63 are not supported by independent analysis of the source of procedures, and simply assert that the facility will have 4,500 procedures each year from the date of opening. In the absence of strong foundations for the procedures, the unit costs are not supported.

Moreover, on Form E the application notes that Medicaid revenue per procedure will be $416, which is less than the Year 3 cost of $462.51. Thus, if the procedures are less than forecast and the Medicaid proportion is more comparable to the need in the population to be served, the project may not have operating revenue sufficient to cover expenses.

The project is not conforming with 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.

The proposed GI procedure rooms will duplicate already licensed and underutilized facilities in the Wake Forest Area. The application provides no reasons why duplication of existing freestanding capacity in Wake Forest service area is necessary.

The application fails to adequately demonstrate that the needs of Wake Forest area residents require approval of the proposed endoscopy facility. The application also fails to prove that the Wake Forest area can support additional procedure rooms given the low utilization of the area's currently licensed rooms.

On page 60, the application indicates that the project is driven by the demand for services at WEC and the need to compress capacity constraints. However, as demonstrated in comments on Criterion 3, these capacity constraints are artificially constructed. Moreover, page 60 shows the unused capacity at Wake Forest Endoscopy.

The application admits on page 61 that the project will result in reduced utilization of WEC Lake Drive facility, but uses performance standards, rather than capacity to assert the absence of duplication of capital expenditures. The application does not address the financial impact on the Lake Drive facility, or the impact on procedures "shifted" from other facilities.

Therefore, the WEC application fails to demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities. As a result, the application is nonconforming with this criterion. Please see discussion in Criteria (3) and (4).

(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.

WEC does not 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 for the following reasons:

- WEC fails to document arrangements for radiology services. This is important because Licensure Regulation 10A NCAC 13C .0701 requires a facility to have the capacity of providing or obtaining diagnostic radiology services.
- WEC fails to document arrangements for anesthetist services. This is important because Licensure Regulation 10A NCAC 13C .0401(b) requires a facility to have available an anesthetist and he or she shall be available to administer regional or general anesthesia.
- On application page 8, Section II.1, WEC states that it will use contracted pharmacy services. However, no documentation is provided that these services are available, as requested by application question II.2. (c).

WEC did not adequately demonstrate that it will make available or otherwise make arrangements for, the provision of the necessary ancillary and support services. Thus, the application is nonconforming to Criterion (8).

(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;

(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;

WEC has not demonstrated that access to care has or will be provided to low income persons in proportion to the need in the service area. In 2011, WEC reports that only three (3) percent of procedures will be covered by Medicaid and self-pay/indigent/charity care patients (Section VI.2 page 70, page 77, and proforma Assumption 1). The most recent North Carolina Department of Health and Human Services statistics estimate that 4.8 percent of Wake County residents over age 21 are Medicaid eligible.[2] On page 70, WEC inappropriately uses a measure of 10 percent of the population of Wake County as Medicaid eligible. This figure is distorted by the high percentage of Medicaid who are children. The Medicaid population over 21 includes old age, blind and disabled persons.

Offering only three percent of procedures to all low income groups combined, is evidence that low income groups are clearly underrepresented at WEC's current practice. The fact that in 2011 only 0.57 percent of WEC's revenue was for charity care highlights WEC's the lack of emphasis on providing access to the underserved (page 73). The applicant does not adequately demonstrate that low income persons will have access to care in proportion to their representation in the service area. Thus, the application is nonconforming with Criterion (13 (a) and (b).

[2] Division of Medical Assistance website. http://www.ncdhhs.gov/dma/pub/index.htm

(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.***

The application erroneously states on page 68 notes that expanded capacity is "desperately needed" in Wake Forest. As noted in comments above. This is not true and is not demonstrated in the application. The proposed facility will more likely result in underutilization of this facility and the Lake Drive WEC facility, or cause existing freestanding GI facilities to operate below their capacity.

As noted, the application does not propose even parity access to underserved groups. It compares poorly with the 15 percent Medicaid and self pay proposed by Wake Forest Endoscopy for its center (J-8502-10). It makes no reference to lower charges and if, as is likely, it remains underused, it will not be a cost effective solution.

(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.***

SECTION .3900 - CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILTIES

.3903 (e) ***An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.***

On page 63, the application refers to Section III.1 for assumptions and methodology. On page 52 forecasts of utilization are supported projected use of the Lake Drive facility and unclear letters from five physicians. Assumptions about patient origin are not provided in the methodology.

10A NCAC 14C .3904 SUPPORTSERVICES

.3904 (d) ***"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide:***

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

The applicant has not provided evidence that doctors Paul Hagan and Mark Dubinski have practice privileges in Wake County or a contiguous county.

(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; and"

The applicant does not provide documentation of an agreement to accept referrals from a hospital.

10A NCAC 14C .3905 STAFFING AND STAFF TRAINING

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

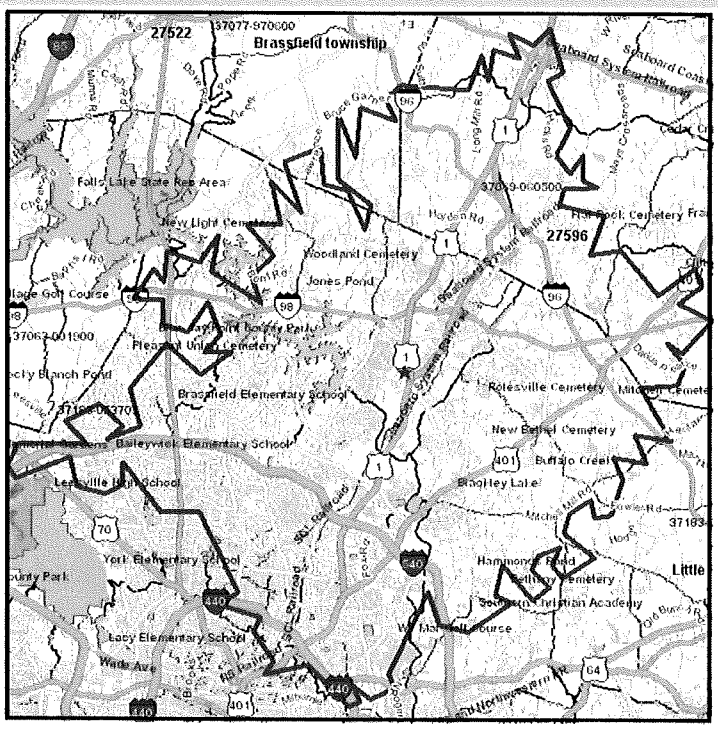
(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;

The facility is not accredited. WEC indicates that it will "pursue accreditation" (page 68).

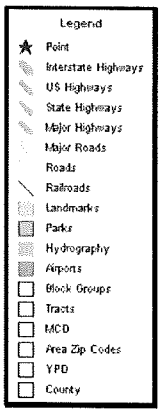
The applicant names Wake County as the proposed service area (page 15). WEC has neither provided evidence nor stated that doctors Paul Hagan and Mark Dubinski are active members in good standing at a general acute care hospital in Wake County.

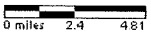
Attachment A
20-MINUTE DRIVE TIME OF PROPOSESD SITE

Area Map



11211 GALLERIA AVE
RALEIGH,NC 27614-8137
Coord: 35.948700, -78.542000
Polygon - See Appendix for Points





Prepared By:

Attachment B
Population Forecasts

Pop. Age 45-84 in 20 minutes Service Area of WEC WF

Age	2012	2013	2014	2015	2016	2017	CAGR	CAGR +1
45 - 54	42,373	43,466	44,588	45,738	46,918	48,129	2.6%	102.6%
55 - 64	27,650	29,188	30,812	32,526	34,335	36,245	5.6%	105.6%
65 - 74	13,640	14,719	15,884	17,141	18,498	19,962	7.9%	107.9%
75 - 84	7,199	7,435	7,679	7,931	8,191	8,460	3.3%	103.3%
Total	90,862	94,808	98,963	103,336	107,942	112,796	4.4%	104.4%

Source: Claritas (2012 Estimate and 2017 Projection)

Pop. Age 50-74 in 20 minute Service Area of WEC WF

Age	2012	2013	2014	2015	2016
50 - 54	20,408	21,150	21,811	22,193	22,523
55 - 64	27,650	29,188	30,812	32,526	34,335
65 - 74	13,640	14,719	15,884	17,141	18,498
Total	61,698	65,057	68,507	71,860	75,356

Claritas and NCOSBM

2012		
Age	Population	Percent
45	14,218	10.3%
46	14,301	10.4%
47	14,392	10.4%
48	14,478	10.5%
49	14,217	10.3%
50	13,960	10.1%
51	13,796	10.0%
52	13,557	9.8%
53	12,828	9.3%
54	12,387	9.0%
Total	138,134	100.0%

% 50-54	48.2%
Population 45-54	42,373
Population 50-54	20,408

2013		
Age	Population	Percent
45	14,603	10.4%
46	14,307	10.2%
47	14,365	10.2%
48	14,447	10.3%
49	14,525	10.3%
50	14,267	10.1%
51	13,993	9.9%
52	13,813	9.8%
53	13,563	9.6%
54	12,837	9.1%
Total	140,720	100.0%

% 50-54	48.7%
Population 45-54	43,466
Population 50-54	21,150

2014		
Age	Population	Percent
45	15,410	10.7%
46	14,692	10.2%
47	14,372	10.0%
48	14,420	10.0%
49	14,494	10.1%
50	14,575	10.1%
51	14,300	10.0%
52	14,011	9.8%
53	13,819	9.6%
54	13,569	9.4%
Total	143,662	100.0%

% 50-54	48.9%
Population 45-54	44,588
Population 50-54	21,811

2015		
Age	Population	Percent
45	16,499	11.2%
46	15,499	10.5%
47	14,759	10.0%
48	14,430	9.8%
49	14,470	9.8%
50	14,546	9.9%
51	14,608	9.9%
52	14,318	9.7%
53	14,017	9.5%
54	13,824	9.4%
Total	**146,970**	**100.0%**

% 50-54	48.5%
Population 45-54	45,738
Population 50-54	**22,193**

2016		
Age	Population	Percent
45	16,615	11.1%
46	16,588	11.0%
47	15,565	10.4%
48	14,815	9.9%
49	14,480	9.6%
50	14,522	9.7%
51	14,580	9.7%
52	14,626	9.7%
53	14,323	9.5%
54	14,023	9.3%
Total	**150,137**	**100.0%**

% 50-54	48.0%
Population 45-54	46,918
Population 50-54	**22,523**

Attachment C
History of GI Endoscopies in Wake Forest Service area

Table C1. Wake County Freestanding Endoscopy Procedures per Person Ages 50-74, FY2011

Endoscopies Performed in Freestanding locations - FY	48,503
Pop. Aged 50 through 74 - CY	207,126
Endoscopies/Person 50-74	**0.23**

Sources: 2012 LRA, NCOSBM

Table C2. Procedure Rooms in Proposed WEC Service Area

	Procedure Rooms
Wake Forest Endo	2
GI Healthcare	2
Raleigh Endo - North	3
WEC Rooms	0
Triangle Gastroenterology	2
Total	**9**

Source: WEC CON

Table C3. Capacity of Existing Freestanding GI Rooms in FY 2011

Licensed Freestanding Rooms in 20-min Service Area	Facility Name	Procedures Performed FY2011	Procedures Per Room
2	Wake Forest Endoscopy (WFE)		0
2	GI Healthcare	2,177	1,089
3	Raleigh Endo – North (REN)	7,692	2,564
0	WEC Rooms	-	
2	Triangle Gastroenterology	4,867	2,434
9	**Total 2011 Procedures**	**14,736**	

Table C4. Average Capacity of Freestanding GI Endoscopy Rooms in Use in Service Area

Notes	Metric	Licensed Freestanding GI Procedure Rooms
a	WFE not yet in use	-2
b	GI Healthcare not in use	-0.9
c	REN per verbal communication	-0.61
d	**Total not in use**	-3.51
e	**Total Licensed**	9
f	**Total in use**	**5.49**

Notes

a. Not licensed until FY 2012
b. See Licensure renewal application, used only 22 hours per week.
c. Raleigh Endoscopy North, which is managed by AmSurg, a national provider of ambulatory surgical services sets its capacity benchmark at 3,276 procedures per room. It is currently providing an annualized 2,608 procedures per room (3 rooms minus 3 times (2608/3582) = 0.61 available room capacity).
d. Sum a + b+ c
e. Table C3
f. Difference e - d

Calculation: Total Procedures (14,736) divided by Rooms in Use (5.49) equals Average Capacity in 2011.

Actual Wake Forest Area Capacity in FY 2011	**2,684**

Attachment D
D1. Proximity of Existing GI Endoscopy Centers to Proposed WEC

10540 Ligon Mill Rd #109, Wake Forest, NC 27587 to 8300 Health Park, Raleigh, NC 27615 - Google Maps

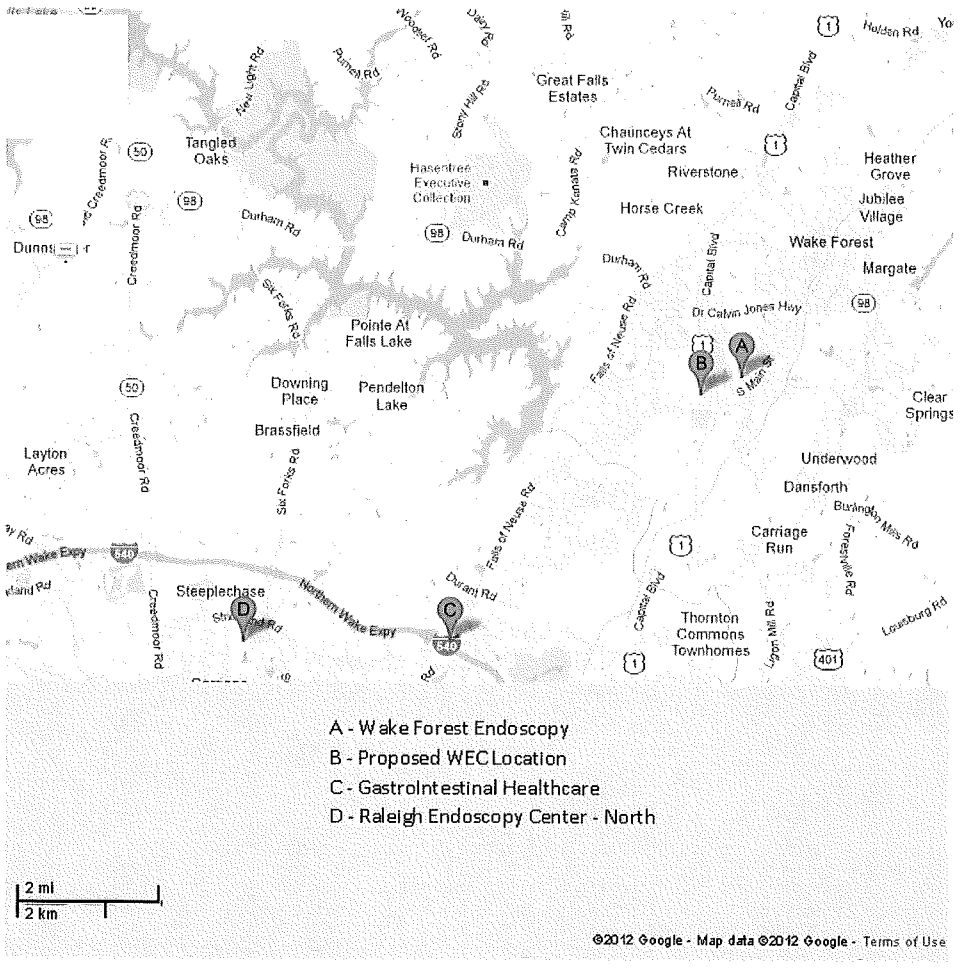
Show for all steps: **Text only** | Maps | Street View ☑ Include large map Print

Roll over the directions to customize each step

Google

Directions to 8300 Health Park, Raleigh, NC 27615
11.2 mi – about 26 mins

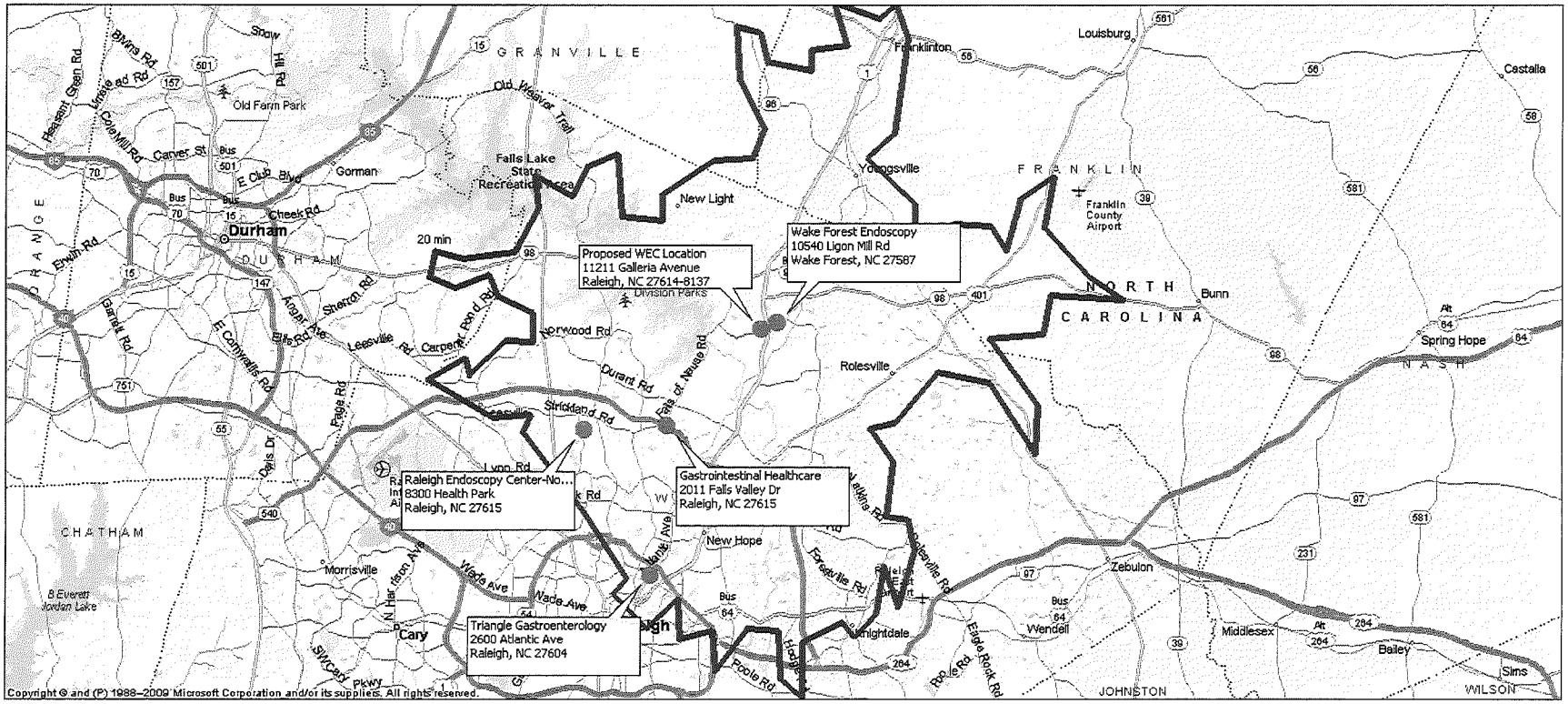
Save trees. Go green!
Download Google Maps on your phone at google.com/gmm



http://maps.google.com/...35.923254,-78.591557&spn=0.054215,0.132093&t=m&z=14&layer=c&ei=33y2T9uyBY2QyASij-mcBw&pw=2[5/18/2012 12:48:25 PM]

Attachment D

D2. GI Endoscopy Locations and 20-Minute Drive Zone from Proposed New GI Endoscopy Location



Note: This map was prepared in MS Mappoint 2010, which software fails to recognize some existing and new roads. Thus, the drive-zone is narrower than the one provided by Nielson Claritas, which has a more robust database of roads.