

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 20, 2023

Findings Date: February 20, 2023

Project Analyst: Gregory F. Yakaboski

Co-Signer: Gloria C. Hale

Project ID #: P-12306-22

Facility: CCHC Endoscopy Center

FID #: 061311

County: Craven

Applicants: CCHC Endoscopy Center, Inc.

CCHC Properties, LLC

Project: Add no more than one GI endoscopy room for a total of no more than four GI endoscopy rooms upon project completion

### REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

### C

CCHC Endoscopy Center, Inc. and CCHC Properties, LLC (hereinafter referred to as “the applicant”) proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC Endoscopy Center (CCHC). CCHC is located at 975 Newman Road, New Bern in Craven County.

The applicant does not propose to

- develop any beds or services for which there is a need determination in the 2022 SMFP,
- acquire any medical equipment for which there is a need determination in the 2022 SMFP,
- offer a new institutional health service for which there are any policies in the 2022 SMFP.

There are no policies in the 2022 SMFP which are applicable to this project.

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

- (2) Repealed effective July 1, 1987.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

**C**

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

**Patient Origin**

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

The following table illustrates historical and projected patient origin.

County	Historical (10/1/2020 to 9/30/2021)		Third Full FY of Operation following Project Completion (10/1/2025 to 9/30/2026)	
	Patients	% of Total	Patients	% of Total
Craven	3,230	60.36%	4,055	60.36%
Carteret	986	18.42%	1,237	18.42%
Pamlico	495	9.25%	621	9.25%
Onslow	260	4.86%	326	4.86%
Jones	161	3.01%	202	3.01%
Beaufort	104	1.94%	130	1.94%
Other NC Counties	89	1.66%	112	1.66%
Other States	27	0.50%	34	0.50%
<b>Total</b>	<b>5,352</b>	<b>100.00%</b>	<b>6,717</b>	<b>100.00%</b>

Source: Tables on pages 31 and 32 of the application.

\*\*Includes all other NC counties, each of which represents less than 1% of total patient origin.

In Section C, page 32, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported because they are based on the historical patient origin from CY2021 as the applicant expects all of the same referring physicians/providers will continue to be the source of referrals for CCHC Endoscopy Center.

### **Analysis of Need**

In C.4, pages 33-43, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 33, the applicant states:

- Robust and increasing GI endoscopy room utilization at CCHC Endoscopy Center (pages 33-34).
- Service area demographics (pages 34-39).
- Focus on preventative screening (pages 39-41).
- Historical patient origin and Craven County as a healthcare center (page 42).
- Cost effectiveness of GI endoscopy ASFs (pages 42-43).

The information is reasonable and adequately supported based on the application, exhibits to the application and information publicly available during the review and used by the Agency, including, but not limited to, the following:

- The applicant provides reliable data to support its projections of population growth, aging and the health status of the population in the service area.
- The applicant adequately demonstrates how the proposed project will provide a cost-effective option.
- CCHC Endoscopy Center's historical utilization for its existing three GI endoscopy rooms.
- The applicant adequately demonstrates the need for GI endoscopy services for treatment of GI conditions and early detection of colorectal cancer.
- Historical utilization of CCHC Endoscopy Centers existing three GI endoscopy procedure rooms exceeds the performance standard in 10A NCAC14C .3903(4) and supports the need for a fourth GI endoscopy room even with no growth in utilization.

### **Projected Utilization**

In Section Q, Form C.3a and C.3b, pages 104-105, the applicant provides historical, interim and projected utilization, as illustrated in the following tables:

**CCHC Endoscopy Center: Historical and Interim Utilization**

	<b>Last Full FY</b>	<b>Interim Full FY</b>	<b>Interim Full FY</b>
	<b>(10/1/2020-9/30/2021)</b>	<b>(10/1/2021-9/30/2022)</b>	<b>(10/1/2022-9/30/2023)</b>
<b># of Rooms</b>	3	3	3
<b># of Outpatient GI Procedures</b>	7,401	8709	8839

**CCHC Endoscopy Center: Projected Utilization**

	1st Full FY	2nd Full FY	3 <sup>rd</sup> Full FY
	(10/1/2023-9/30/2024)	(10/1/2024-9/30/2025)	(10/1/2025-9/30/2026)
# of Rooms	4	4	4
# of Outpatient GI Procedures	8,972	9,106	9,242

In Section Q, pages 106-107, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step #1) Historical and Projected CCHC Endoscopy Center GI Endoscopy Procedures (page 106).

The applicant calculated the 6-year compound annual growth rate (CAGR) for GI endoscopy procedures at CCHC. For the period of FFY2016 to FFY2022 the CAGR was 4.49%.

To project utilization through the 3<sup>rd</sup> project year (FFY2026) the applicant used 1.5%, or one-third of the 6-year historical CAGR [ $4.49\%/3 = 1.50\%$ ] as shown in the table below.

**CCHC Endoscopy Center: Projected Utilization**

	FFY2022	FFY2023	FFY2024	FFY2025	FFY2026	4-Year CAGR
Procedures	8,709	8,839	8,972	9,106	9,242	1.50%
Growth Rate		1.5%	1.5%	1.5%	1.5%	

Step #2) Project CCHC Endoscopy Center Patients (pages 106-107).

The applicant first calculated the 5-year procedure/patient ratio at CCHC Endoscopy Center as shown in the table below:

**Historical GI Procedure/Patient Ratio**

Row		FFY2018	FFY2019	FFY2020	FFY2021	FFY2022	Total
A	GI Endoscopy Procedures	6,810	6,782	6,848	7,401	8,709	36,550
B	GI Endoscopy Cases/Patients	5,229	5,089	5,043	5,352	5,853	26,566
C	Procedure/Patient Ratio	1.30	1.33	1.36	1.38	1.49	1.38*

\*Row A/Row B = Row C.

The applicant then projected the number of patients for the first three project years by applying the historical GI Procedure/Patient Ratio to the projected GI endoscopy procedures.

**CCHC Endoscopy Center: Projected Patients**

	FFY2023	FFY2024	FFY2025	FFY2026
Procedures	8,839	8,972	9,106	9,242
Procedure/Patient Ratio	1.38	1.38	1.38	1.38
Patients	6,425 [6,405]	6,521 [6,501]	6,618 [6,599]	6,717 [6,697]

\*Project Analyst's corrections are in brackets.

*Performance Standard for GI endoscopy rooms*

Pursuant to 10A NCAC 14C .3903(4) the GI endoscopy rooms shall project to perform an average of at least 1,500 GI procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project. As shown in the table below utilization in CCHC Endoscopy Center’s GI endoscopy rooms (3 existing and one proposed) exceeds the 1,500 GI procedures per GI endoscopy room for each of the first three project years following completion of the proposed project.

**CCHC Endoscopy Center: Projected Utilization**

	<b>1st Full FY</b>	<b>2nd Full FY</b>	<b>3<sup>rd</sup> Full FY</b>
	<b>(10/1/2023-9/30/2024)</b>	<b>(10/1/2024-9/30/2025)</b>	<b>(10/1/2025-9/30/2026)</b>
# of Rooms	4	4	4
# of Outpatient GI Procedures	8,972	9,106	9,242
Average # of Procedures Per Room	2,243	2,276	2,310
Standard per Performance Rule	1,500	1,500	1,500

Furthermore, the project analyst notes that in CCHC Endoscopy Center’s last full fiscal year for which historical data is available (FFY2021) utilization exceeded the 1,500 GI procedures per GI endoscopy room even if the fourth (proposed) GI endoscopy room was added into the calculation as shown in the table below.

**CCHC Endoscopy Center: Historical and Interim Utilization**

	<b>Last Full FY</b>
	<b>(10/1/2020-9/30/2021)</b>
# of Rooms	4
# of Outpatient GI Procedures	7,401
Average # of Procedures Per Room	1,850
Performance Standard	1,500

Projected utilization is reasonable and adequately supported based on the application, exhibits to the application and information publicly available during the review and used by the Agency, including, but not limited to, the following:

- Projected utilization is based on CCHC Endoscopy Centers historical utilization projected forward at 33% of the facility’s 6-year CAGR.
- The applicant states that existing referral sources from physicians/providers are not expected to change based on the addition of a fourth GI endoscopy room.
- Using historical utilization from the last full fiscal year available (FFY2021) CCHC Endoscopy Center already meets the performance standard based on four GI endoscopy rooms (3 existing and one proposed).
- Projected utilization in the third full fiscal year following project completion exceeds the performance standard set forth in 10A NCAC 14C .3903(4).

**Access to Medically Underserved Groups**

In Section C, page 48, the applicant states, “CCHC is committed to providing services to all persons regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay. Outpatient GI endoscopy services at CCHC Endoscopy Center will continue to be available to all persons listed above, including the medically indigent, the uninsured and the underinsured.” The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

<b>Medically Underserved Groups</b>	<b>Percentage of Total Patients (FFY2026)</b>
Low-income persons	13.2%
Racial and ethnic minorities	12.0%
Women	57.4%
Persons with Disabilities	11.3%
Persons 65 and older	54.9%
Medicare beneficiaries	51.3%
Medicaid recipients	1.8%

Source: Table on page 49 of the application.

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

**Conclusion**

The Agency reviewed the:

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

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

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

**NA**

The applicant 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 one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

In Section E, pages 58-60, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- *Maintain the Status Quo*- The applicant states that in FFY2022, based on the performance standard of 1,500 procedures per GI endoscopy room, CCHC Endoscopy Center's three existing GI endoscopy rooms operated at 194 percent and that for the last seven years have far exceeded the 1,500 procedures per GI endo room standard. CCHC Endoscopy Center now has four physicians and only three GI endo rooms which creates scheduling conflicts. Patients in need of routine screening currently have to wait five months. Therefore, this is not the most effective alternative.
- *Add more than One GI Endoscopy Room*- The applicants determined that this was not the most effective alternative and also a more costly alternative as constructing two additional GI endoscopy rooms would have necessitated a larger capital cost and a longer project lead time. Further, the applicant determined that one additional GI endoscopy room at this time will sufficiently decompress the capacity constraints at CCHC Endoscopy Center.
- *Refer Patients to Local Hospital-Based GI Endoscopy Rooms*- The applicant states that having a GI endoscopy procedure performed at a hospital-based GI endoscopy room, as opposed to at an ASF, costs the patient more. Therefore, this is not the least costly alternative.
- *Establish an additional GI Endoscopy ASF in a Different Geographic Location*- The applicant states that this is a more costly alternative as this option would necessitate either buying or building a new facility in addition to equipping that new facility and staffing the new facility. Further, this option would be unnecessarily duplicative of the existing CCHC Endoscopy Center. Therefore, the applicant determined that this was not the least costly nor the most effective alternative.

On pages 58-60, the applicant states that its proposal is the most effective alternative because:

- Constructing one additional GI Endoscopy room is the least costly, quickest, and most efficient way to decompress the current capacity constraints at CCHC Endoscopy Center.
- The facility cannot extend its hours of operation because due to fasting constraints it is impractical to schedule GI endoscopy procedures late in the day.
- The applicant states that it is not cost-effective to refer patients to a hospital-based GI endoscopy room as it costs a patient less to have a GI endoscopy procedure performed at an ASF as opposed to a hospital-based GI endoscopy room.

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

- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. CCHC Endoscopy Center, Inc. and CCHC Properties, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC Endoscopy Center.**
- 3. Upon project completion, CCHC Endoscopy Center shall be licensed for no more than four GI endoscopy rooms.**
- 4. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. The first progress report shall be due on October 1, 2023.**
- 5. 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.**



6. **No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  7. **For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
  8. **The certificate holder shall 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 one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

**Capital and Working Capital Costs**

In Section Q, Form F.1a, page 108, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$235,000
Miscellaneous Costs	\$242,532
<b>Total</b>	<b>\$477,532</b>

In Section F.1, page 61, Form F.1a, and Exhibits F.1.1 and F.1.2. the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides a written cost estimate of projected construction costs, architectural and engineering fees from a construction firm.
- The applicant provides written cost estimates from vendors regarding equipment.
- The applicant relies on its experience acquiring information technology and other associated systems.

In Section F.3, page 63, the applicant states that there will be no working capital costs (start-up costs and initial operating expenses) associated with the proposed project because CCHC Endoscopy Center is an existing, licensed and operational facility that currently operates GI endoscopy rooms.

### **Availability of Funds**

In Section F, page 61, the applicant states that the capital cost will be funded, as shown in the table below.

<b>Sources of Capital Cost Financing</b>			
<b>Type</b>	<b>CCHC Endoscopy Center, Inc.</b>	<b>CCHC Properties, LLC</b>	<b>Total</b>
Loans	\$0	\$0	\$0
Accumulated reserves or OE *	\$182,532	\$295,000	\$477,532
Bonds	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
<b>Total Financing</b>	<b>\$182,532</b>	<b>\$295,000</b>	<b>\$477,532</b>

\* OE = Owner's Equity

Exhibit F.2 (Tab 13) contains a letter dated November 3, 2022 Chief Executive Officer of Coastal Carolina Health Care, PA (CCHA) which is the ultimate parent of the two applicants in this review. The Chief Executive Officer confirms that he has authority to commit funds to cover the capital costs of the proposed project and that upon approval of the proposed project the necessary funds will be transferred to both CCHC Endoscopy Center, Inc. and CCHC Properties, LLC with no obligation for the funds to be repaid.

Exhibit F.2 (Tab 13) further contains a copy of a bank statement for CCHC from an account with First Citizens Bank for the period October 1, 2022 to October 31, 2022 showing approximately \$11 million in CCHC's checking account.

In addition, Exhibit F.2 (Tab 13) also contains two letters, both dated November 3, 2022, committing that CCHC Endoscopy Center, Inc. and CCHC Properties, LLC will use the funds from CCHC for the proposed project.

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

### **Financial Feasibility**

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

	<b>1<sup>st</sup> Full Fiscal Year</b>	<b>2<sup>nd</sup> Full Fiscal Year</b>	<b>3<sup>rd</sup> Full Fiscal Year</b>
Total Procedures*	8,972	9,106	9,242
Total Gross Revenues (Charges)	\$9,719,611	\$10,013,010	\$10,315,266
Total Net Revenue	\$2,927,046	\$3,015,403	\$3,106,427
Average Net Revenue per procedures	\$326	\$331	\$336
Total Operating Expenses (Costs)	\$2,629,346	\$2,762,703	\$2,878,212
Average Operating Expense per procedures	\$293	\$303	\$311
Net Income	\$297,700	\$252,701	\$228,215

\*Procedures are GI endoscopy procedures.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, Form F.2/3 Assumptions, page 116. [The Project Analyst notes that there are three pages numbered “116” which are all part of Form.F.2/3 Assumptions. The Project Analyst concludes that two page numbers were typographical errors.] The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Payor mix, used to calculate gross revenue, is based on the applicant’s historical experience of operating CCHC Endoscopy Center.
- Percentages for contractual allowances, bad debt and employee benefits are all based on the applicants experience operating the facility.
- Percentage increases in annual wages, direct (non-salary) and indirect expenses are all provided.
- The applicant projects a 1.5% annual increase in charges.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
  - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
  - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

**C**

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

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

The 2022 SMFP, Table 6F *Endoscopy Room Inventory*, page 87, shows there are three existing facilities with GI endoscopy rooms in Craven County, as shown below.

**Craven County Endoscopy Facilities and Rooms**

Existing Facilities	# of Endoscopy Rooms	Adjustments for CONS	Endoscopy Cases	Endoscopy Procedures
CarolinaEast Internal Medicine	3	0	2,171	2,174
CarolinaEast Medical Center	2	0	2,133	3,985
CCHC Endoscopy Center*	3	0	5,043	6,848

\*Neither the applicant, nor a related entity, owns or controls any other GI endoscopy rooms in Craven County.

In Section G, pages 70-71, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Craven County. The applicant states:

*“CCHC Endoscopy Center demonstrates the need the population has for the additional GI endoscopy room based on demographic data specific to the defined service area, high colorectal cancer incidence rates, historical GI endoscopy utilization at CCHC Endoscopy Center, and the benefit of enhanced access to a busy freestanding facility with non-HOPD charges.”*

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

- CCHC Endoscopy Center’s three existing GI endoscopy rooms have consistently performed above the performance standard for GI endoscopy services, demonstrating the need for an additional GI endoscopy room at CCHC Endoscopy Center.
- The applicant does not own or control any other GI endoscopy rooms in Craven County, nor does the applicant have a related entity that owns or controls any other GI endoscopy rooms in Craven County.
- The applicant adequately demonstrates that the proposed GI endoscopy room is needed in addition to the existing or approved GI endoscopy rooms.

### **Conclusion**

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

### **C**

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

In Section Q, Form H, page 113, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	(10/1/2022)	3rd Full Fiscal Year (10/1/2025-9/30/2026)
Registered Nurses	8.50	9.00
Licensed Practical Nurses	1.00	1.00
Certified Nurse Aides/Nursing Assistants	1.00	1.25
Director of Nursing	1.00	1.00
Surgical Technicians (GI endo)	1.00	1.25
Clerical	1.00	1.00
Other	6.00	6.00
<b>TOTAL</b>	<b>19.50</b>	<b>20.50</b>

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form 3b. In Section H.2 and H.3, pages 72-74, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs.

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

- CCHC Endoscopy Center is an existing operational facility.
- CCHC Endoscopy Center uses a variety of ways to recruit, including staff recruitment/referral bonus, and maintain low staff turnover including excellent benefits, paid time off and flexible employment options.
- The applicant states that CCHC Endoscopy Center will continue to offer comprehensive training and continuing education to all staff members, based on industry standards, recommended practices and guidelines.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

### **Ancillary and Support Services**

In Section I, page 76, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 76-77, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibits I.1.1, I.1.2 and I.1.3. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- CCHC is an existing outpatient GI endoscopy center with systems and agreements already in place to provide the necessary ancillary and support services.
- The applicant states that it will continue to provide corporate services including: compliance and internal audit, human resources, billing/revenue, legal, information technology, accounting and interpreter services.

### **Coordination**

In Section I.2, pages 77-78, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that CCHC Endoscopy Center will continue to work local partners such as the county health department, social service providers and numerous community organizations.
- The applicant states that CCHC Endoscopy Center has well-established relationships with other providers including a transfer agreement with the local acute care hospital.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

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

NA

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

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

C

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

In Section K, page 81, the applicant states that the project involves constructing 400 square feet of new space. Line drawings are provided in Exhibit K.1.

On pages 81-82, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:



- The applicant states that the proposed project costs are the most reasonable alternative based on the experience, expertise and knowledge of the contractor, architect and the applicant.
- The materials and labor costs were based by the architect on escalation factors including construction industry forecasts and inflation predictions.
- The project is being constructed at an existing ASF that is already appropriately zoned for these services reducing costs and potential project delays.
- The contractor based estimated costs on historical construction cost data and experience designing similar medical projects.

On page 82, 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 based on the following:

- The applicant states that CCHC Endoscopy Center is an ASF and that ASFs are able to offer GI endoscopy services at a lower cost than a full-service hospital.
- The applicant states that ASFs *“provide cost-effective care that can moderate healthcare costs for the patient, government, and third-party payors.”*
- The applicant states that this project will not increase the charges or projected reimbursement for services.

On pages 82-83, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

**C**

In Section L, page 86, the applicant provides the historical payor mix during for the last full fiscal year (10/1/2020 to 9/30/2021) for the proposed services, as shown in the table below.

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	0.49%
Charity Care	0.24%
Medicare*	51.29%
Medicaid*	1.81%
Insurance*	41.74%
TRICARE	4.43%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 86.

\*Including any managed care plans.

In Section L, page 87, the applicant provides the following comparison.

	<b>Percentage of Total Patients Served by the Facility or Campus during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	57.55%	49.60%
Male	42.56%	50.40%
Unknown	0.00%	0.00%
64 and Younger	45.05%	79.70%
65 and Older	54.95%	20.30%
American Indian	0.09%	0.70%
Asian	0.58%	3.00%
Black or African American	10.89%	21.10%
Native Hawaiian or Pacific Islander	0.09%	0.20%
White or Caucasian	79.62%	63.80%
Other Race	0.30%	11.20%
Declined / Unavailable	8.43%	0.00%

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

**C**

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 88, the applicant states:

*“CCHC Endoscopy Center has no obligation under federal regulations to provide uncompensated care or community service or access by minorities and handicapped persons.”*

In Section L, page 89, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

**C**

In Section L, page 89, the applicant projects the following payor mix for the proposed services during the third full fiscal year (10/1/2025 to 9/30/2026) of operation following completion of the project, as shown in the table below.

<b>Payor Category</b>	<b>Percent of Total Patients Served</b>
Self-Pay	0.49%
Charity Care	0.24%
Medicare*	51.29%
Medicaid*	1.81%
Insurance*	41.74%
TRICARE	4.43%
<b>Total</b>	<b>100.0%</b>

Source: Table on page 89.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.49% of total services will be provided to self-pay patients, 0.24% to charity care patients, 51.29% to Medicare patients and 1.81% 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 following:

- CCHC Endoscopy will continue to rely on the same existing referring physicians/providers for referrals.
- The applicant states that the addition of a fourth GI endoscopy room will have no impact on the existing referring physicians/providers or its source of referrals.
- CCHC Endoscopy projects the payor mix for the first three full fiscal years following project completion based on the historical payor mix for CY2021.

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.5, page 91, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

## C

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

In Section M, page 92, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- CCHC Endoscopy Center has an existing training affiliation agreement with Edgecombe Community College.
- The applicant states that CCHC Endoscopy Center “*accepts students for clinical rotations that are enrolled in Practitioner, Medical Assistant, Phlebotomy, Radiography, and Information Technology academic programs.*”
- The applicant states that CCHC Endoscopy Center will enter into other training affiliations as well as maintain clinical training affiliations.

### **Conclusion**

The Agency reviewed the:

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

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

(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 one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

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

The 2022 SMFP, Table 6F *Endoscopy Room Inventory*, page 87, shows there are three existing facilities with GI endoscopy rooms in Craven County, as shown below.

**Craven County Endoscopy Facilities and Rooms**

Existing Facilities	# of Endoscopy Rooms	Adjustments for CONS	Endoscopy Cases	Endoscopy Procedures
CarolinaEast Internal Medicine	3	0	2,171	2,174
CarolinaEast Medical Center	2	0	2,133	3,985
CCHC Endoscopy Center	3	0	5043	6,848

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

*“The addition of one GI endoscopy room at CCHC Endoscopy Center will promote competition in the service area because it will enable the facility to better meet the needs of its existing patient population, and to ensure timely provision of and convenient access to high quality, cost-effective outpatient GI endoscopy services for residents of Craven County and surrounding communities.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 93-95, the applicant states:

*“This GI endoscopy room addition project will make lower cost GI endoscopy services more broadly available to credentialed physicians and their patients. ... Freestanding GI endoscopy centers are more cost effective for insurance companies and for patients because they do not have the higher overhead costs of hospitals. ... This GI endoscopy addition project will not increase the charges or projected reimbursement for these services, which are established by Medicare, Medicaid, and/or existing private payor contracts.”*

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

Regarding the impact of the proposal on quality, in Section N, pages 95-96, the applicant states:

*“The proposed project will promote safety and quality in the delivery of healthcare services. CCHC Endoscopy Center will continue to be dedicated to providing excellent care for patients ... CCHC Endoscopy Center will continue to be licensed by the State of North Carolina, certified for participation in Medicare and Medicaid, and accredited by the Accreditation Association for Ambulatory Health Care (AAAHC). ... CCHC Endoscopy Center will continue to adhere to high standards and quality of care ... CCHC Endoscopy Center will continue to require all employees to participate in initial orientation, ongoing in-service education, and to have regular performance evaluations.”*

See also Section O of the application and any exhibits.

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

*“CCHC Endoscopy Center is committed to providing services to all persons, regardless of race, ethnicity, gender, age, religion, creed, disability, national origin, or ability to pay ... Outpatient GI endoscopy services will continue to be available to all persons, including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved persons including the medically indigent, the uninsured and the underinsured. CCHC Endoscopy Center will continue to provide free aids and services to people with disabilities in order to communicate effectively with them.”*

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

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

## **Conclusion**

The Agency reviewed the:

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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

### C

The applicant proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at CCHC.

In Section Q, Form O, page 114, the applicant identifies the GI endoscopy facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one of this type of facility located in North Carolina.

In Section O, page 100, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care did not occur in this facility. According to the files in the Acute and Home Care Licensure and Certification 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 had not occurred in this facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at this facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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

### C

The application is conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903. The specific criteria are discussed below.

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



### **.3903 PERFORMANCE STANDARDS**

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

*(1) identify the proposed service area;*

- C- In Section C, page 51, the applicant states the primary service area for CCHC Endoscopy Center is Craven County and the secondary service area includes Carteret and Pamlico counties. Section 10A NCAC 14C .3901(6), defines the service area as “*the county where the proposed GI endoscopy room will be developed.*” The proposed GI endoscopy room will be developed at CCHC Endoscopy Center in Craven County. Thus, the service area for the facility is Craven County.

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

- C- In Section C, page 51, the applicant states that neither the applicant nor a related entity own or operate any GI endoscopy rooms in the service area in addition to the three existing GI endoscopy rooms at CCHC Endoscopy Center.

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

- C- In Section Q, Forms C.3a and C.3b, pages 104-105, and in Form C.3a/b Assumptions and Methodology, page 106, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project for all existing and approved GI endoscopy rooms at CCHC Endoscopy Center.

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

- C- In Section Q, page 106, in Form C.3a/b Assumptions and Methodology, the applicant projects to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy procedure room during the third full fiscal year of operation following project completion.

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

- C- In Section Q, pages 106-107, the applicant provides the assumptions and methodology used to project the utilization required by this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.