

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: July 19, 2019

Findings Date: July 19, 2019

Project Analyst: Mike McKillip

Team Leader: Fatimah Wilson

Project ID #: J-11705-19

Facility: Wake Endoscopy Center-Cary

FID #: 190209

County: Wake

Applicant: Wake Endoscopy Center, LLC

Project: Develop a new ambulatory surgical center with three gastrointestinal endoscopy rooms

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. §131E-183(a) The Agency 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 applicant, Wake Endoscopy Center, LLC (WEC) proposes to develop a new ambulatory surgical center (ASC), Wake Endoscopy Center-Cary (WEC-Cary), with three gastrointestinal (GI) endoscopy rooms.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP).

Policies

There is one policy in the 2019 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 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 proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.4, pages 12-13, 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 assure 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

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 2019 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 for the following reason:
 - 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, WEC, proposes to develop a new ASC with three GI endoscopy rooms to be located at 1805 Kildare Farm Road in Cary (Wake County). In Section C.1, page 14, the applicant states that WEC currently owns and operates an ASC with four GI endoscopy rooms located in Raleigh, and that the managing members of WEC hold 51 percent ownership of Wake Forest Endoscopy Center, LLC (WFEC), which is an ASC with three GI endoscopy rooms located in Wake Forest.

Patient Origin

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3901(6) defines the service area "*as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*" In Section Q, page 96, the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C.3, page 22, the applicant provides the projected patient origin for the first three full fiscal years following the completion of the project, as summarized in the following table:

WEC-Cary Projected Patient Origin						
	CY2021		CY2022		CY2023	
County or State	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Wake	3,567	86.3%	3,666	88.8%	3,766	89.8%
Johnston	209	5.1%	190	4.6%	193	4.6%
Harnett	106	2.6%	108	2.6%	110	2.6%
Durham	75	1.8%	77	1.9%	35	0.8%
Nash	19	0.5%	0	0.0%	0	0.0%
Chatham	15	0.4%	15	0.4%	15	0.4%
Lee	14	0.3%	15	0.4%	15	0.4%
Granville	13	0.3%	14	0.3%	14	0.3%
Orange	13	0.3%	14	0.3%	14	0.3%
Sampson	9	0.2%	9	0.2%	9	0.2%
Cumberland	7	0.1%	7	0.2%	8	0.2%
Moore	5	0.1%	5	0.1%	5	0.1%
Alamance	4	0.1%	4	0.1%	4	0.1%
Carteret	4	0.1%	4	0.1%	4	0.1%
Franklin	0	0.0%	0	0.0%	0	0.0%
Vance	0	0.0%	0	0.0%	0	0.0%
Wilson	0	0.0%	0	0.0%	0	0.0%
Other	69	1.7%	70	1.7%	72	1.7%
Total*	4,132	100.0%	4,127	100.0%	4,192	100.0%

*Totals may not sum due to rounding

Source: Table in Section C.3, page 22 of the application. The applicant identifies the counties included in the "Other" category in a footnote to the table.

In Exhibit C.3, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 24-36, the applicant explains why it believes the population projected to utilize the proposed GI endoscopy rooms needs the proposed services. The applicant states that the need for the project is based on the following factors:

- Historical and projected growth of the service area (Wake County) population and in the age group (ages 50-74) that is expected to utilize the GI endoscopy services (pages 24-27).
- Wake County is one of the most populous counties in the state and serves as a referral center for specialty health services such as GI endoscopy procedures (pages 30-32).
- Increased traffic congestion in southwestern Wake County has had negative impacts on the accessibility to health care services in Raleigh, making it necessary to expand

access to that population by providing services in more convenient locations (pages 33-36).

- Freestanding GI endoscopy centers provide patients with more convenient and cost-effective alternatives to hospital-based services (page 36).
- The existing WEC facility in Raleigh is constrained by the limitations of the current building, which make it impractical to expand services at that site (page 36).

The information is reasonable and adequately supported for the following reasons:

- The applicant provides data to support its projections of population growth and aging in the proposed service area.
- The applicant provides data regarding the historical utilization of GI endoscopy services by the proposed service area population.
- The applicant provides supporting information regarding traffic congestion and accessibility difficulties by the proposed service area population.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization as illustrated in the following table.

	Interim (Partial) Year FY2020*	FY1 CY2021	FY2 CY2022	FY3 CY2023
# of GI Endoscopy Rooms	3	3	3	3
# of GI Endoscopy Procedures	2,683	4,671	4,745	4,820
Annual Percent Change	---	74%	2%	2%
Average # of GI Procedures Per GI Room	894	1,557	1,582	1,607

*Applicant assumes the project will become operational on June 1, 2020.

As shown in the table above, the applicant projects that it will perform 4,671 total GI endoscopy procedures in three GI endoscopy rooms in the first full operating year, and 4,745 GI endoscopy in the second full operating year, which is an average of 1,582 procedures per room [4,745 procedures / 3 rooms = 1,582 procedures per room], which exceeds the utilization threshold of 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

In Section Q, pages 97-101, the applicant provides the assumptions and methodology used to project the need for GI endoscopy services, which is summarized below.

Step 1 – The applicant defines the service area as Wake County and provides the population projections for the service area from 2019 to 2024 from the North Carolina Office of State Budget and Management (NCOSBM).

Step 2 – The applicant projects GI endoscopy cases and procedures for the Wake County population from 2019 to 2024 based on the statewide GI case and procedure use rates for 2017.

Step 3 – The applicant projects GI endoscopy cases and procedures from 2019 to 2024 for the residents outside the proposed Wake County service area based on the statewide GI case and procedure use rates for 2017.

Step 4 – The applicant projects the GI endoscopy room need in the service area from 2019 to 2024 based on the projected GI endoscopy procedures (Steps 2 and 3) and the assumption that 1,500 GI procedures will be performed in each room each year.

Step 5 – The applicant projects the need for GI endoscopy rooms in Cary based on population estimates provided by Claritas.

In Section Q, pages 102-108, the applicant provides the assumptions and methodology used to project utilization at WEC and WEC-Cary, which is summarized below.

Step 1 – The applicant identifies the total GI endoscopy procedures performed at WEC from FFY2014 to FFY2018.

Step 2 – The applicant projects GI endoscopy procedures for WEC based on the assumption that total GI endoscopy procedures at the facility will increase commensurate with the projected Wake County population growth from 2019 to 2024.

Step 3 – The applicant projects GI endoscopy cases and procedures for WEC-Cary based on the historical experience of the three WEC physicians who will transfer to the proposed WEC-Cary facility (See Exhibit H-4 for copies of letters from WEC physicians expressing their support for the proposed project and intention to perform procedures at the facility).

Step 4 – The applicant projects the GI endoscopy procedure volume at WEC following the proposed transfer of physicians from WEC to WEC-Cary.

Step 5 – The applicant projects the total GI endoscopy procedures that will shift from WEC to WEC-Cary and WFEC based on ZIP code data provided by WEC.

Step 6 – The applicant projects the total GI endoscopy procedure volumes at WEC-Cary from FY2020 through FY2023.

Step 7 – The applicant projects utilization at WEC and WEC-Cary through the first three operating years. In Section C.1, pages 107-109, the applicant provides projected utilization of WEC-Cary and WEC for the first three operating years, as summarized in the following tables.

WEC-Cary Projected Utilization

	OY1 June 2020- May 2021	OY2 June 2021- May 2022	OY3 June 2022- May 2023
# of GI Endoscopy Rooms	3	3	3
# of GI Endoscopy Procedures	4,671	4,745	4,820
Average # of GI Procedures Per GI Room	1,557	1,582	1,607

WEC Projected Utilization

	OY1 June 2020- May 2021	OY2 June 2021- May 2022	OY3 June 2022- May 2023
# of GI Endoscopy Rooms	4	4	4
# of GI Endoscopy Procedures	6,168	6,249	6,485
Average # of GI Procedures Per GI Room	1,543	1,581	1,621

On pages 109-112, the applicant projects utilization for WFEC as follows:

Step 8 – The applicant identifies the total GI endoscopy procedures performed at WFEC from FFY2014 to FFY2018.

Step 9 – The applicant projects GI endoscopy procedures for WFEC based on the assumption that total GI endoscopy procedures at the facility will increase commensurate with the projected Wake County population growth from 2019 to 2024.

Step 10 – The applicant projects GI endoscopy cases and procedures for WFEC based on the additional cases expected to transfer from WEC following the addition of a third GI endoscopy room at the WFEC facility. [Note: WFEC was approved to add one GI endoscopy room for a total of three GI endoscopy rooms pursuant to a settlement in Project I.D. # J-8822-12. The third GI endoscopy room at WFEC became operational in May 2019].

Step 11 – The applicant projects utilization at WFEC through the first three operating years. In Section C.1, page 112, the applicant provides projected utilization of WFEC for the first three operating years, as summarized in the following tables.

WFEC Projected Utilization

	OY1 June 2020- May 2021	OY2 June 2021- May 2022	OY3 June 2022- May 2023
# of GI Endoscopy Rooms	3	3	3
# of GI Endoscopy Procedures	4,533	4,613	4,695
Average # of GI Procedures Per GI Room	1,511	1,538	1,565

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected number of GI endoscopy procedures to be performed by the three gastroenterologists that will transfer to the proposed Cary facility are reasonable based on the historical number of GI endoscopy procedures performed by these physicians at the existing WEC.
- Project utilization of the proposed WEC-Cary facility is supported by the historical utilization of the existing WEC and WFEC facilities.
- Projected utilization is based on the projected Wake County population growth rate.

Access

In Section C.8, page 40, 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.” In Section L, page 81, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Payor Category	GI Endo Room Services as Percent of Total
Self-Pay	0.60%
Medicare*	47.52%
Medicaid*	1.76%
Insurance*	47.97%
TRICARE	0.82%
Other (MedCost, Railroad Insurance)	1.36%
Total	100.00%

Source: Table on page 81 of the application.

*Including any managed care.

The projected payor mix is reasonable and adequately supported.

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 identified the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- 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.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant does not propose to reduce, eliminate or relocate GI endoscopy rooms or services; 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.

CA

The applicant, WEC, proposes to develop a new ambulatory surgical center with three gastrointestinal endoscopy rooms to be located in Cary (Wake County).

In Section E.2, pages 50-52, 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 this was not an effective alternative due to the fact that it would not provide the additional capacity to meet the need for GI endoscopy services in the proposed service area.
- Increase the hours of operation at WEC – The applicant states this was not an effective alternative because extending hours of operation results in patient inconvenience due to earlier and later procedure preparation requirement, and additional staffing problems such as overtime pay and staff burnout.
- Expanding the existing WEC facility – The applicant states this was not an effective alternative because there is no available space in the existing building.
- Relocate existing GI endoscopy rooms from the WEC or WFEC facility – The applicant states this was not an effective alternative because relocating existing GI endoscopy rooms from WEC or WFEC would negatively impact those facilities.

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

- The application is conforming to all statutory and regulatory review criteria.
- The alternative will meet the need for additional capacity to perform GI endoscopy procedures for WEC patients from southwestern Wake County.
- The alternative is more cost-effective and convenient for patients and staff.

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 shall materially comply with all representations made in the certificate of need application.**
- 2. Wake Endoscopy Center, LLC shall develop a new ambulatory surgical facility in Cary with three gastrointestinal endoscopy procedure rooms.**

- 3. Upon completion of the project Wake Endoscopy Center-Cary shall be licensed for no more than three gastrointestinal endoscopy procedure rooms.**
 - 4. Wake Endoscopy Center, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.**
 - 5. Wake Endoscopy Center, LLC 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.**
 - 6. For the first three years of operation following completion of the project, Wake Endoscopy Center, LLC shall not increase charges more than 5% of the charges projected in Sections F and 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.**
 - 7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Wake Endoscopy Center, LLC 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.**
 - 8. Wake Endoscopy Center, LLC 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 develop a new ambulatory surgical center with three gastrointestinal endoscopy rooms to be located in Cary (Wake County).

Capital and Working Capital Costs

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

Construction/Renovation Costs	\$1,552,380
Architect/Engineering Fees	\$181,200
Medical Equipment	\$458,355
Miscellaneous (Fees, contingency)	\$148,006
Total	\$2,339,940

In Section Q, page 119, the applicant provides the assumptions used to project the capital cost.

In Section F.3, page 56, the applicant projects \$202,693 in start-up costs and \$286,865 in initial operating expenses, for total working capital required of \$489,558.

Availability of Funds

In Section F.2, page 54, the applicant states the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Wake Endoscopy Center, LLC	Total
Loans	\$2,339,940	\$2,339,940
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,339,940	\$2,339,940

* OE = Owner's Equity

In Section F.3, page 57, the applicant states the working capital cost will be funded as shown in the table below.

Sources of Working Capital Cost Financing

Type	Wake Endoscopy Center, LLC	Total
Loans	\$489,558	\$489,558
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$489,558	\$489,558

* OE = Owner's Equity

Exhibit F.2 contains a letter dated May 8, 2019 from the Senior Vice President of First Citizens Bank expressing the bank's intention to fund the capital and working capital costs of the proposed project. The applicant adequately demonstrate that sufficient funds will be available for the capital and working capital needs of 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.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures	4,671	4,745	4,820
Total Gross Revenues (Charges)	\$8,656,124	\$8,968,419	\$9,292,611
Total Net Revenue	\$4,778,479	\$4,950,877	\$5,129,842
Average Net Revenue per Procedure	\$1,023	\$1,043	\$1,064
Total Operating Expenses (Costs)	\$3,795,310	\$3,944,744	\$4,019,823
Average Operating Expense per Procedure	\$813	\$831	\$834
Net Income	\$983,169	\$1,006,133	\$1,110,019

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by 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 and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - 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 costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

The applicant proposes to develop a new ambulatory surgical center with three gastrointestinal endoscopy rooms to be located in Cary (Wake County).

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3901(6) defines the service area “*as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” In Section Q, page 96, the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

The 2019 State Medical Facilities Plan, Table 6F: Endoscopy Room Inventory, pages 96-97, includes a table showing the existing providers of GI endoscopy services in Wake County, which is summarized below.

Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Procedures	Percent of Capacity
Center for Digestive Diseases & Cary Endoscopy Center	ASC	3	2,390	53.1%
Duke GI at Brier Creek	ASC	4	8,352	139.2%
Duke Raleigh Hospital	Hospital	3	3,761	83.6%
GastroIntestinal Healthcare	ASC	2	1,631	54.4%
Kurt Vernon, MD PA	ASC	1	2,767	184.5%
Raleigh Endoscopy Center	ASC	4	12,312	205.2%
Raleigh Endoscopy Center-Cary	ASC	4	11,546	192.4%
Raleigh Endoscopy Center-North	ASC	3	7,000	155.6%
Rex Hospital	Hospital	4	5,841	97.4%
Triangle Gastroenterology	ASC	2	4,311	143.7%
Wake Forest Endoscopy Center	ASC	2	4,030	134.3%
Wake Endoscopy Center	ASC	4	11,810	196.8%
WakeMed	Hospital	6	5,712	63.5%
WakeMed Cary Hospital	Hospital	4	2,614	43.6%

Source: 2019 State Medical Facilities Plan, Table 6F.

In Section G, page 64, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Wake County. The applicant states:

“This proposal will not result in unnecessary duplication of existing GI endoscopy services in the service area. As Section C of this application demonstrates, population growth in Wake County, health status, increasing demand for outpatient healthcare services, and Wake County’s status as a referral hub, will all contribute to a sustained need for additional capacity in the proposed service area.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed GI endoscopy facility is needed in addition to the existing or approved GI endoscopy facilities.

Conclusion

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 application is conforming to this criterion for the reasons stated 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

In Section Q, Form H, the applicant provide rojected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff
	2nd Full Fiscal Year (FY2022)
Physicians	3.83
Clerical Medical Record	1.00
Registered Nurses	4.00
Surgery Technicians	3.00
Central Sterilization Technicians	1.00
Administrator	0.25
Clerical Administration	1.00
Chief Financial Officer	1.00
Business Office Manager	0.50
TOTAL	16.00

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 65-66, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H.4 page 66, the applicant identifies the proposed medical director. In Exhibit H.4, the applicant provides a letter from the medical director indicating an interest in serving as medical director for the proposed services.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

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.

- (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

In Section I, page 69, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Business Office
- Anesthesia
- Housekeeping and Support Services
- Material Management
- Medical Records
- Pathology and Lab
- Sterile Processing

The applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I.2, page 70, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

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.

- (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 applicants do 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

In Section K, page 72, the applicant state the proposed GI endoscopy facility will occupy 8,000 square feet of leased space in the medical office building currently under development. Line drawings are provided in Exhibit K.3.

In Section K.4, page 73, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit K.4.

In Section K.4, page 74, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section K.4, page 74, the applicant identifies any applicable energy saving features that will be incorporated into the proposed project.

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.

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

C

In Section L.1, page 79, the applicant provides the historical payor mix for the GI endoscopy services at WEC in CY2018, which are shown in the table below.

WEC Payor Mix: CY2018

Payor Category	GI Endoscopy Services as Percent of Total
Self-Pay	0.60%
Medicare*	47.52%
Medicaid*	1.76%
Insurance*	47.97%
TRICARE	0.82%
Other (MedCost, Railroad Insurance)	1.36%
Total	100.00%

Source: Table on page 79 of the application.

*Including any managed care.

In Section L.1, page 79, the applicant provides the following comparison.

	Percentage of Total Patients Served by the WEC Facility CY2018	Percentage of the Population of the Wake County Service Area
Female	54.0%	51.9%
Male	46.0%	48.1%
64 and Younger	70.0%	88.5%
65 and Older	30.0%	11.5%
American Indian	1.1%	1.1%
Asian	2.1%	6.7%
Black or African-American	10.6%	22.3%
Native Hawaiian or Pacific Islander	NA	NA
White or Caucasian	66.0%	67.0%
Other Race	1.0%	2.8%
Declined / Unavailable	1.3%	NA

The Agency reviewed the:

- Application
- Exhibits to the application

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 80, the applicant states that the facility is under no obligation under any applicable federal regulations.

In Section L.2, page 80, the applicant states that during the last five years, no patient civil rights access complaints have been filed against the facility or 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.3, the applicant project the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below.

WEC-Cary Payor Mix: Year 2

Payor Category	GI Endoscopy Services as Percent of Total
Self-Pay	0.60%
Medicare*	47.52%
Medicaid*	1.76%
Insurance*	47.97%
TRICARE	0.82%
Other (MedCost, Railroad Insurance)	1.36%
Total	100.00%

Source: Table on page 81 of the application.

*Including any managed care.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 47.52 percent of total services will be provided to Medicare patients and 1.76 percent to Medicaid patients. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 82, 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

In Section M, page 84, the applicant describes the extent to which health professional training programs in the area have will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive

impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a new ambulatory surgical center with three gastrointestinal endoscopy rooms to be located in Cary (Wake County).

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3901(6) defines the service area “*as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” In Section Q, page 96, the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

The 2019 State Medical Facilities Plan, Table 6F: Endoscopy Room Inventory, pages 96-97, includes a table showing the existing providers of GI endoscopy services in Wake County, which is summarized below.

Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Procedures	Percent of Capacity
Center for Digestive Diseases & Cary Endoscopy Center	ASC	3	2,390	53.1%
Duke GI at Brier Creek	ASC	4	8,352	139.2%
Duke Raleigh Hospital	Hospital	3	3,761	83.6%
GastroIntestinal Healthcare	ASC	2	1,631	54.4%
Kurt Vernon, MD PA	ASC	1	2,767	184.5%
Raleigh Endoscopy Center	ASC	4	12,312	205.2%
Raleigh Endoscopy Center-Cary	ASC	4	11,546	192.4%
Raleigh Endoscopy Center-North	ASC	3	7,000	155.6%
Rex Hospital	Hospital	4	5,841	97.4%
Triangle Gastroenterology	ASC	2	4,311	143.7%
Wake Forest Endoscopy Center	ASC	2	4,030	134.3%
Wake Endoscopy Center	ASC	4	11,810	196.8%
WakeMed	Hospital	6	5,712	63.5%
WakeMed Cary Hospital	Hospital	4	2,614	43.6%

Source: 2019 State Medical Facilities Plan, Table 6F.

In Section N, pages 86-88, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 86, the applicant states,

“WEC-Cary will increase competition in Cary. It will provide increased access to freestanding ASF-based procedures and will offer more easily accessible and high quality, safe patient care at lower cost and charges than a hospital facility. ... The project will

strengthen the capacity of this low-cost provider (WEC) to continue offering price competitive GI endoscopy services.”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

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.

- (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

In Section O.3, page 90, the applicant states the managing members of Wake Endoscopy Center, LLC own or manage three other licensed ambulatory surgical facilities with GI endoscopy rooms in North Carolina.

In Section O.3, page 90, the applicant states that none of the related facilities have operated out of compliance with any Medicare Conditions of Participation during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHRSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at the three facilities, 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.

- (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

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

.3903 PERFORMANCE STANDARDS

- (a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*
- NA- The applicant does not propose to develop operating rooms. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI-Endo procedures only per GI-Endo room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*
- C- The applicant owns two licensed GI endoscopy facilities in the proposed services area: Wake Endoscopy Center (WEC) and Wake Forest Endoscopy Center (WFEC). In Section C, page 43, the applicant projects to perform an average of 1,567 GI endoscopy procedures per GI endoscopy room in the proposed Cary facility during the second year of operation following completion of the project. Also, in Section Q of the application, the applicant projects to perform an average of 1,581 GI endoscopy procedures per GI endoscopy room in the existing WEC facility during the second year of operation following completion of the project, and the applicant projects to perform an average of 1,538 GI endoscopy procedures per GI endoscopy room in the existing WFEC facility during the second year of operation following completion of the project.
- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall demonstrate that at least the following types of GI-Endo procedures will be provided in the proposed facility or GI-Endo room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*

- C- In Section C, page 44, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at the proposed WEC-Cary facility.

- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*
 - (1) *if the applicant or a related entity performs GI-Endo procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI-Endo cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or*
 - (2) *demonstrate that GI-Endo procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*

- NA- In Section C, page 44, the applicant states that neither it nor any related entities own any inpatient operating rooms, outpatient operating rooms or shared operating rooms.

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

- C- In Section Q, 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.