

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 27, 2023

Findings Date: February 3, 2023

Project Analyst: Tanya M. Saporito

Co-Signer: Micheala Mitchell

Project ID #: J-12250-22

Facility: Wake Endoscopy Center-Holly Springs

FID #: 220577

County: Wake

Applicant: Wake Endoscopy Center, LLC

Project: Develop a new ASF with no more than two GI endoscopy rooms

### REVIEW CRITERIA

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 (hereinafter referred to as “the applicant”, or WEC), proposes to develop a new ambulatory surgical facility (ASF), Wake Endoscopy Center-Holly Springs (WEC-Holly Springs), in Holly Springs with no more than two gastrointestinal endoscopy (GI) procedure rooms upon project completion.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2022 SMFP,
- acquire any medical equipment for which there is a need determination in the 2022 SMFP,

- offer a new institutional health service for which there are any policies in the 2022 SMFP.

Therefore, Criterion (1) is not applicable to 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- (2) Repealed effective July 1, 1987.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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

**Patient Origin**

N.C. Gen. Stat. §131E-176(24a) states, “Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “the county where the proposed GI endoscopy room will be developed.” The proposed facility will be developed in Wake County. Thus, the service area for the proposed facility is Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to develop a new freestanding GI endoscopy facility, therefore, there is no historical patient origin to report.

The following table illustrates projected patient origin, from Section C, page 34:

COUNTY/ZIP CODE	1 <sup>ST</sup> FULL FY (CY 2025)		2 <sup>ND</sup> FULL FY (CY 2026)		3 <sup>RD</sup> FULL FY (CY 2027)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
27526 (Wake/Harnett)	612	34.9%	825	34.9%	834	34.9%
27540 (Wake/Harnett)	462	26.3%	622	26.3%	629	26.3%
27562 (Wake/Chatham)	27	1.5%	36	1.5%	37	1.5%
27559 (Chatham)	28	1.6%	38	1.6%	38	1.6%
27592 (Wake/Johnston)	209	11.9%	281	11.9%	284	11.9%
27501 (Harnett/Johnston)	242	13.8%	325	13.8%	328	13.8%
Other*	175	10.0%	236	10.0%	239	10.0%
<b>Total</b>	<b>1,755</b>	<b>100.0%</b>	<b>2,364</b>	<b>100.0%</b>	<b>2,389</b>	<b>100.0%</b>

Source: application page 34

Numbers may not sum due to rounding

\*The applicant states "other" includes other ZIP codes that may be in the same counties.

In Section C, page 34, the applicant provides assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin for the proposed facility based on historical patient origin for its existing Wake County facilities and the projected increased demand for GI endoscopy services in the area it proposes to serve.
- The applicant projects patient origin based on its analysis of projected population growth in the proposed service area.

### **Analysis of Need**

In Section C, pages 37-46, the applicant explains why it believes the population projected to be served by the proposed project needs the proposed services, summarized as follows:

- Demographics of Holly Springs and Wake County – The applicant examined population data from Claritas and the North Carolina Office of State Budget and Management (NCOSBM) as well as recommendations from the US Preventive Services Task Force's recommendations on colorectal cancer screening to project population increase in the area and the need for GI endoscopy services through its third project year, CY 2027 (*pages 37-39*).
- Health status of Wake County service area population – The applicant states the WEC physicians are experts in prevention and diagnosis of colon cancer as well as other digestive and liver diseases. The applicant examined preventable risk factors in the service area to gain an understanding of the need for the proposed services (*pages 40-41*).
- Wake county as a referral center and historical patient origin patterns of existing WEC providers – The applicant examined historical patient origin patterns for existing WEC providers to determine the percentage of patients needing GI endoscopy services in Wake County and the other counties that comprise the proposed service area (*pages 41-42*).
- Residential and commercial development in southern Wake County – The applicant examined projected development in southern Wake County and the existing and projected highway and road development. The applicant states that traffic on roads around WEC can reach daily counts of up to 35,000 vehicles. As population density and traffic congestion increases, the need for additional GI endoscopy services in southern Wake County will likewise increase (*pages 43-44*).

- Cost of care for GI endoscopy patients – The applicant states that for most patients in need of outpatient GI endoscopy services, a freestanding facility is more cost-effective and efficient than hospital outpatient services. The applicant examined cost data provided by Blue Cross Blue Shield of North Carolina for GI endoscopy services within a 25-mile radius from ZIP code 27540 (Holly Springs) and found that the cost for a screening colonoscopy in that area can range from \$811 to \$6,128. The applicant states it will bill globally and include physician and facility fees in one bill, thereby containing costs for its patients (*pages 45-46*).
- Availability of freestanding GI endoscopy providers in the Holly Springs area – The applicant states that currently, there are no freestanding facilities in the Holly Springs area that provide GI endoscopy services. The closest facilities are to the north and west in Cary and to the south and east in Fuquay-Varina, which is not sufficient to effectively serve current and projected patients in the area in need of cost-effective GI endoscopy services (*page 46*).

The information is reasonable and adequately supported based on the following:

- The applicant provides reliable data to support its projections of population growth, aging and the health status of the population in the proposed service area.
- The applicant provides reliable data to support its projections of projected economic and residential growth and projected traffic congestion and plans in the proposed service area.
- The applicant adequately demonstrates how the proposed project will provide a more cost-effective option and improve geographical access in the proposed service area.

Projected Utilization

In Section Q, page 108, the applicant provides projected utilization, as illustrated in the following table:

WEC-HOLLY SPRINGS	PARTIAL FY (9/1/24- 12/31/4)	1 <sup>ST</sup> FULL FY (CY 2025)	2 <sup>ND</sup> FULL FY (CY 2026)	3 <sup>RD</sup> FULL FY (CY 2027)
# GI Endoscopy Rooms	2	2	2	2
# Procedures	502	2,281	3,073	3,105
# Procedures/Room	251	1,141	1,537	1,553

Numbers rounded by Project Analyst

In Section Q, pages 109-120, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

**Forecast Need Based on Population Growth**

Step 1: Review Historical GI Endoscopy Procedures

The applicant begins with identifying the proposed service area by ZIP code based on data from Claritas Environics from CY 2022-CY 2027. The applicant calculates a compound annual growth rate (CAGR) for the five year period and applied that CAGR to project interim year by year population growth. See the table on page 111 that illustrates projected population growth in the ZIP codes that comprise the service area.

#### Step 2: Calculate Wake County GI Endoscopy Use Rates in Wake County

The applicant determined an average procedure per case by calculating use rates for historical GI endoscopy procedures in Wake County from federal fiscal years (FFY) 2018 to 2021, using data from LRAs for existing acute care hospitals and freestanding facilities in Wake County and population estimates from the NCOSBM. The applicant states the four-year average is reasonable because it accounts for and smooths the temporary decline in utilization during the COVID-19 pandemic. See the table on page 112 that illustrates the applicant's data and calculations.

#### Step 3: Project GI Endoscopy Cases and Procedures in Proposed Service Area

Applying the use rate from Step 2 to the projected population growth in Step 1, the applicant projects the number of GI endoscopy procedures and cases in the proposed service area. The applicant states the use of Wake County data to project utilization in the proposed service area that includes Harnett, Johnston and Chatham counties is reasonable, because the proposed facility will be located in Wake County which has historically been a healthcare referral hub for the area. See the table on page 113 that illustrates the applicant's projection.

#### Step 4: Determine GI Endoscopy Room Need in the Primary Service Area by CY 2027

The applicant applied the total projected procedures by the standard of 1,500 procedures per room pursuant to 10A NCAC 14C .3903(b). The applicant calculated a forecast need for up to 7 GI endoscopy procedure rooms by FY 2027, based on a calculated deficit of GI endoscopy procedure rooms by FY 2027. See the table on page 114 that illustrates the projected GI endoscopy procedure room need.

### **Forecast Utilization**

Having calculated a projected deficit of up to seven GI endoscopy procedure rooms in the proposed service area by FY 2027, the applicant projects utilization as follows:

#### Step 1: Determine GI Endoscopy Procedures Performed in Existing WEC Facilities

The applicant calculates the historical utilization of all licensed GI endoscopy procedure rooms in facilities owned by WEC, using data from the WEC 2019-2022 LRAs. The applicant notes that the data in the LRAs is for FFYs. The applicant holds utilization data for its existing facilities constant into the project years for the proposed facility, to remain conservative in its projections. See the table on page 115 that illustrates actual utilization of WEC's existing facilities in Wake County.

### Step 2: Determine Projected GI Endoscopy Room Utilization

Even holding forecast utilization constant through the three project years for the proposed facility, the applicant projects that each WEC Wake County facility will operate above the standard of 1,500 GI endoscopy procedures per procedure room in each licensed facility. The applicant accounts for the new Cary facility approved for three GI endoscopy procedure rooms in Project ID #J-11705-19. The applicant determined that each of the existing and approved GI endoscopy procedure rooms will operated in excess of 1,500 procedures per room by FY 2027. See the table on page 117 that illustrates projected GI endoscopy procedure room utilization in all WEC facilities through FY 2027.

### Step 3: Determine GI Endoscopy Procedures in WEC-Holly Springs Primary Service Area Currently Served by Existing or Approved WEC Facilities

The applicant notes that two ZIP codes in this application's proposed primary Wake County service area are also ZIP codes that are in the WEC-Cary service area (*see Project ID #J-11705-19*). The applicant states approximately 21.2% of the procedures projected to be served at WEC-Cary come from these two ZIP codes. Thus, the applicant subtracts the WEC-Cary GI procedures from the total procedures in the two ZIP codes to project procedures for WEC-Holly Springs in those ZIP codes. See the table on page 118 that illustrates total procedures expected in the primary service area, minus those projected to be served by WEC-Cary for the remaining procedures in the primary service area.

### Step 4: Forecast WEC-Holly Springs GI Endoscopy Procedures

To project GI endoscopy procedures to be performed at WEC-Holly Springs, the applicant estimates a market share of GI endoscopy procedures in the primary service area that will be performed at WEC-Holly Springs. The applicant projects that the WEC-Holly Springs market share will begin in the partial interim year at 15% and incrementally increase to 30% by the third project year. The applicant notes that there is currently only one licensed GI endoscopy procedure room in the area, located in Fuquay-Varina, south and east of Holly Springs. See the table on page 119 that illustrates the calculations and projections.

### Step 5: Determine Projected GI Endoscopy Room Utilization in Wake County

The applicant relies on the previous steps and data it researched to project utilization of all WEC Wake County GI procedure rooms in the third project year for WEC-Holly Springs. The applicant determined that by 2027, each existing and proposed GI endoscopy procedure room in Wake County (12 by 2027) will perform 1,965 procedures per room, which exceeds the standard of 1,500 procedures per room.

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based on WEC’s historical GI endoscopy procedure data for all of its existing Wake County GI endoscopy procedure rooms.
- The applicant’s projected growth rates used to project utilization of GI endoscopy procedures are conservative and supported by the growing population in all of Wake County and surrounding areas, cancer incidence, prevalence rates for gastrointestinal conditions, and the increased focus on preventive screening for colorectal cancer.
- The assumptions used to project the market share of GI endoscopy procedures projected to be performed at WEC-Holly Springs are reasonable and adequately supported.

**Access to Medically Underserved Groups**

In Section C, page 51, the applicant states that WEC will provide “*accessible care to medically underserved groups, including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved persons including the medically indigent, uninsured, or underinsured.*”

On page 53, the applicant provides the estimated percentage for each medically underserved group for the third full fiscal year, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	3.0%
Racial and ethnic minorities	28.9%
Women	53.6%
Persons with Disabilities	10.0%
Persons 65 and older	48.1%
Medicare beneficiaries	45.7%
Medicaid recipients	0.7%

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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.

C

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

In Section E, pages 62-63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that this alternative would eliminate capital costs involved in developing a new facility. However, it would not provide a long term effective solution for projected demand for GI endoscopy services in Wake County, given the existing wait times and current utilization.
- Increase hours of operation at existing facilities - The applicant states that this alternative would likewise provide an expedient solution to existing demand and wait times and would save on capital costs associated with developing a new facility. However, this is not a sustainable solution for projected demand, and would negatively impact patients who would have to arrive earlier for procedures and fast for longer periods of time.
- Expand by fewer GI endoscopy procedure rooms – The applicant states it considered applying for fewer GI endoscopy procedure rooms, which would lower construction costs. However, operating a facility with only one GI endoscopy procedure room would not efficiently address patient throughput and physician times and would likely result in increased wait times for patients. \
- Expand in place – The applicant considered adding rooms to one of its current locations rather than developing a new facility. However, the applicant states the



existing locations do not adapt well to this alternative, since the current location is on the second floor of a leased multi-complex and there is no space within which to expand.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The proposal will provide needed access to GI Endoscopy services in Wake County while meeting the needs of a growing population.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Wake Endoscopy Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a freestanding GI endoscopy, Wake Endoscopy Center-Holly Springs, with no more than two licensed GI endoscopy rooms in Holly Springs.**
- 3. Upon project completion, Wake Endoscopy Center-Holly Springs shall be licensed for no more than two GI endoscopy rooms.**

### **Progress Reports:**

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
- b. The certificate holder shall complete all sections of the Progress Report form.**

- c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
          - d. **The first progress report shall be due on July 1, 2023.**
  4. **The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
  5. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
  6. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  7. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  8. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency 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.

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

**Capital and Working Capital Costs**

In Section Q, Form F.1.b, the applicant projects the total capital cost of the project, as shown in the table below.

<b>WAKE ENDOSCOPY CENTER-HOLLY SPRINGS</b>		
<b>CAPITAL COSTS</b>		
	<b>WAKE ENDOSCOPY CENTER, LLC</b>	<b>TOTAL</b>
Construction Costs	\$1,245,221	\$1,245,221
Miscellaneous Costs	\$967,394	\$967,394
<b>Total</b>	<b>\$2,212,615</b>	<b>\$2,212,615</b>

In Section Q, page 122, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because it is based on the estimated cost to develop a freestanding GI endoscopy center and the applicant’s historical experience with similar projects.

In Section F, page 66, the applicant projects that start-up costs will be \$104,635 and initial operating expenses will be \$245,940 for a total working capital of \$350,575. In Section Q, page 122 and referenced exhibits, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions based on the following:

- Start-up costs include the cost to hire and train new staff prior to operation and continuing six months.
- Both start-up costs and initial operating expenses are based on the applicant’s experience with other similar projects.

**Availability of Funds**

In Section E, page 64, the applicant states that the capital cost will be funded as shown in the following table:

**Sources of Capital Cost Financing**

TYPE	WAKE ENDOSCOPY CENTER, LLC	TOTAL
Loans	\$2,212,614	\$2,212,614
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$2,212,614</b>	<b>\$2,212,614</b>

\* OE = Owner's Equity

In Section E, page 67, the applicant states that the working capital needs of the project will be funded as shown in the following table:

**Sources of Working Capital Financing**

TYPE	WAKE ENDOSCOPY CENTER, LLC	TOTAL
Loans	\$350,575	\$350,575
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$350,575</b>	<b>\$350,575</b>

\* OE = Owner's Equity

Exhibit F.2 contains a letter dated August 5, 2022, from the Senior Vice President of First Citizens Bank, documenting their intent to consider a loan for up to \$3 million for the project. Exhibit F.2 also contains a letter dated August 9, 2022, committing the loan funds to the proposed project..

**Financial Feasibility**

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal year following project completion, as shown in the following table:

WEC-HOLLY SPRINGS	INTERIM PERIOD (9/1/2024- 12/31/2024)	1 <sup>ST</sup> FULL FY CY 2025	2 <sup>ND</sup> FULL FY CY 2026	3 <sup>RD</sup> FULL FY CY 2027
Total Procedures	502	2,281	3,073	3,105
Total Gross Revenues (Charges)	\$1,117,717	\$5,082,388	\$6,847,321	\$6,918,715
Total Net Revenue	\$561,160	\$2,551,658	\$3,437,759	\$3,473,603
Average Net Revenue / Procedure	\$1,118	\$1,119	\$1,119	\$1,119
Total Operating Expenses (Costs)	\$678,347	\$2,482,287	\$2,976,933	\$3,048,919
Average Operating Expense / Procedure	\$1,351	\$1,088	\$969	\$982
Net Income	(\$117,187)	\$69,371	\$460,826	\$424,684

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Payor mix, used to calculate gross revenue, is based on the applicant's experience operating other similar facilities in Wake County.
- The assumptions used to project revenues and expenses are likewise based on the applicant's experience with other similar facilities in Wake County.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

### C

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, "*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*" The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "*...the county where the proposed GI endoscopy*

*room will be developed.*” The facility will be developed in Wake County. Thus, the service area for this facility is Wake County. Facilities may also serve residents of counties not included in their service area.

Table 6F, on pages 94-95 of the 2022 SMFP shows there are 46 existing GI endoscopy rooms in 14 facilities in Wake County, and three facilities and 11 GI endoscopy rooms that have been approved but are not yet licensed. Table 6F also shows there are 12 GI endoscopy procedure rooms that have been approved but are not licensed. The applicant provides a table in Section G, page 74 to illustrate the Wake County GI endoscopy procedure rooms and includes the approved but unlicensed GI endoscopy procedure rooms; thus, the table on page 46 shows a total of 58 GI endoscopy procedure rooms in Wake County [46 + 12 = 58].

In Section G, page 75, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Wake County, summarizing the information provided in Section C and reiterating the increasing demand for GI endoscopy services in Wake County, the existing wait and drive times, and the proposed location of the facility. The applicant states:

*“In the aggregate, licensed Wake County GI endoscopy rooms are operating at 114 percent of the performance standard in 10 NCAC 14C .3903.*

...

*WEC-Holly Springs will bring the support of RMG physicians and other referring physicians. Providing access to board-certified RNG gastroenterologists [in the] area will increase resident access to quality GI Endoscopy care in the proposed service area.”*

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved GI endoscopy services in the service area based on the following:

- The applicant adequately demonstrates that the proposed of GI endoscopy rooms are needed in addition to the existing or approved of GI endoscopy rooms in the proposed service area.
- The proposal will enhance accessibility to residents in need of GI endoscopy services, while providing those services in a cost-effective setting.
- The proposal will decrease existing wait times, travel times and other accessibility issues currently faced by existing and projected GI endoscopy patients, thereby allowing the applicant to provide a higher quality of GI endoscopy services to those patients.

## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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 applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

In Section Q, Form H, page 129, the applicant projects full-time equivalent (FTE) staffing for the proposed services for each of the three project years, as illustrated in the following table:

<b>POSITION</b>	<b>PARTIAL YEAR (4 MONTHS)</b>	<b>1<sup>ST</sup> FULL FY FY 2025</b>	<b>2<sup>ND</sup> FULL FY FY 2026</b>	<b>3<sup>RD</sup> FULL FY FY 2027</b>
Registered Nurse	0.67	2.00	2.00	2.00
Licensed Practical Nurse	0.33	1.00	1.00	1.00
Assistant Director of Nursing	0.17	0.50	0.50	0.50
Surgical Technician	0.67	2.00	2.00	2.00
Administrator/CEO	0.07	0.20	0.20	0.20
Clerical	0.33	1.00	1.00	1.00
Central Sterile Supply	0.33	1.00	1.00	1.00
Other (Physicians)	0.32	1.45	1.96	1.98
<b>Total</b>	<b>2.89</b>	<b>9.15</b>	<b>9.66</b>	<b>9.68</b>

The assumptions and methodology used to project staffing are provided in Section Q, page 126. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 78, the applicant describes the methods used to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- As an established employer in Wake County and current provider of GI endoscopy services, the applicant does not anticipate difficulty recruiting and retaining staff, stating that some existing employees have expressed interest in the anticipated positions in Holly Springs.

- The facility will require all clinical staff to complete orientation and training specific to their position, maintain licensure and certification, and provide annual evidence of continued qualifications.
- The facility will require all clinical staff to attend continuing education programs and regular in-service training.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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 proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

### **Ancillary and Support Services**

In Section I, page 80, the applicant identifies the necessary ancillary and support services for the proposed GI endoscopy services. On page 81, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because the applicant currently provides GI endoscopy services in Wake County and has the ancillary and support services available. The applicant states those services will be available at the new proposed facility.

### **Coordination**

In Section I, page 81, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the applicant's established relationships with local health care and social service providers, which will be extended to WEC-Holly Springs when the facility is developed.



## **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.

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

C

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

In Section K, page 83, the applicant states that the project involves renovating 6,271 square feet of existing space in a physician office building that is currently under construction by a third party builder. Line drawings showing the areas to be renovated are provided in Exhibit K.2.

On page 86, the applicant identifies the proposed site and provides information about the zoning and special use permits, and the availability of water, sewer and waste disposal and power at the site. Supporting documentation is provided in Exhibits K.3 and K.4. The site appears to be suitable for the proposed GI endoscopy facility based on the applicant's representations and supporting documentation.

On pages 84-85, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states it will lease space and thus the only costs it will incur are those related to upfit and lease expenses.
- The applicant's architecture and design staff will design the layout to maximize space and include several cost-saving elements, thus lowering patient cost and increasing efficiency.
- The architecture and construction teams are familiar with North Carolina health care construction standards and will ensure that the facility is built to the latest standards.
- The architecture and construction teams are familiar with ASC construction and have been involved in previous projects with the applicant.

On page 85, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed GI endoscopy services or the costs and charges to the public for the proposed services. A freestanding facility can provide GI endoscopy services at a lower cost and avoid other costs associated with a hospital-based facility, saving the patient, government, and third-party payors money.

On page 85, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit K.3.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (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 persons with disabilities, 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 applicant proposes to develop a new facility. Therefore, there is no historical payor mix to report. However, in Section L, page 88, the applicant provides the historical payor mix for its other existing GI endoscopy facilities in Wake County during calendar year (CY) 2021, as shown in the following table:

<b>WAKE ENDOSCOPY CENTER, LLC HISTORICAL PAYOR MIX, CY 2021 ALL WAKE COUNTY FACILITIES</b>	
<b>PAYOR CATEGORY</b>	<b>GI ENDOSCOPY SERVICES AS PERCENT OF TOTAL</b>
Self-Pay	2.5%
Charity Care*	--
Medicare**	36.6%
Medicaid**	0.7%
Insurance**	59.3%
Other (TRICARE MCST, Projecta, RRMCRE)	0.8%
<b>Total</b>	<b>100.0%</b>

\*The applicant states charity care is 1% of gross revenue.

\*\*Includes managed care plans.

In Section L, page 90, the applicant provides the following comparison for the last full FY prior to submission of the application, CY 2021:

WAKE ENDOSCOPY CENTER, LLC	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	53.6%	51.4%
Male	46.4%	48.6%
Unknown	NA	NA
64 and Younger	51.9%	88.0%
65 and Older	48.1%	12.0%
American Indian	1.4%	8.0%
Asian	3.2%	7.7%
Black or African-American	11.6%	21.0%
Native Hawaiian or Pacific Islander	0.2%	0.1%
White or Caucasian	71.1%	67.9%
Other Race	0.9%	2.8%
Declined / Unavailable	11.7%	NA

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the applicant adequately documents 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. 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 persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section L, page 92, the applicant states that the proposed facility is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 92, the applicant states the proposed project does not involve an existing facility.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

In Section L, page 93, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation (CY 2027) following project completion, as shown in the following table:

WAKE ENDOSCOPY CENTER-HOLLY SPRINGS 3 <sup>RD</sup> FULL FY, CY2027	
PAYOR CATEGORY	GI ENDOSCOPY SERVICES AS PERCENT OF TOTAL
Self-Pay	2.5%
Charity Care*	--
Medicare**	36.6%
Medicaid**	0.7%
Insurance**	59.3%
Other (TRICARE, MCST, Projecta, RRMCRE)	0.8%
<b>Total</b>	<b>100.0%</b>

\*The applicant states charity care is 1% of gross revenue.

\*\*Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.5% of total services will be provided to self-pay patients, 36.6% to Medicare patients and 0.7% to Medicaid patients.

On page 93, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on its historical payor mix at its existing Wake County GI endoscopy facilities.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

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

C

In Section L, page 95, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to 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

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

In Section M, page 96, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- Wake Endoscopy Center, LLC has established clinical education agreements with existing colleges and universities and will include WEC-Holly Springs once it becomes operational.
- In Exhibit M.1 the applicant provides a copy of a letter dated August 5, 2022 from Campbell University, offering to extend the existing agreement to the proposed Holly Springs facility.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
  
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “*...the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Wake County. Thus, the service area for this facility is Wake County. Facilities may also serve residents of counties not included in their service area.

Table 6F, on pages 94-95 of the 2022 SMFP shows there are 46 existing GI endoscopy rooms in 14 facilities in Wake County, and three facilities and 11 GI endoscopy rooms that have been approved but are not yet licensed. Table 6F also shows there are 12 GI endoscopy procedure rooms that have been approved but are not licensed.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 97, the applicant states:

*“The proposed facility will increase competition in the proposed Holly Springs service area. It will provide a new access location for freestanding GI endoscopy procedures. There is only one freestanding GI endoscopy room in the WEC-Holly Springs primary service area. With more capacity, WEC can offer patients more access to the preferred early schedule. The proposed new facility will be a freestanding setting, which will be more physically accessible*

*to parking, and present lower risk of delays or infections at a lower cost than a hospital facility.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 97-98, the applicant states:

*“...freestanding GI endoscopy centers are more cost-effective than those in hospitals. Hospital-based GI endoscopy rooms have more expensive rates. Medicare, the benchmark for payment structures, establishes a higher fee rate for the same GI endoscopy service when it occurs in a hospital.*

*Patients are becoming more value savvy regarding healthcare services. Patients are better informed than in the past, and therefore are willing to shop for providers that offer lower out-of-pocket costs, especially for planned procedures like screening colonoscopies. Providing additional access to a low-cost, high-quality provider ensures that Wake County residents will seek the preventive care they need.”*

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 98, the applicant states:

*“All WEC physicians are board-certified and benchmark themselves to national standards. The proposed new facility will maintain the same standards.*

*WEC-Holly Springs will be subject to third-party oversight. It will be accredited by the AAAHC, licensed by the State of North Carolina and certified by CMS for Medicare and Medicaid participation.*

*Staff and patient safety are designed into the patient flow. The facility will be staffed to minimize turnover time while providing patients time to recover and understand discharge instructions at their own pace.”*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 98, the applicant states:

*“WEC has a policy of accepting low-income persons, racial and/or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons including the medically indigent, uninsured or underinsured.”*

See also Sections C and L of the application and any referenced exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a



positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost-effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described above.

- (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

The applicant proposes to develop a new ASF in Holly Springs with no more than two GI endoscopy procedure rooms upon project completion.

In Section O, page 100, the applicant identifies the acute care and ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five of this type of facility located in three counties in North Carolina.

In Section O, page 101, the applicant states that, during the 18 months immediately preceding the submittal of the application, all WEC facilities listed in Section O did not have any deficiencies in quality of care at any its licensed facilities. In Exhibit O.4, the applicant provides a letter dated August 10, 2022 from the GI Administrator of Wake Endoscopy Center, LLC, confirming that all of WEC's facilities have provided quality care and have not received any violations or Civil Rights access complaints during the

18 months preceding application submission. After reviewing and considering the information provided by the applicant and considering the quality of care provided, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

## C

The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903, are applicable to this review.

### **SECTION .3900 – CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES**

#### **.3903 PERFORMANCE STANDARDS**

*An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:*

(1) *identify the proposed service area;*

-C- In Section C, page 39, the applicant states the service area for WEC-Holly Springs will include six ZIP codes in or adjacent to southwestern Wake County.

(2) *identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;*

-C- In Section C, page 56, the applicant states that WEC or a related entity owns or operates seven GI endoscopy procedure rooms in Wake County.

(3) *provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;*

-C- In Section Q, Table 6 the applicant provides projected utilization for each of the existing WEC GI endoscopy procedure rooms located in Wake County.

(4) *project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and*

-C- In Section Q, page 120, the applicant projects to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy procedure room during the third full fiscal year of operation following project completion.

(5) *provide the assumptions and methodology used to project the utilization required by this Rule.*

-C- In Section Q, pages 109-120, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the proposed and existing facilities. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.