

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 9, 2023

Findings Date: August 9, 2023

Project Analyst: Cynthia Bradford

Co-Signer: Mike McKillip

Project ID #: J-12385-23

Facility: Raleigh Endoscopy Center

FID #: 923422

County: Wake

Applicants: The Raleigh NC Endoscopy ASC, LLC  
Amsurg Holdings, Inc.

Project: Relocate the facility and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

## 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.

C

The Raleigh NC Endoscopy ASC, LLC, and Amsurg Holdings, Inc. (hereinafter referred to as “the applicant”, or REC), proposes relocate the facility and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

### Policies

There is one policy in the 2023 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

**Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**, on pages 30 of the 2023 SMFP, states:

*“Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate, or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.*

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

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

The capital expenditure of the project is over \$5 million. In Section B, page 26, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plans to ensure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

### **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 the following reasons:

- The applicant does not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2023 SMFP.
- The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application

includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

- (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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy 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 2023 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 following table illustrates historical patient origin, from Section C, page 30:

County	Raleigh Endoscopy Center Historical Patient Origin	
	Last Full FY 01/01/2022-12/31/2022	
	Patients	% of Total
Wake County	7,932	80.4%
Johnston County	679	6.9%
Durham County	239	2.4%
Franklin County	178	1.8%
Harnett County	166	1.7%
Nash County	100	1.0%
Other^	573	5.8%
<b>Total</b>	<b>9,867</b>	<b>100.0%</b>

Source: Section C, page 30

\*Other includes 34 North Carolina counties and other State counties.

The following table illustrates projected patient origin, from Section C, page 32:

Raleigh Endoscopy Center Projected Patient Origin						
COUNTY/ZIP CODE	1 <sup>ST</sup> FULL FY (CY 2026)		2 <sup>ND</sup> FULL FY (CY 2027)		3 <sup>RD</sup> FULL FY (CY 2028)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
Wake County	7,975	80.4%	7,957	80.4%	8,114	80.4%
Johnston County	683	6.9%	681	6.9%	695	6.9%
Durham County	240	2.4%	240	2.4%	244	2.4%
Franklin County	179	1.8%	179	1.8%	182	1.8%
Harnett County	167	1.7%	167	1.7%	170	1.7%
Nash County	101	1.0%	101	1.0%	102	1.0%
Other^	576	5.8%	575	5.8%	586	5.8%
<b>Total</b>	<b>9,920</b>	<b>100.0%</b>	<b>9,898</b>	<b>100.0%</b>	<b>10,093</b>	<b>100.0%</b>

Source: Section C, page 32

Numbers may not sum due to rounding.

^The applicant provides a list of included in the “other” category on page 32 of the application.

In Section C, page 32, the applicant provides assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported because the applicant projects patient origin for the proposed facility based on historical patient origin for its existing Wake County facilities.

**Analysis of Need**

In Section C, pages 34-45, The applicant explains why it believes the population projected to be served by the proposed project needs the proposed services, summarized as follows:

- **Use of and Need for Endoscopy Services for Diagnosis, Treatment, and Prevention of GI Conditions:** The applicant discusses how GI endoscopy procedures are done and states that timely use can prevent colorectal cancer or detect it at earlier stages, thus increasing survival rates. The applicant states the National Institute of Diabetes and Digestive and Kidney Diseases estimates that between 60 and 70 million Americans are diagnosed with a digestive disorder each year, resulting in approximately 250,000 deaths annually. In addition, the applicant states that early cancer detection at stage 1 or stage 2 has a 5-year survival rate of 90% and that, conversely, cancer detected at stage 3 has a 71% survival rate. (Pages 35-36)
- **The Need for Additional GI Endoscopy Capacity in Wake County:** The applicant states that Wake County accounted for 460 new cases of colorectal cancer and 153 deaths due to colorectal cancer in 2022, the highest mortality rate in North Carolina for this condition for that year. In addition, GI endoscopy procedure volume performed in Wake County grew seven times faster than the State overall from FFY2019 through FFY 2021. The applicant states that while

REC facilities comprise approximately 24% of all GI endoscopy rooms in Wake County, REC has completed more than 36% of all GI endoscopy procedures performed in the same service area. All three of the GI clinics run by REC in Wake County are performing between 193.3% to 231.1% of the performance standard of 1500 procedures per GI endoscopy room. Moreover, the applicant states that in CY2021, 16.1% of GI endoscopy procedures were conducted on patients who reside outside of Wake County, demonstrating that the need for the proposed services is driven, in part, by them. (pages 36-42)

- **Population Growth and Aging:** The applicant states that the fastest growing counties in the United States and that neighboring counties, including Durham, Johnston, and Harnett counties are also listed in the highest growth tier. In addition, the applicant states that older residents (aged 45+) utilize healthcare services at a higher rate than younger residents, and that as the populations in Wake County and neighboring counties grow, so does the demand for GI endoscopy services. (pages 42-45)

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

- The applicant uses historical data of its existing GI endoscopy services in the proposed service area to support the need for additional GI endoscopy services in the same service area.
- 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.

Projected Utilization

In Section Q, Form C, the applicant provides the historical and projected utilization for REC as illustrated in the following tables:

Historical Utilization for Raleigh Endoscopy Center	Last FY1 CY2022	Interim FY2 CY2023	Interim FY3 CY2024
GI Endo Procedures	13,545	13,812	14,084
Total # GI Endo Rooms	4	4	4
Average Procedures per Room	3,386	3,453	3,521

Source: Section Q, Form C.3.a

Projected Utilization for Raleigh Endoscopy Center	Partial Fiscal Year CY2025	1 <sup>st</sup> Fiscal Year CY2026	2 <sup>nd</sup> Fiscal Year CY2027	3 <sup>rd</sup> Fiscal Year CY2028
GI Endo Procedures	13,643	13,619	13,588	13,855
Total # GI Endo Rooms	6	6	6	6
Average Procedures per Room	2,274	2,270	2,265	2,309

Source: Section Q, Form C.3.b

In Section Q, Form C, the applicant provides the assumptions and methodology used to project utilization, as summarized below.

- The applicant analyzed historical utilization of its 11 existing GI endoscopy rooms in Wake County.
- The total number of GI endoscopy cases grew 4.1% from CY19 to CY22 and the total number of GI endoscopy procedures performed at REC facilities grew 4.4% annually over the same time period, as illustrated in the table below.

<b>REC Historical Utilization per GI Endoscopy Room</b>					
	<b>CY19</b>	<b>CY20^^</b>	<b>CY21</b>	<b>CY22</b>	<b>CY19-22 CAGR^</b>
Raleigh Endoscopy Center GI Cases	9,530	7,545	9,907	9,867	1.2%
Raleigh Endoscopy Center Cary GI Cases	9,146	6,448	9,368	10,788	5.7%
Raleigh Endoscopy Center North GI Cases	5,848	4,643	6,978	7,046	6.4%
Total GI Cases	24,524	18,636	26,253	27,701	4.1%
Total GI Procedures	33,434	25,429	36,176	38,028	4.4%
Procedures per Case*	1.36	1.36	1.38	1.37	
Endoscopy Rooms	11	11	11	11	
Procedures per Room**	3,039	2,312	3,289	3,457	

Source: REC Internal Data

^Compound Annual Growth Rate

^^Numbers Impacted by COVID Restrictions

\*Procedures per case = Total GI Procedures/Total GI Cases

\*\*Procedures per Room = Total GI Procedures/ Endoscopy Rooms

- Next, the applicant reviewed projected population growth for Wake County from 2022-2027, using estimates from the North Carolina Office of State Budget and Management. Wake County’s total population is projected to grow by 2% annually from 2022 to 2027. Wake County’s 45+ population is projected to grow by 3.1% annually from the same time period. (Section C.4) To be conservative, the applicant utilized an annual growth rate of 2% to project utilization of its existing and proposed GI endoscopy rooms annually through CY27. This growth rate is less than half the annual growth rate of its GI endoscopy facilities’ GI case volume from CY2019 to CY 2022.
- The applicant states that during CY22, approximately 15.1% of all GI endoscopy cases treated at its three existing REC facilities originated from the seven zip codes within the proposed facility’s primary service area. REC proposes to shift a portion of these GI endoscopy cases from their existing ASFs to REC Holly Springs and increase the percentage of shift gradually over the first three operating years of the proposed project. REC expects that by the end of CY28, its third operating year, the percentage of GI endoscopy cases treated by REC from the proposed service area at all four of its facilities in Wake County will be similar. The projected shift is illustrated in the table below:

<b>Projected Shift of GI Endoscopy Cases to REC- Holly Springs</b>				
<b>Site</b>	<b>CY25</b>	<b>CY26 (PY1)</b>	<b>CY27 (PY2)</b>	<b>CY28 (PY3)</b>
Raleigh Endoscopy Center Shift Percentage	5.5%	7.0%	9.0%	9.0%
Raleigh Endoscopy Center Cary Shift Percentage	15.0%	20.0%	25.0%	25.0%
Raleigh Endoscopy Center North Shift Percentage	1.0%	2.0%	3.0%	3.0%
Raleigh Endoscopy Center GI Cases to Shift	523	747	979	998
Raleigh Endoscopy Center Cary GI Cases to Shift	1,716	2,333	2,973	3032
Raleigh Endoscopy Center North GI Cases to Shift	75	152	233	238
<b>Total GI Cases to Shift to REC - Holly Springs</b>	<b>2,313</b>	<b>3,232</b>	<b>4,185</b>	<b>4,267</b>

Source: Form C Utilization page 3

- Next, in Section Q, Form C page 4, the applicant states that in order to project utilization of the three proposed GI endo rooms alongside REC’s 11 existing GI endo rooms, REC multiplied the projected number of GI endoscopy cases at each facility by 1.37, the average ratio of procedures per case at REC facilities in CY 2022, to determine the projected shift of GI endoscopy procedure volume to Raleigh Endoscopy Center-Holly Springs through PY3. The CY 2022 average of 1.37 procedures per case matches the four-year average procedures per case for CY 2019 through CY 2022. The applicant provides projected GI endoscopy cases at all three existing REC facilities in the proposed service area after the shift of cases to the proposed facility. The projected cases are illustrated in the table below:

<b>Projected GI Endoscopy Cases at all REC Facilities After Shift</b>						
<b>Site</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>	<b>CY2026 (PY1)</b>	<b>CY2027 (PY2)</b>	<b>CY2028 (PY3)</b>
Raleigh Endoscopy Center	13,812	14,084	13,643	13,619	13,588	13,855
Raleigh Endoscopy Center Cary	15,101	15,398	13,346	12,808	12,244	12,485
Raleigh Endoscopy Center North	9,863	10,057	10,153	10,248	10,343	10,547
Raleigh Endoscopy Center Holly Springs (Proposed)	-	-	3,176	4,436	5,745	5,858
<b>Total GI Procedures</b>	<b>38,776</b>	<b>39,540</b>	<b>40,318</b>	<b>41,111</b>	<b>41,920</b>	<b>42,746</b>

- The applicant projects the three proposed GI endoscopy rooms will meet the 1,500 GI endoscopy procedures per room performance standard by CY 2027, the third full fiscal year of the proposed project as illustrated in the table below.

<b>Projected Utilization at Raleigh Endoscopy Center</b>			
	<b>CY26 (PY1)</b>	<b>CY27 (PY2)</b>	<b>CY28 (PY3)</b>
GI Endo Procedures	13,619	13,588	13,855
GI Endo Rooms	6	6	6
Procedures per Room	2,270	2,265	2,309
Utilization Capacity*	151.3%	151.0%	153.9%

\*Utilization Capacity = Procedures Per Room / 1,500 threshold

- The applicant projects that by CY 2028, the third project year for the proposed project, 42,746 GI endoscopy procedures or approximately 2,672 procedures per room will be performed in the 16 GI endoscopy rooms at REC facilities in Wake County which exceeds the 1,500 procedures per room performance standard as illustrated in the table below.

<b>Projected CY 2028 GI Endoscopy Procedures per Room at All REC Facilities</b>				
<b>Site</b>	<b>CY28 (PY3) Procedures</b>	<b>GI Endo Rooms</b>	<b>Procedures per Room</b>	<b>Utilization Capacity</b>
Raleigh Endoscopy Center	13,855	6	2,309	153.9%
Raleigh Endoscopy Center Cary	12,458	4	3,121	208.1%
Raleigh Endoscopy Center North	10,547	3	3,516	234.4%
Raleigh Endoscopy Center - Holly Springs	5,858	3	1,953	130.2%
<b>Total</b>	<b>42,746</b>	<b>16</b>	<b>2,672</b>	<b>178.1%</b>

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

- Projected utilization is based on REC’s historical GI endoscopy procedure data for all of its three existing Wake County GI endoscopy procedure rooms.
- The applicant’s projected growth rates used to project utilization of GI endoscopy procedures are 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 REC are reasonable and adequately supported.

**Access to Medically Underserved Groups**

In Section C, page 52, the applicant states that REC “will maintain and improve access to GI endoscopy services in the service area, including to historically medically underserved groups. REC has long-promoted economic access to its services as it historically has provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay.”

On page 52, the applicant provides the estimated percentage for each medically underserved group for the third full fiscal year, as shown in the following table.



<b>MEDICALLY UNDERSERVED GROUPS</b>	<b>PERCENTAGE OF TOTAL PATIENTS</b>
Low-income persons	
Racial and ethnic minorities	54.7%
Women	59.9%
Persons with Disabilities	
Persons 65 and older	27.9%
Medicare beneficiaries	22.0%
Medicaid recipients	0.3%

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 because the applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

**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.

- (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.

C

The applicant proposes to relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

In Section D, page 58, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 58, the applicant states:

*“The proposed site for the relocated and expanded ASF is located within one mile and less than five minutes from the existing Raleigh Endoscopy Center. As such,*

*the proposed project will not materially change the location in Raleigh off Blue Ridge Road and Edwards Mill Road and proximate to UNC Health Rex Hospital and many other healthcare providers and facilities.”*

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

- The two locations are approximately one mile and 5 minutes driving time from each other, according to Google Maps. Thus, the GI endoscopy services will still be accessible to the same population at the new location.
- The applicant is not proposing to reduce any services at the current location.

### **Access to Medically Underserved Groups**

In Section D, page 59, the applicant states:

*“REC has long-promoted economic access to its services as it historically has provided services to all persons in need of medical care, regardless of race, sex, creed, age, national origin, handicap, or ability to pay and will continue to do so at the relocated and expanded Raleigh Endoscopy Center following completion of the proposed project. In addition, the proposed project will be located on the first floor of the Macon Pond Road MOB, making it easily accessible for elderly individuals and persons with disabilities, and will serve to enhance temporal access for existing and future patients of Raleigh Endoscopy Center while simultaneously maintaining geographic access in the central part of Wake County.”*

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use GI endoscopy services will be adequately met following completion of the project because services will still be accessible to the same population at the new location.

### **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 needs of the population currently using the services to be relocated will be adequately met following project completion for all the reasons described above.

- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.
- (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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

In Section E, pages 63-64, 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:

- Relocate REC in a different location in Wake County – The applicant states that they considered relocating to a different location in Wake County. The applicant states, *“If REC were to develop the proposed ASF in a different area of Wake County, patients that live in central Wake County and the surrounding areas would still be forced to travel longer distances for GI endoscopy services than the proposed relocation site. In addition, the new location will be developed on the first floor which will improve accessibility for seniors and patients with disabilities.”*
- Develop a Different Number of New GI Endoscopy Rooms – The applicant states it considered applying for fewer GI endoscopy procedure rooms. However, operating a facility with fewer GI endoscopy rooms would not efficiently address the high utilization of REC, and would likely result in increased wait times for patients. The applicant states that if they were to develop a higher number of GI endoscopy rooms, then the development of the proposed project would be more costly and more time-intensive than developing the project as proposed.
- Develop the Proposed GI Endoscopy Rooms in an Existing Facility – The applicant considered adding rooms to one of its current locations rather than developing a new facility. However, the applicant states the renovation needed for existing locations would not be cost effective, create disruptions and delays in care, and would create a potential issue with access to services.

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. Raleigh NC Endoscopy ASC, LLC, and Amsurg Holdings, Inc., (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall relocate Raleigh Endoscopy Center and add no more than two GI endoscopy rooms for a total of six GI endoscopy rooms upon project completion.**
- 3. Upon project completion, Raleigh Endoscopy Center shall be licensed for no more than six GI endoscopy rooms.**
- 4. The certificate holder shall develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes.**
- 5. 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 January 1, 2024.**
6. **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.**
  7. **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.**
  8. **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.**
  9. **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.

C

The applicant proposes to relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

**Capital and Working Capital Costs**

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

<b>Capital Costs for Raleigh Endoscopy Center</b>			
	<b>The Raleigh NC Endoscopy ASC, LLC.</b>	<b>Amsurg Holdings, Inc.</b>	<b>Total Sum of Applicant Contribution</b>
Construction/ Renovation Contracts	\$4,655,000	\$4,845,000	\$9,500,000
Architect/ Engineering Fees	\$245,000	\$255,000	\$500,000
Medical Equipment	\$1,347,500	\$1,402,500	\$2,750,000
Non-Medical Equipment	\$392,000	\$408,000	\$800,000
Furniture	\$98,000	\$102,000	\$200,000
<b>Total Capital Cost</b>	<b>\$6,737,500</b>	<b>\$7,012,500</b>	<b>\$13,750,000</b>

In Section Q, Form F.1.a assumptions, 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 relocate a freestanding GI endoscopy center and the applicant's historical experience with similar projects.

In Section F, pages 67-70, the applicant projects that there will be no start-up, initial operating expenses, or working capital for this project because the project does not involve a new service.

**Availability of Funds**

In Section F, page 65, and in Exhibits F.2-1 and F.2-2, the applicant states that the capital cost will be funded as shown in the following table:

<b>Sources of Capital Cost Financing</b>			
<b>TYPE</b>	<b>THE RALEIGH ENDOSCOPY CENTER, LLC</b>	<b>AMSURG HOLDINGS, INC.</b>	<b>TOTAL</b>
Loans	\$6,737,500	\$0	\$6,737,500
Accumulated reserves or OE *	\$0	\$7,012,500	\$7,012,500
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$6,737,500</b>	<b>\$7,012,500</b>	<b>\$13,750,000</b>

\* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated May 15, 2023, from the Senior Vice President of First Citizens Bank, documenting their intent to consider a loan for up to \$6,737,500 for the project. Exhibit F.2-2 also contains a letter dated May 15, 2023, from the President of Raleigh Endoscopy Center, LLC. committing the capital funds for 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 Section Q, Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following project completion, as shown in the following table:

<b>RALEIGH ENDOSCOPY CENTER</b>	<b>1<sup>ST</sup> FULL FY CY2026</b>	<b>2<sup>ND</sup> FULL FY CY2027</b>	<b>3<sup>RD</sup> FULL FY CY2028</b>
Total Procedures	13,619	13,588	13,855
Total Gross Revenues (Charges)	\$21,971,659	\$22,579,952	\$23,715,087
Total Net Revenue	\$7,314,777	\$7,517,289	\$7,895,197
Average Net Revenue / Procedure	\$537.10	\$533.20	\$569.84
Total Operating Expenses (Costs)	\$7,246,726	\$7,388,913	\$7,562,942
Average Operating Expense / Procedure	\$532.10	\$543.78	\$545.86
<b>Net Income</b>	<b>\$68,051</b>	<b>\$128,376</b>	<b>\$332,256</b>

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:

- The assumptions used to project revenues and expenses are likewise based on the applicant's experience with other similar facilities in Wake County.
- Projected utilization is based on reasonable and adequately supported assumptions, see the discussion regarding utilization in Criterion (3) which is incorporated herein for reference.

**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 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 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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy 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 2023 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: Endoscopy Room Inventory, on pages 91-92 of the 2023 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 is one GI endoscopy room that has been approved in an existing facility but is not licensed. The information from Table 6F of the 2023 SMFP is summarized below.



2023 SMFP Table 6F: Endoscopy Room Inventory				
Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Center for Digestive Diseases & Cary Endoscopy Center	ASC	3	2,320	2,320
Duke GI at Brier Creek	ASC	4	5,832	7,255
Duke GI at Green Level*	ASC	4	0	0
Duke Gastroenterology of Raleigh *	ASC	4	0	0
Duke Raleigh Hospital	Hospital	3	3,423	4,564
Gastrointestinal Healthcare	ASC	2	1,587	1,721
Kurt Vernon, MD PA	ASC	1	2,687	2,834
Raleigh Endoscopy Center	ASC	4	9,154	13,461
Raleigh Endoscopy Center-Cary	ASC	4	8,798	11,892
Raleigh Endoscopy Center-North	ASC	3	804	5,383
Rex Hospital	Hospital	4	4,404	6,565
Triangle Gastroenterology	ASC	2	3,968	4,090
Wake Forest Endoscopy Center	ASC	2	2,959	3,751
Wake Endoscopy Center	ASC	4	9,538	10,782
Wake Endoscopy Center-Cary*	ASC	3	0	0
WakeMed	Hospital	6	6,086	7,255
WakeMed Cary Hospital	Hospital	4	2,235	2,755

\*New facility currently under development.

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. The applicant states:

*“As previously discussed in Section C.4, REC’s existing GI endoscopy rooms have continually operated well above the performance standard of 1,500 procedures per GI endoscopy room each year from CY 2019 through CY 2022, ...*

...

*Given the current and projected high utilization of REC’s existing GI endoscopy rooms detailed in Form C Assumptions and Methodology and the projected population growth and aging of Wake County discussed in Section C.4, REC believes that the proposed project will not result in an unnecessary duplication of services.”*

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 because the applicant adequately demonstrates that the proposed GI endoscopy rooms are needed in addition to the existing or approved of GI endoscopy rooms in the proposed service area.

**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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

In Section Q, Form H, 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>Raleigh Endoscopy Center Projected Staffing</b>			
<b>POSITION</b>	<b>1<sup>ST</sup> FULL FY CY2026</b>	<b>2<sup>ND</sup> FULL FY CY2027</b>	<b>3<sup>RD</sup> FULL FY CY2028</b>
Registered Nurses	18	18	18
Charge Nurse	1	1	1
Scope Technicians	3	3	3
Endo Technicians	6	6	6
ASC Administrator	1	1	1
Center Director	1	1	1
Receptionist	2	2	2
Administration Assistant	1	1	1
Supervisor/Educator	1	1	1
AP Specialist	1	1	1
Patient Representative	3	3	3
<b>Total</b>	<b>38</b>	<b>38</b>	<b>38</b>

The assumptions and methodology used to project staffing are provided in Section Q, Form H Assumptions. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 77-78, and Exhibit H.3, 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:

- REC recruits new employees across multiple venues, including employee referrals. REC offers a competitive wage and benefits package, and a good working environment. Hard to fill positions have their recruitment plan evaluated and revised annually, and REC is an equal opportunity employer.
- 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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

### **Ancillary and Support Services**

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed GI endoscopy services. On page 79, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. 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 80, 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.

## **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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

In Section K, page 83, the applicant states that the project involves renovating 20,500 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 C.1-1.

On page 83, 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 C.1-1 and C.1-2. The site appears to be suitable for the proposed GI endoscopy facility based on the applicant's representations and supporting documentation.

On pages 83-84, 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 upfit leased 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 ASF construction and have been involved in previous projects with the applicant.

On page 84, 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 84, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **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

In Section L, page 87, the applicant provides the historical payor mix during CY 2022 for the proposed services, as shown in the table below.

<b>Raleigh Endoscopy Center Historical Payor Mix 01/01/2022-12/31/2022</b>	
<b>Payor Category</b>	<b>GI Endo Services as Percent of Total</b>
Self-Pay	0.7%
Medicare*	28.6%
Medicaid*	0.7%
Insurance*	70.1%
<b>Total^</b>	<b>100.0%</b>

\*Including any managed care

^ Total may not sum due to rounding

In Section L, page 89, the applicant provides the following comparison.

<b>Raleigh Endoscopy Center</b>	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	56.9%	51.1%
Male	43.1%	48.9%
Unknown	0.0%	0.0%
64 and Younger	72.1%	87.4%
65 and Older	27.9%	12.6%
American Indian	1.8%	0.8%
Asian	18.7%	8.3%
Black or African-American	25.5%	21.0%
Native Hawaiian or Pacific Islander	0.5%	0.1%
White or Caucasian	26.3%	67.1%
Other Race	8.2%	2.8%
Declined / Unavailable	19.0%	0.0%

\*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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 90, 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 90, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against any similar facilities owned by the applicant or a related entity and located in North Carolina.

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 91, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation (FY2028) following project completion, as shown in the following table:



<b>RALEIGH ENDOSCOPY CENTER 3<sup>RD</sup> FULL FY 2028</b>	
<b>PAYOR CATEGORY</b>	<b>GI ENDOSCOPY SERVICES AS PERCENT OF TOTAL</b>
Self-Pay	0.7%
Medicare**	28.6%
Medicaid**	0.7%
Insurance**	70.1%
<b>Total</b>	<b>100.0%</b>

\*The applicant does not include charity care as a payor source

\*\*Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.7% of total services will be provided to self-pay patients, 28.6% to Medicare patients and 0.7% to Medicaid patients.

In Section Q, Form F.2 Assumptions, 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 three 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, pages 91-92, 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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

In Section M, page 93, 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 states,

*“REC will continue to offer training programs in the area access to learning opportunities at Raleigh Endoscopy Center, as applicable and appropriate. Given the nature of the proposed service and the types of FTEs used to provide the service, REC expects that the training opportunity will be largely limited to therapy and nursing students who wish to observe the patients being treated at the facility...”*

*As an existing provider in the service area, REC currently allows students to observe and learn in its facilities. The same will apply to the relocated and expanded facility at the Macon Pond Road MOB in Raleigh.”*

The applicant adequately demonstrates that health professional training programs in the area have will have access to the facility for training purposes based on the following:

- The applicant’s commitment to accommodate students from health professional training programs in the area.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conditionally 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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy 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 2023 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: Endoscopy Room Inventory, on pages 91-92 of the 2023 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 is one GI endoscopy room that has been approved in an existing facility but is not yet licensed. The information from Table 6F of the 2023 SMFP is summarized below.

2023 SMFP Table 6F: Endoscopy Room Inventory				
Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Center for Digestive Diseases & Cary Endoscopy Center	ASC	3	2,320	2,320
Duke GI at Brier Creek	ASC	4	5,832	7,255
Duke GI at Green Level*	ASC	4	0	0
Duke Gastroenterology of Raleigh *	ASC	4	0	0
Duke Raleigh Hospital	Hospital	3	3,423	4,564
Gastrointestinal Healthcare	ASC	2	1,587	1,721
Kurt Vernon, MD PA	ASC	1	2,687	2,834
Raleigh Endoscopy Center	ASC	4	9,154	13,461
Raleigh Endoscopy Center-Cary	ASC	4	8,798	11,892
Raleigh Endoscopy Center-North	ASC	3	804	5,383
Rex Hospital	Hospital	4	4,404	6,565
Triangle Gastroenterology	ASC	2	3,968	4,090
Wake Forest Endoscopy Center	ASC	2	2,959	3,751
Wake Endoscopy Center	ASC	4	9,538	10,782
Wake Endoscopy Center-Cary*	ASC	3	0	0
WakeMed	Hospital	6	6,086	7,255
WakeMed Cary Hospital	Hospital	4	2,235	2,755

\*New facility currently under development.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 94, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to freestanding GI endoscopy services in Wake County.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, page 94, the applicant states:

*“The proposed project will enhance REC’s capacity to provide cost-effective, freestanding GI endoscopy services at its main facility in Raleigh. For those patients who do not require a more intensive setting, ASFs are able to provide care at a lower cost because of the lower intensity setting.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 94-95, the applicant states:

*“REC meets or exceeds all state and federal guidelines for quality. The board certified physicians that treat patients at REC facilities are an elite group of thought leaders and prominent digestive health practitioners, and REC*

*facilities are accredited by the Accreditation Association for Ambulatory Health Care (AAAHC). This accreditation shows that REC voluntarily seeks and meets stringent national standards for healthcare quality and safety. The same will be true at the proposed Raleigh Endoscopy Center upon completion of the proposed project.”*

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 95-96, the applicant states:

*“Patients who do not qualify for financial assistance will be offered an installment payment plan. Patients will receive the appropriate medical screening examination and any necessary stabilizing treatment for emergency medical conditions, regardless of ability to pay.”*

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 relocate Raleigh Endoscopy Center and develop no more than two new GI endoscopy rooms for a total of no more than six GI endoscopy rooms upon project completion.

In Section Q, Form O, the applicant identifies the ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of six of this type of facility located in North Carolina.

In Section O, page 99, the applicant states that, during the 18 months immediately preceding the submittal of the application, none of the REC facilities or related entities listed on Form O had any situations resulting in a finding of immediate jeopardy during the 18-month look back period.

According to the files in the Acute Care and Home Licensing Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in seven of these facilities. After reviewing and considering the information provided by the applicant and by the Acute and Home Care Licensure and Certification Section considering the quality of care provided at all seven facilities, the applicant provided at all six facilities, 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 32, the applicant states the service area for REC 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 Q, Form O, the applicant states that REC or a related entity owns or operates 14 GI endoscopy 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, Form C, page 4, the applicant provides projected utilization for each of the existing REC GI endoscopy facilities located in Wake County for each of the first three fiscal years of operation following completion of the project as follows:

<b>Projected GI Endoscopy Cases at all REC Facilities After Shift</b>						
<b>Site</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>	<b>CY2026 (PY1)</b>	<b>CY2027 (PY2)</b>	<b>CY2028 (PY3)</b>
Raleigh Endoscopy Center	13,812	14,084	13,643	13,619	13,588	13,855
Raleigh Endoscopy Center Cary	15,101	15,398	13,346	12,808	12,244	12,485
Raleigh Endoscopy Center North	9,863	10,057	10,153	10,248	10,343	10,547
Raleigh Endoscopy Center Holly Springs (Proposed)	-	-	3,176	4,436	5,745	5,858
<b>Total GI Procedures</b>	<b>38,776</b>	<b>39,540</b>	<b>40,318</b>	<b>41,111</b>	<b>41,920</b>	<b>42,746</b>

(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, Form C, page 5, the applicant projects to perform the following number of GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following project completion, as shown in the table below:

<b>Projected CY 2028 GI Endoscopy Procedures per Room at All REC Facilities</b>				
<b>Site</b>	<b>CY28 (PY3) Procedures</b>	<b>GI Endo Rooms</b>	<b>Procedures per Room</b>	<b>Utilization Capacity</b>
Raleigh Endoscopy Center	13,855	6	2,309	153.9%
Raleigh Endoscopy Center Cary	12,458	4	3,121	208.1%
Raleigh Endoscopy Center North	10,547	3	3,516	234.4%
Raleigh Endoscopy Center - Holly Springs	5,858	3	1,953	130.2%
<b>Total</b>	<b>42,746</b>	<b>16</b>	<b>2,672</b>	<b>178.1%</b>

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

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