

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: January 26, 2020

Findings Date: January 26, 2020

Project Analyst: Gregory F. Yakaboski

Assistant Chief: Lisa Pittman

Project ID #: K-11941-20

Facility: Four County Endoscopy Center

FID #: 200639

County: Granville

Applicant: Four County Endoscopy Center, LLC

Project: Develop a new licensed ambulatory surgical facility with 2 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.

NA

The applicant, Four County Endoscopy Center, LLC, proposes to develop a new ambulatory surgical facility (ASF), Four County Endoscopy Center (FCEC), with two gastrointestinal endoscopy (GI endo) rooms in Oxford, Granville County. Wake Endoscopy Center, LLC (WEC) is the sole member of FCEC and will be the managing member of FCEC. The ASF's and GI Endoscopy rooms owned by WEC and related entities are identified in Section Q.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2020 State Medical Facilities Plan (SMFP)
- acquire any medical equipment for which there is a need determination in the 2020 SMFP

- offer a new institutional health service for which there are any policies in the 2020 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new ASF with two GI endoscopy rooms.

**Patient Origin**

The 2020 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 104, the applicant identifies the service area as Granville, Vance, Warren Counties, North Carolina and Mecklenburg County, Virginia Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

	1 <sup>st</sup> Full FY (CY2023)		2 <sup>nd</sup> Full FY (CY2024)		3 <sup>rd</sup> Full FY (CY2025)	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Granville	543	27.0%	1,095	35.0%	1,104	35.2%
Vance	393	19.5%	788	25.2%	790	25.2%
Warren	171	8.5%	342	11.0%	342	10.9%
Mecklenburg, VA	903	44.9%	900	28.8%	898	28.6%
Total	2,010	100.0%	3,126	100.0%	3,135	100.0%

Source: Section C.3, page 23

In Section C, page 24, the applicant provides the assumptions and methodology used to project its patient origin. “The applicant based FCEC patient origin on population distribution for Granville, Vance, and Warren counties, promised referrals from Dr. Allen, and procedure to case ratios of WEC physicians and Dr. Allen.” The applicant’s assumptions are reasonable and adequately supported based on the following reasons:

- WEC member companies and Dr. Allen, one of the named physicians that will practice at FCEC, have historically provided services to residents of the proposed service area counties.

- For the 12 months ending June 30, 2020 ... combined...WEC facilities and Dr. Allen served 1,883 patients across the four service area counties.

**Analysis of Need**

In Section C.4, pages 25-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states that the need for the project is based on the following factors:

- The health status of the service area population (pages 26-31).
- Based on state average and health status the history of low GI endoscopy service utilization in the proposed service area (page 31).
- Cost of GI endoscopy services by other providers in the service area (page 32).
- Traffic congestion along the traffic corridor into Wake and Durham counties (pages 32-36).
- The projected growth and aging of the population demographics in the four-county service area (pages 37-40).

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

- 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.
- The applicant provides data to support its projections of population growth, aging and the health status of the population in the proposed service area.
- The applicant provides data to support that fact that freestanding GI endoscopy centers are less costly than hospital-based GI endo rooms.

*Projected Utilization*

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

	<b>FFY1 (CY2023)</b>	<b>FFY2 (CY2024)</b>	<b>FFY3 (CY2025)</b>
# of GI Endoscopy Rooms	2	2	2
# of GI Endoscopy Procedures*	2,297	3,594	3,604
Average # of GI Procedures Per GI Room	1,148	1,797	1,802
Annual Percent Change	na	56.5%	0.3%

\*Note: The number of GI Endoscopy Procedures came from Section Q, page 111. The project analyst notes that the number of GI Endoscopy Procedures in Form C, page 102, for FFY1 to FFY3 are 2,294, 3,591 and 3,602 which are 3, 3 and 2 procedures less, respectively, for FFY1 to FFY3 than those listed on page 111. This is a de minimis difference and the number of GI Endoscopy Procedures from Section Q, page 111, were used as they were supported by the methodology.

In Section Q, pages 103-112, the applicant provides the assumptions and methodology used to project utilization for the proposed GI endoscopy services, which is summarized below.

*Step 1 – Identify the Service Area*

The applicant defines the service area as consisting of three counties in North Carolina: Granville, Warren and Vance Counties as well as one county in Virginia: Mecklenburg County.

In addition, that applicant provides the population projections for the three counties in North Carolina from 2020 to 2025 from Claritas. The applicant states that it finds the projected population data from Claritas to be more conservative than that provided by the North Carolina Office of State Budget and Management (NCOSBM).

	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>
Projected Population of Granville, Warren and Vance Counties	125,604	126,233	126,866	127,504	128,147	128,794

Source: Table on page 104.

*Step2 – Calculate the Projected Growth of GI endoscopy cases and procedures in future years for the NC service area counties by using state use rates*

1<sup>st</sup>: Utilizing data from the 2017-2020 North Carolina Department of Health Service Regulation (NCDHSR) Hospital and Ambulatory Surgery Center Databases and population estimates from NCOSBM the applicant calculates GI case rates of 52.9 per 1,000 population and GI procedure rates of 65.5 per 1,000 population. [Use rate calculations shown in Exhibit C.3, page 11.]

2<sup>nd</sup>: The applicant applies the GI case rate and the GI procedure rate to the projected population from Step 1 to provide estimated GI cases and GI procedures for 2020-2025 for the Granville, Warren and Vance counties as illustrated in the table below.

	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>CY2023</b>	<b>CY2024</b>	<b>CY2025</b>
Projected Population of Granville, Warren and Vance Counties	125,604	126,233	126,866	127,504	128,147	128,794
GI Cases (population x state use rate)	6,641	6,674	6,708	6,742	6,776	6,810
GI Procedures (population x state use rate)	8,225	8,266	8,307	8,349	8,391	8,433

Source: Table on page 105.

**Step 3- Determine GI Endoscopy Room Need in NC Service Area Counties by 2025**

	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025
GI Procedures	8,225	8,266	8,307	8,349	8,391	8,433
GI Endoscopy Room Annual Performance Standards for Procedures	1,500	1,500	1,500	1,500	1,500	1,500
GI Endoscopy Rooms Needed	5.5	5.5	5.5	5.6	5.6	5.6
Existing GI Endoscopy Room Inventory	3	3	3	3	3	3
Projected GI Endoscopy Room Surplus/(Deficit)	(2)	(3)	(3)	(3)	(3)	(3)

Source: Table on page 106.

*Step 4 – Determine GI Endoscopy Room Need in Mecklenburg County, VA by 2025*

	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025
Mecklenburg VA Population	30,547	30,467	30,388	30,308	30,229	30,150
NC State GI Procedure Use Rate	65.5	65.5	65.5	65.5	65.5	65.5
Estimated GI Endoscopy Procedures	2,000	1,995	1,990	1,985	1,979	1,974
GI Endoscopy Room Annual Performance Standards for Procedures	1,500	1,500	1,500	1,500	1,500	1,500
Projected GI Endoscopy Rooms Needed	1.33	1.33	1.33	1.32	1.32	1.32
Existing GI Endoscopy Room Inventory	--	--	--	--	--	--
Projected GI Endoscopy Room Surplus/(Deficit)	(1)	(1)	(1)	(1)	(1)	(1)

Source: Table on page 107

*Step 5- Determine GI Endoscopy procedures in the Service Area Not Served by Dedicated NC Service Area GI Endoscopy Rooms*

	CY2020	CY2021	CY2022	CY2023	CY2024	CY2025
Estimated GI Procedures	8,225	8,266	8,307	8,349	8,391	8,433
Estimated GI Procedures at GHS	1,293	1,303	1,314	1,325	1,336	1,347
Estimated GI Procedures at MPH	1,859	1,864	1,870	1,876	1,882	1,887
Remaining Unserved GI Endoscopy Procedures	5,073	5,098	5,123	5,148	5,174	5,200

Source: Table on page 108

*Step 6- Determine FCEC Market Share of Unserved GI Endoscopy Procedures in NC Service Area Counties, 2023-2025*

	CY2023	CY2024	CY2025
Estimated Unserved GI Endoscopy Procedures	5,148	5,174	5,200
FCEC Market Share	25%	50%	50%
FCEC GI Endoscopy Procedures	1,287	2,587	2,600

Source: Table on page 109

*Step 7- Estimate Dr. Allen Mecklenburg County, VA GI endoscopy procedures at FCED, 2023-2025*

	CY2023	CY2024	CY2025
Estimated Dr. Allen Mecklenburg Procedures Total	1,289	1,285	1,282
Estimated Outpatient portion of all Dr. Allen Cases	97.9%	97.9%	97.9%
Estimated Outpatient Procedures	1,262	1,259	1,252
Percent of Dr. Allen Procedures that will transfer to FCEC	80.0%	80.0%	80.0%
Estimated Dr. Allen Procedures at FCEC	1,010	1,007	1,004

Source: Table on page 110

*Step 8- Determine Total Number of GI Endoscopy Procedures at FCEC by 2025*

	CY2023	CY2024	CY2025
FCEC NC GI Endoscopy Procedures	1,287	2,587	2,600
FCEC Dr. Allen Procedures	1,010	1,007	1,004
Total Projected FCEC GI Endoscopy Procedures	2,297	3,594	3,604

Source: Table on page 111

*Step 9- Determine Number of GI Endoscopy Procedures Per GI Endoscopy Room at FCEC during Second Operating Year, 2025*

	CY2023	CY2024	CY2025
Total Projected FCEC GI Endoscopy Procedures	2,297	3,594	3,604
# of GI Endoscopy Rooms at FCEC	2	2	2
GI Endoscopy procedures per room at FCEC	1,148	1,797	1,802

Source: Table on page 111

As shown in the table above, the applicant projects that it will perform 3,594 total GI endoscopy procedures in two GI endoscopy rooms in the second full operating year, which is an average of 1,797 procedures per room [3,594 procedures / 2 rooms = 1,797 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).

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

- Project utilization of the proposed FCEC facility is supported by the historical patient origin and number of GI endoscopy procedures performed by a physician who will be performing GI endoscopy procedures exclusively at FCEC upon project completion.
- Projected utilization is based on the projected Granville, Vance and Warren Counties population growth rate.
- Projected number of GI endoscopy procedures to be performed is based on the four-year average state use rate based on the data from the NCDHSR Hospital and Ambulatory Surgery Database for 2017-2020.
- The projected number of GI endoscopy procedures are based on a conservative projection of market share for the three North Carolina counties which are part of the service area.
- The projected number of GI endoscopy procedures from Mecklenburg County, VA are based on a letter of support and referral from Dr. Allen, a physician who will be practicing at the proposed FCEC, based on his historical practice and patient origin.

**Access to Medically Underserved Groups**

In Section C, page 46, the applicant states:

*“FCEC will adopt the same practices as its parent, WEC. 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.”*

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Medically indigent or Low-income persons	26.0%
Racial and ethnic minorities	49.6%
Women	51.0%
Persons with Disabilities	13.2%
The elderly	41.0%
Medicare beneficiaries	41.0%
Medicaid recipients	24.0%

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

### **Conclusion**

The Agency reviewed the:

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

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

- The applicant adequately identifies 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 describes the extent to which all residents, including underserved groups, are likely to have access to the proposed services 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 a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

#### CA

The applicant proposes to develop a new ASF with two GI endoscopy rooms.

In Section E.2, pages 57-59, 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 freestanding GI endoscopy centers are more cost-effective than hospital-based and that currently there are no other freestanding GI endoscopy centers in the proposed service area. Patients would must utilize hospital-based GI services or travel out of the service area to utilize the services or a cost-effective freestanding GI endoscopy center if the status quo was maintained. Therefore, the applicant determined that this was not the most effective alternative.
- *Joint Venture*- The applicant states that developing a joint venture structure involves capital risks that rural entities are reluctant to take on without a “CON in hand”. Therefore, the applicant determined that this was not the least costly or most effective alternative.
- *Relocation of Existing GI endoscopy rooms*- The applicant considered relocating GI endo rooms from either one of its member facilities or from one of the hospitals in the service area. WEC facilities have no GI endoscopy rooms in the service area and none of the hospitals were interested in relocating a GI endo room to the proposed facility. Therefore, the applicant determined that this was not the most effective alternative.
- *Operate the new ASF with a Single Physician*- The applicant considered operating the proposed new ASF with a single physician. However, due to efficiencies with working with RMG board-certified gastroenterologists, to prevent physician burnout and to help support recruitment and retention to the underserved area this was determined to not be the most effective alternative.
- *Develop more/less GI endoscopy rooms*- The applicant considered both developing only one GI endoscopy room and developing more than two GI endoscopy rooms, however, based on the experience of its parent, WEC, one GI endoscopy room would not sufficiently meet projected need and more than two GI endoscopy rooms added too much cost. Therefore, the applicant determined that this was neither the least costly nor most effective alternative.

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 applicant provides credible information to explain why it believes the proposed project is the most effective alternative.
- Renovating an existing building was a more cost-effective alternative to building new.

## **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. Four County Endoscopy Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new licensed ambulatory surgical facility with 2 gastrointestinal endoscopy rooms.**
- 3. Upon completion of the project, Four County Endoscopy Center shall be licensed for no more than two GI endo rooms.**
- 4. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 5. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 6. 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. **Progress reports shall be due on the first day of every third month. The first progress report shall be due on April 2, 2021. The second progress report shall be due on July 2, 2021 and so forth.**
7. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project’s proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
8. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
- a. **Payor mix for the services authorized in this certificate of need.**
  - b. **Utilization of the services authorized in this certificate of need.**
  - c. **Revenues and operating costs for the services authorized in this certificate of need.**
  - d. **Average gross revenue per unit of service.**
  - e. **Average net revenue per unit of service.**
  - f. **Average operating cost per unit of service.**
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 develop a new ASF with two GI endoscopy rooms.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 114, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$705,958
Miscellaneous Costs	\$484,966
<b>Total</b>	<b>\$1,190,924</b>

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

In Section F, page 64, the applicant projects that start-up costs will be \$89,673 and initial operating expenses will be \$579,723 for a total working capital of \$669,396. On page 64 and in Section Q, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

**Availability of Funds**

In Section F, page 62, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

Type	Four County Endoscopy Center, LLC	Total
Loans	\$1,190,924	\$ 1,190,924
Accumulated reserves or OE *	\$	\$
Bonds	\$	\$
Other (Specify)	\$	\$
<b>Total Financing</b>	<b>\$1,190,924</b>	<b>\$1,190,924</b>

\* OE = Owner's Equity

In Section F, page 65, the applicant states that the working capital needs of the project will be funded, as shown in the table below.

Sources of Financing for Working Capital		Amount
(a)	Loans	\$589,467
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$
(c)	Lines of credit	\$
(d)	Bonds	\$
(e)	<b>Total *</b>	<b>\$589,467</b>

Exhibit F.2 contains a letter dated August 11, 2020 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 up to \$2,500,000. Exhibit F.2 also contains a letter date August 17, 2020 from the Administrator or Four County Endoscopy Center, LLC committing the First Citizens Bank funds to the 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 Form F.2, the applicant projects that revenues will exceed operating expenses in the second and third operating years of the project, as shown in the table below.

	1 <sup>st</sup> Full Fiscal Year	2 <sup>nd</sup> Full Fiscal Year	3 <sup>rd</sup> Full Fiscal Year
Total Procedures	2,297	3,594	3,604
Total Gross Revenues (Charges)	\$5,093,000	\$8,132,260	\$8,318,444
Total Net Revenue	\$2,143,874	\$3,423,235	\$3,501,608
Average Net Revenue per Procedure	\$933	\$952	\$972
Total Operating Expenses (Costs)	\$2,478,850	\$3,111,090	\$3,159,736
Average Operating Expense per Procedure	\$1,079	\$866	\$877
Net Income	(\$334,976)	\$312,145	\$341,872

\*Note: The number of GI Endoscopy Procedures came from Section Q, page 111. The project analyst notes that the number of GI Endoscopy Procedures in Form C, page 102, for FFY1 to FFY3 are 2,294, 3,591 and 3,602 which are 3, 3 and 2 procedures less, respectively, for FFY1 to FFY3 than those listed on page 111. This is a de minimis difference and the number of GI Endoscopy Procedures from Section Q, page 111, were used as they were supported by the methodology.

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 based on the following:

- 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.

C

The applicant proposes to develop a new ASF with two GI endoscopy rooms.

The 2020 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 104, the applicant identifies the service area as Granville, Vance, Warren Counties, North Carolina and Mecklenburg County, Virginia. Facilities may also serve residents of counties not included in their service area.

The 2020 State Medical Facilities Plan, Table 6E: Endoscopy Room Inventory, pages 87 and 92, includes a table showing the existing providers of GI endoscopy services in Granville and Vance counties, which is summarized below.

Existing Facilities	Facility Type	County	# of GI Endo Rooms	Endoscopy Procedures	Average per Room
Granville Health System	Hospital	Granville	1	830	830
Maria Parham Health	Hospital	Vance	2	2,270	1,135

Source: 2020 State Medical Facilities Plan, Table 6E, pages 87 and 92.

There are no GI endoscopy rooms in Warren County. In Section G, page 70, the applicant states that the applicant does not have access to public data regarding any operational GI endoscopy rooms in Mecklenburg, VA.

In Section G, page 70, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Granville, Vance and Warren Counties, NC, and Mecklenburg County in VA. 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, health status, low use rates, increasing demand for outpatient care, and public cost of care, will all contribute to a sustained need for additional freestanding licensed GI procedure room capacity in the 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 provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Projected FTE Staff
	2nd Full Fiscal Year (CY2024)
Physicians	2.11
Registered Nurses	3.00
Surgery Technicians	3.00
Aides/Orderlies	2.00
Clerical Staff	1.00
Medical Records	1.00
Central Sterilization Supply	1.00
Administrator	1.00
Chief Financial Officer	0.50
Business Office	1.00
<b>TOTAL</b>	<b>15.61</b>

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, page 74, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3 page 78, the applicant identifies the proposed medical director. In Exhibit I.1, 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 76, the applicant states that the following ancillary and support services are necessary for the proposed services:

- Business Office
- Anesthesia
- Housekeeping / Laundry
- Material Management
- Medical Records
- Pathology
- Sterile Processing
- Pre- and Post- Anesthesia, Recovery

On page 76, the applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1.

In Section I.2, page 77, the applicant describes its efforts to develop 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 applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the

North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
  - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
  - (iii) would cost no more than if the services were provided by the HMO; and
  - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

The applicant proposes to develop a new ASF with two GI endoscopy rooms.

In Section K, page 82, the applicant states that the project involves up fitting 6,400 square feet of leased space located at 625 Lewis Street in Oxford. Line drawings are provided in Exhibit K.2.

On page 83, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal.

On page 84, 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 B.4, pages 14-15 and in Section K, page 84, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.



On pages 85-86, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal and power at the site.

**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;

NA

Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13a) is not applicable to this review.

(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;

NA

Neither the applicant nor any related entities own, operate or manage an existing health service facility located in the service area. Therefore, Criterion (13b) is not applicable to this review.

(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 89, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

Payor Category	GI Endoscopy Services as Percent of Total
Self-Pay	0.60%
Medicare*	41.00%
Medicaid*	24.00%
Insurance*	32.21%
TRICARE	0.82%
Other (MCST, Projects, RRMCRE)	1.36%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 89 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.60% of total services will be provided to self-pay patients, 41.0% to Medicare patients and 24.0% to Medicaid patients.

On page 89, the applicant provides the assumptions and methodology used to project payor mix during the first three) full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the experience, FY2019 internal data and information derived from confirming referral sources and visiting the service area provided by the applicant's parent company.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 90, 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 92, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates 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 ASF with two GI endoscopy rooms.

The 2020 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 104, the applicant identifies the service area as Granville, Vance, Warren Counties, North Carolina and Mecklenburg County, Virginia. Facilities may also serve residents of counties not included in their service area.

The 2020 State Medical Facilities Plan, Table 6E: Endoscopy Room Inventory, pages 87 and 92, includes a table showing the existing providers of GI endoscopy services in Granville and Vance counties, which is summarized below.

Existing Facilities	Facility Type	County	# of GI Endo Rooms	Endoscopy Procedures	Average per Room
Granville Health System	Hospital	Granville	1	830	830
Maria Parham Health	Hospital	Vance	2	2,270	1,135

Source: 2020State Medical Facilities Plan, Table 6E, pages 87 and 92.

There are no GI endoscopy rooms in Warren County. In Section G, page 70, the applicant states that the applicant does not have access to public data regarding any operational GI endoscopy rooms in Mecklenburg, VA.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

*“...the project will foster competition by providing expanded access to GI Endoscopy services in a cost-effective and convenient outpatient location ... this will be the only free-standing GI endoscopy ASF in the four-county service area. ... The project will allow this low-cost provider to offer price competitive GI endoscopy services. ... This will encourage competition in the service area.”*

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

*“...freestanding GI endoscopy centers are more cost-effective and efficient than those in hospitals. ...*

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

*“The proposed new ASF will be subject to third-party oversight. It will maintain accreditation by the AAAHC, licensure by the State of North Carolina, and certification by CMS for Medicare and Medicaid participation.”*

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 94-95, the applicant states:

*“FCEC will adopt WEC’s 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. ... The location, ADA compliant building*

*design, and willingness to accept Medicare, Medicaid, hardship patients, and uninsured will all increase access for patients...”.*

Considering all the information in the application, 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 (see Sections C, F, N and Q of the application and any exhibits)
- Quality (see Sections C, N and O of the application and any exhibits)
- Access to medically underserved groups (see Sections L and N of the application and any exhibits)

### **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 based on 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 Q, page 101, the applicant identifies the ambulatory surgical facilities with GI endoscopy rooms located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of 5 (4 existing and 1 under development) of this type of facility located in North Carolina.

In Section O, page 97, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. According to the files in the & Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and by the & Section and considering the quality of care provided at all four of the existing 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

The application is conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities. The specific criteria are discussed below.

**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- In Section C, page 50, and in Section Q, page 111, the applicant projects to perform an average of 1,797 GI endoscopy procedures per GI endoscopy room in the proposed FCEC facility during the second year of operation following completion of the project. Neither the applicant nor any related entities own any other licensed facilities providing GI endoscopy services in the proposed service area.
- (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 51, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at the proposed FCEC 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 51, the applicant states that neither it nor any related entities own any operating rooms in the proposed service area.
  
- (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.