

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: February 24, 2023

Findings Date: February 24, 2023

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala Mitchell

Project ID #: Q-12302-22

Facility: Carolinas Endoscopy Center

FID #: 061341

County: Pitt

Applicant: Carolinas Endoscopy Center, LLC

Project: Add no more than one GI endoscopy room for 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

Carolinas Endoscopy Center, LLC (hereinafter referred to as “the applicant”) proposes to develop one GI endoscopy room for a total of four GI endoscopy rooms at Carolinas Endoscopy Center (CEC). CEC is located at 2210 Hemby Lane, Greenville in Pitt County. The facility was formerly known as Gastroenterology East.

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- (2) Repealed effective July 1, 1987.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 CEC.

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 CEC in Pitt County. Thus, the service area for the facility is Pitt 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 (CY 2021)		Third Full FY of Operation following Project Completion (CY 2027)	
	Patients	% of Total	Patients	% of Total
Pitt	2,340	24.3%	2,368	24.3%
Beaufort	1,060	11.0%	1,073	11.0%
Bertie	451	4.7%	457	4.7%
Hertford	412	4.3%	417	4.3%
Martin	929	9.6%	941	9.6%
Nash	385	4.0%	390	4.0%
Wayne	836	8.7%	846	8.7%
Other *	3,218	33.4%	3,255	33.4%
Total	9,631	100.0%	9,747	100.0%

Source: Tables on pages 33-36 of the application.

*Includes all other NC counties and other states that are at less than 4.0% of the total.

In Section C, page 35, 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 no change in the percent of patient distribution.

Analysis of Need

In C.4, pages 38-48, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 38, the applicant identifies:

- Demographics of HSA VI (pages 39-40).
- Health status of HSA VI (pages 41-43).
- Pitt County as a referral center and historical patient pattern of CEC (pages 44-45).
- High utilization of GI endoscopy services at CEC (pages 45-46).
- Cost of care for GI endoscopy patients (pages 46).
- Changes in the GI endoscopy healthcare delivery system in HSA VI (pages 47-48).

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 highlighted points listed below:

- The applicant provides reliable data to support its projections of population growth.
- The applicant documents the shortage of gastroenterologists in support of the need of residents from a wide-range of counties in HSA VI relying on and traveling to CEC for GI procedures.
- The applicant adequately demonstrates how the proposed project will provide a cost-effective option.
- The applicant adequately demonstrates the need of the population in HSA VI has for GI endoscopy services for treatment of GI conditions and early detection of colorectal cancer.
- Historic utilization of CEC existing three GI endoscopy procedure rooms greatly 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 107 and 109, the applicant provides historical, interim and projected utilization, as illustrated in the following tables:

CEC Endoscopy Center: Historic and Interim Utilization

	Last Full FY	Interim Full FY	Interim Full FY	Interim Partial	Interim Partial
	CY20221	CY2022	CY2023	1/1/2024 to 2/29/2024	3/1/2024 to 12/31/2024
# of Rooms	3	3	3	3	4
# of Outpatient GI Procedures	9,731	9,821	9,913	1,667	8,337

CEC Endoscopy Center: Projected Utilization

	1st Full FY	2nd Full FY	3rd Full FY
	CY2025	CY2026	CY2027
# of Rooms	4	4	4
# of Outpatient GI Procedures	10,098	10,191	10,191

In Section Q, pages 110-123, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Forecast Need

Step #1) Determine CEC’s primary service area (pages 110-112).

- Pursuant to 10ANCAC 14C .3901 “*service area*” for a GI endoscopy room is “*the county where the proposed GI endoscopy room will be developed*”. However, the applicant states that based on historic patient origin for the last three years CEC served patients from the 29 counties of HSA VI. Therefore, the population of HSA VI was included to develop both need and utilization projections.

Step #2) Determine the estimated population of HSA VI (page 113).

Step #3) Determine the primary service area GI endoscopy case and procedure use rate, 2018-2021 (page 114).

Step #4) Project GI endoscopy cases and procedures in primary service area, 2022-2028 (pages 115-116).

- The applicant calculates that there will be a need for 86,000 GI endoscopy procedures in HSA VI by the third project year (CY2027).

Forecast Utilization

Step #5) Determine the average annual growth rate of procedures at CEC, CY2018 to CY2021 (page 117).

- The applicant calculated the 4-year average annual growth rate for CEC GI endoscopy procedures for CY2018-CY2021 to be 8.0%. [The project analyst notes that for the same 4-year period the compound annual growth rate (CAGR) was 6.04%.]

Step #6) Forecast annual GI endoscopy of procedures by county performed at CEC at estimated growth rate, 2022-2028 (page 118).

- The applicant only projected growth in GI endoscopy procedures at 0.9%
- The applicant projects no growth in GI endoscopy procedures for the third project year (CY2027). The applicant projects CEC will perform the same number of GI endoscopy

procedures for CY2027 as for CY2026. This was done to be conservative in projecting utilization.

Step #7) Calculate CEC’s average procedure per case, CY2018-2021 (page 119).

- The applicant notes that some patients receive more than one procedure at a time. The applicant calculated the average ratio of patients (cases) to GI procedures for the 4-year period of CY2018-CY2021. This ratio was 1.05.

Step #8) Forecast annual GI endoscopy cases by county at CEC, CY2022-CY2028 (page 120).

- Utilizing the ratio of patients (cases) to procedures and the projected number of procedures the applicant calculated projected CEC GI endoscopy patients for the interim and first three project years.

Performance Standard Threshold and Capacity Tests

Step #9) Ensure CEC forecast procedures meet performance standard (page 121).

CED Endoscopy Center: Projected Utilization

	1st Full FY	2nd Full FY	3rd Full FY
	CY2025	CY2026	CY2027
# of Rooms	4	4	4
# of Outpatient GI Procedures	10,098	10,191	10,191*
Avg # of GI Procedures per Room	2,524	2,548	2,548
Performance Standard per Room**	1,500	1,500	1,500

*Note: The applicant keeps projected growth flat from CY2026 to CY2027.

**See 10A NCAC 14C .3903

Step #10) CEC GI endoscopy procedure room and physician capacity, sensitivity test (pages 122-123).

The project analyst notes, furthermore, that in CECs last full fiscal year for which historic 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.

CEC: Last Full Year of Historic Utilization

	Last Full FY
	CY2021
# of Rooms*	4
# of Outpatient GI Procedures	9,731
Average # of Procedures Per Room	2,433
Performance Standard Per Room*	1,500

*See 10A NCAC 14C .3903

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 highlighted points listed below:

- Projected utilization at CEC is based on historical utilization projected forward at 0.9% which is conservative as compared to CECs 4-year annual average growth rate of 8.0% or CECs 4-year CAGR of 6.04%.
- Using historical utilization from the last full fiscal year available (FFY2021) the number of GI endoscopy procedure performed at CEC exceeds the performance standard based on four GI endoscopy rooms (3 existing and the one proposed).
- CEC is proposing to add a GI endoscopy room and a physician.
- 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 53, the applicant states, “*CEC provides accessible care to medically underserved groups, including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved persons, including the medically indigent, uninsured, or underinsured.*” The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	10.0%
Racial and ethnic minorities	41.7%
Women	62.0%
Persons with Disabilities	12.0%
Persons 65 and older	36.3%
Medicare beneficiaries	29.0%
Medicaid recipients	7.0%

Source: Table on page 54 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 CEC.

In Section E, pages 63-65, 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 maintaining the status quo does not address increasing demand for GI endoscopy services. Maintaining the status quo does not allow for capacity for additional providers, does not provide for long-term scalable solutions to meet expected demand, will result in overworked staff, increased wait times and risk impacting quality of care. Therefore, this is not the most effective alternative.
- *Increase Hours of Operations*- The applicant states that this would increase staffing costs, lead to physician burnout or inability of physicians to see clinic patients. CEC already operates every week of the year, Monday through Friday and one Saturday per month for seven hours per day. Adding hours at the end of the day would require patients to fast for longer periods which decreases patient satisfaction and comfort. Therefore, this was neither the least costly nor the most effective alternative.
- *Add more than One GI Endoscopy Room*- The applicant determined that this was not the most effective alternative as the existing ASF is limited to what space can be renovated. In addition, adding more than one additional GI endoscopy room could put undue strain on support spaces. An expansion of more than one GI endoscopy room would be very costly and not fit within CEC's leased space. Therefore, this was neither the least costly nor most effective alternative.
- *Build a New Freestanding ASF*- The applicant states that this is a much more costly alternative given the price of both land and construction costs, even if a parcel of land as ideally situated as the current location could be located. Therefore, the applicant determined that this was not the least costly nor the most effective alternative.

On page 65, the applicant states that its proposal is the most effective alternative because:

- The physicians and endoscopy center are in the same building.
- The existing leased space has a room that can be converted into the fourth GI endoscopy room at a very low cost.
- Renovating existing space to add the fourth GI endoscopy room allows CEC to take advantage of the pre-existing support spaces, central sterile, reception, pre-and post-op bays all at no additional cost.
- The existing location is within one mile of ECU medical center and centrally located in Pitt County.

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. Carolinas 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 one GI endoscopy room for a total of four GI endoscopy rooms at Carolinas Endoscopy Center.**
- 3. Upon project completion, Carolinas 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 CEC.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 124, the applicant projects the total capital cost of the project, as shown in the table below.

Site Costs	\$0
Construction Costs	\$235,395
Miscellaneous Costs	\$378,479
Total	\$613,874

In Section F.1, page 66, Form F.1a Capital Cost Assumptions, and Exhibit F.1. 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 and architectural fees. See Exhibit F.1.
- The applicant provides written cost estimates from vendors regarding equipment. See Exhibit F.1.
- The applicant provides for a contingency of 1.5% above costs.

In Section F.3, page 69, the applicant states that there will be no working capital costs (start-up costs and initial operating expenses) associated with the proposed project because CEC is an existing, licensed and operational facility.

Availability of Funds

In Section F, page 66, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Carolinas Endoscopy Center, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$613,874	\$613,874
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$613,874	\$613,874

* OE = Owner's Equity

Exhibit F.2 contains a letter dated September 2, 2022, from the Senior Vice President of First Citizens Bank attesting that Gastroenterology East PA has the funds to cover the cost of the proposed project up to \$630,000. [Carolinas Endoscopy Center, LLC is co-owned by Covenant Physicians Partners, Inc. (51%) and Gastroenterology East PA (49%)]

Exhibit F.2 also contains a letter signed September 23, 2022, from Gastroenterology East PA stating that the funds will be transferred to Carolinas Endoscopy Center, LLC to pay for the cost of the proposed project.

Exhibit F.2 also contains a letter dated October 26, 2022, from the managing member of Carolinas Endoscopy Center, LLC stating that she has the authority to commit the funds for completion of 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.

	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	10,098	10,191	10,191
Total Gross Revenues (Charges)	\$36,547,871	\$36,887,315	\$36,887,315
Total Net Revenue	\$11,902,098	\$12,012,641	\$12,012,641
Average Net Revenue per procedures	\$1,179	\$1,179	\$1,179
Total Operating Expenses (Costs)	\$10,293,043	\$10,519,241	\$10,729,733
Average Operating Expense per procedures	\$1,019	\$1,032	\$1,053
Net Income**	\$1,609,056	\$1,493,400	\$1,282,908

*Procedures are GI endoscopy procedures.

** The average charge was based on CEC's 2021 experience. The average charge is held constant through the third project year which accounts for the decreasing net income.

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q, Form F.2a and F.2b Assumptions, page 128. 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 CEC in 2021.
- Percentages for contractual allowances are based on the applicants experience operating the facility and held constant through the project years.
- The average charge was based on CEC's 2021 experience. The average charge is held constant through the third project year.
- 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 CEC.

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 CEC in Pitt County. Thus, the service area for the facility is Pitt County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP, Table 6F Endoscopy Room Inventory, page 93, shows there are six existing facilities with GI endoscopy rooms in Pitt County, as shown below.

Pitt County Endoscopy Facilities and Rooms

Existing Facilities	# of Endoscopy Rooms	Adjustments for CONS	Endoscopy Cases	Endoscopy Procedures
Atlantic Gastroenterology Endoscopy Center	2	0	3,239	3,418
Carolina Digestive Diseases	2	0	3,333	3,504
Carolinas Endoscopy Center*	3	0	7,831	7,831
East Carolina Endoscopy Center	2	0	1,884	2,150
Quadrangle Endoscopy Center	6	0	3,701	4,256
Vidant Medical Center	4	1	5,491	7,962

*Neither the applicant, Carolinas Endoscopy Center, LLC, nor a related entity, owns or controls any other GI endoscopy rooms in Pitt County.

In Section G, page 76, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Pitt County. The applicant states:

“In the aggregate in FY2021, Pitt County GI procedure rooms are operated at 114 percent of the performance standard in 10A NCAC 14C .3903. ... The proposed project is not designed to address the inadequacy or inability of existing providers. The proposed project is intended to increase the capacity, access and quality of the services provided by CEC and to address current and expected future demand for those procedures. History strongly supports and justifies the additional room at CEC.”

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:

- CEC’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 CEC.
- The applicant does not own or control any other GI endoscopy rooms in Pitt County, nor does the applicant have a related entity that owns or controls any other GI endoscopy rooms in Pitt 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 CEC.

In Section Q, Form H, page 133, the applicant provides projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

CEC: Projected Staffing

	1st Full FY (CY2025)	2nd Full FY (CY2026)	3rd Full FY (CY2027)
Registered Nurses	17	17	17
Licensed Practical Nurses	1	1	1
Director of Nursing	1	1	1
Nurse Practitioners/Physician Assistants	4	4	4
Physicians	3	3	3
Other- GI Tech	11	11	11
Other-Receptionist	3	3	3
Total	40	40	40

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, page 78, 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:

- CEC is an existing operational facility.
- CEC uses a variety of ways to recruit. including job fairs, maintain relationships with area training programs and a generous benefits package.
- The applicant states that CEC tracks staff credentials to ensure that all remain current with state and professional certification and licensure. CEC also provides a stipend to each tech and nurse to cover the cost of qualified training.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

Ancillary and Support Services

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed services. On pages 80-81, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- CEC is an existing outpatient GI endoscopy center with systems and agreements already in place to provide the necessary ancillary and support services.
- The applicant provides a letter from the managing member of CEC attesting to the availability of all necessary ancillary and support services for the proposed project. See Exhibit I.1.

Coordination

In Section I.2, pages 81-82, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that CEC is an established provider in Pitt County and HSA VI.
- The applicant states that CEC maintains extensive and continuous working relationships with area healthcare providers including area physician groups and ECU Health Medical Center. See Exhibit I.2 for letters of support.

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 CEC.

In Section K, page 84, the applicant states that the project involves renovating 615 square feet of existing space. Line drawings are provided in Exhibit K.2.

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

- The applicant states that the cost, design, and means of construction represent the most reasonable alternative.
- The project is being constructed at an existing ASF that is already appropriately zoned for these services reducing costs and potential project delays.
- The applicant is relying on experienced architects. The architect states that he as “*designed and supervised construction of GI endoscopy rooms in North Carolina for more than a decade*”. The applicant also has cost estimates from a contractor.

On page 85, 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 “*Even with no increase in procedures, current demand supports the proposed expansion. ... This project will add very little to expense and will enable the Applicant to continue to operate very efficiently.*”
- The applicant states that this project will not increase the charges or projected reimbursement for services.

On page 85, 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 88, the applicant provides the historical payor mix during for the last full fiscal year (CY 2021) for the proposed services, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	1.0%
Medicare*	29.0%
Medicaid*	7.0%
Insurance*	57.0%
Other (TRICARE and VA)	6.0%
Total	100.0%

Source: Table on page 88.

*Including any managed care plans.

In Section L, page 90, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	62.0%	51.6%
Male	38.0%	48.4%
Unknown	na	na
64 and Younger	63.7%	78.8%
65 and Older	36.3%	21.2%
American Indian	na	1.3%
Asian	na	1.5%
Black or African-American	18.0%	36.8%
Native Hawaiian or Pacific Islander	na	0.5%
White or Caucasian	42.0%	57.2%
Other Race	2.0%	2.6%
Declined / Unavailable	38.0%	na

The Agency reviewed the:

- Application

- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and 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 91, the applicant states that CEC is under no obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L, page 91, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed in North Carolina against this facility or any other parties related to this entity.

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 92, the applicant projects the following payor mix for the proposed services during the third full fiscal year (CY 2027) of operation following completion of the project, as shown in the table below.

Payor Category	Percent of Total Patients Served
Self-Pay	1.0%
Medicare*	29.0%
Medicaid*	7.0%
Insurance*	57.0%
Other (TRICARE and VA)	6.0%
Total	100.0%

Source: Table on page 92.

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.0% of total services will be provided to self-pay patients, 29.0% to Medicare patients and 7.0% to Medicaid patients.

On page 92, 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:

- CEC is an established provider.
- The applicant states that CEC has consistent patient patterns and bases projected payor mix on historic payor mix (CY2021).
- The applicant expects that payor mix to remain constant through the third project year with its historic payor mix from 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, page 95, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application

- Exhibits to the application

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

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

C

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

In Section M, page 96, 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:

- CEC has an existing relationship with Pfeiffer University's Physician's Assistant program.
- The applicant states that CEC "*maintains ongoing relationships with schools and training programs to both support the training programs and facilitate staff recruiting. The proposed project will also participate in these efforts.*"

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 CEC.

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 CEC in Pitt County. Thus, the service area for the facility is Pitt County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP, Table 6F Endoscopy Room Inventory, page 93, shows there are six existing facilities with GI endoscopy rooms in Pitt County, as shown below.

Pitt County Endoscopy Facilities and Rooms

Existing Facilities	# of Endoscopy Rooms	Adjustments for CONS	Endoscopy Cases	Endoscopy Procedures
Atlantic Gastroenterology Endoscopy Center	2	0	3,239	3,418
Carolina Digestive Diseases	2	0	3,333	3,504
Carolinas Endoscopy Center*	3	0	7,831	7,831
East Carolina Endoscopy Center	2	0	1,884	2,150
Quadrangle Endoscopy Center	6	0	3,701	4,256
Vidant Medical Center	4	1	5,491	7,962

*Neither the applicant, Carolinas Endoscopy Center, LLC, nor a related entity, owns or controls any other GI endoscopy rooms in Pitt County.

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

“CEC will promote competition in the service area because it will enable the Applicant to better meet the needs of the growing and aging population. With more capacity, it can better ensure timely provision of and convenient access to high quality, cost-effective, outpatient care for a specialized service. ... Additional capacity at CEC that offers these competitive prices and quality care will only serve to encourage competition in the proposed service area.”

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

“The proposal will have a positive impact on cost effectiveness of services because the proposal will utilize existing space to offer additional services. ... Freestanding GI endoscopy centers are more cost-effective than those in hospitals. Hospital-based GI endoscopy rooms have more expensive rates.”

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 98, the applicant states:

“The proposal will have a positive impact on quality of GI endoscopy services offered. ... Adding a fourth GI endoscopy room will allow CEC to increase the availability of GI endoscopy services to its patients with minimum stress on staff. ... All CEC physicians are board-certified and benchmark themselves to national standards. CEC is subject to third-party oversight. It is accredited by the AAAHC, licensed by the State of North Carolina, and certified by CMS for Medicare and Medicaid participation.”

See also Section O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 98-99, the applicant states:

“CEC will continue to serve medically underserved groups. Additional capacity means additional access for these groups.

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

See also 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 CEC.

In Section Q, Form O, page 134, 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, 101, and Exhibit I.1, 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 56, the applicant states the service area for CEC is Pitt 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 57, 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 CEC.

(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 C, page 57, and in Section Q, Form C.3b, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms at CEC.

(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 C, page 57 and in Section Q, Form C.3b, page 109, 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 110-123, 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.