

## REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: May 29, 2024

Findings Date: May 29, 2024

Project Analyst: Gregory F. Yakaboski

Co-Signer: Micheala Mitchell

Project ID #: P-12482-24

Facility: CarolinaEast Gastroenterology

FID #: 240128

County: Craven

Applicant: CarolinaEast Health System

Project: Relocate existing ASF with three GI endoscopy rooms

### 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.

NA

CarolinaEast Health System (hereinafter referred to as “the applicant”), proposes to relocate its licensed, three-room gastrointestinal (GI) endoscopy ambulatory surgical facility (ASF), CarolinaEast Gastroenterology (CarolinaEast) to a new location less than 2.0 miles away in an existing medical office building (MOB).

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2024 SMFP
- acquire any medical equipment for which there is a need determination in the 2024 SMFP
- offer a new institutional health service for which there are any policies in the 2024 SMFP

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

- (2) Repealed effective July 1, 1987.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

**C**

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

**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 2024 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.” CarolinaEast is currently located in Craven County and, with this application, is proposing to relocate to another location also within 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 CarolinaEast’s historical and projected patient origin.

| County   | Historical<br>(7/1/2022 to 6/30/2023) |            | Third Full FY of Operation following<br>Project Completion<br>(7/1/2027 to 6/30/2028) |            |
|----------|---------------------------------------|------------|---|------------|
|          | Patients                              | % of Total | Patients  | % of Total |
| Craven   | 1,526                                 | 61.0%      | 2,265   | 61.0%      |
| Carteret | 382                                   | 15.3%      | 567   | 15.3%      |
| Onslow   | 265                                   | 10.6%      | 393   | 10.6%      |
| Pamlico  | 127                                   | 5.1%       | 189   | 5.1%       |
| Jones    | 140                                   | 5.6%       | 207   | 5.6%       |
| Other*   | 60                                    | 2.4%       | 89  | 2.4%       |
| Total    | 2,500                                 | 100.0%     | 3,711   | 100.0%     |

Source: Tables on pages 30 and 32 of the application.

\*Other Counties include Beaufort, Duplin, Lenoir, Wilson, Greene and Pitt counties in NC.

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. The applicant does not expect the proposed relocation to impact projected patient origin as the proposed site is located within

two miles and a six-minute drive from the existing location and, as such, will have not material impact on the ability of existing patients to access the proposed services.

**Analysis of Need**

In Section C.4, pages 34-39, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

- The use of GI endoscopy services for detection, diagnosis, and prevention of GI conditions (pages 35-36).
- The need to relocate the licensed GI endoscopy ASF (pages 36-38).
- Population aging and growth (pages 38-39).

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 from the North Carolina Office of State Budget and Management (NC OSMB) to support its projections of population growth, aging and in the service area.
- The applicant adequately documents that the existing location is too small to provide adequate pre- and post- procedure space with no additional room available without costly renovations. In addition, an exterior door was added to the leased space several years ago which has the effect of limiting space, particularly recovery space for GI endoscopy patients.
- The facility is leased, not owned, by CarolinaEast Health System, which limits the construction potential of the site. The new location is a MOB owned by the applicant.
- The GI practice, currently co-located with CarolinaEast, is being relocated to the proposed new site. To maintain sufficient staffing, convenient access for patients and providers, and to avoid confusion regarding where to go for GI appointments the applicant states that it is important that the GI endoscopy ASF and the GI practice continue to be co-located in a facility with sufficient space.

**Projected Utilization**

In Section Q, Form C.3b, page 96, the applicant provides projected utilization, as illustrated in the following table:

**CarolinaEast: Projected Utilization**

|                                      | <b>1st Full FY</b>          | <b>2nd Full FY</b>          | <b>3<sup>rd</sup> Full FY</b> |
|--------------------------------------|-----------------------------|-----------------------------|-------------------------------|
|                                      | <b>(7/1/2025-6/30/2026)</b> | <b>(7/1/2026-6/30/2027)</b> | <b>(7/1/2027-6/30/2028)</b>   |
| <b># of Rooms</b>                    | 3                           | 3                           | 3                             |
| <b># of Outpatient GI Procedures</b> | 3,578                       | 3,655                       | 3,735                         |

In Section Q, pages 97-99, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The facility name on its license is currently CarolinaEast Internal Medicine. The facility name will be changed upon project completion to CarolinaEast Gastroenterology.

The first three project years will correspond to the State Fiscal Year (SFY), which is CarolinaEast Health System’s fiscal year.

- Project Year One: July 1, 2025 to June 20, 2026
- Project Year Two: July 1, 2026 to June 20, 2027
- Project Year Three: July 1, 2027 to June 20, 2028

Step #1) Historical Utilization

The applicant converted the data from its License Renewal Applications (LRA’s) from Federal Fiscal Year to SFY utilization data.

**CarolinaEast: Historical Utilization**

|                         | SFY20 | SFY21 | SFY22 | SFY23 | 4-year CAGR * |
|-------------------------|-------|-------|-------|-------|---------------|
| GI Endoscopy Procedures | 2,359 | 2,355 | 2,479 | 2,516 | 2.2%          |

\*Compound Annual Growth Rate

The applicant notes that two factors have impacted the volumes of GI endoscopy procedures at CarolinaEast:

- #1) The number of GI endoscopy procedures declined in SFY20 due to the impacts of the COVID-19 pandemic and are still returning; and
- #2) An exterior door was added a few years ago that impacted recovery space in the current location, limiting throughput and constraining overall volume at the facility.

Step #2) Projected Utilization

CarolinaEast currently has three GI endoscopy physicians. CarolinaEast Health System is in the process of recruiting a fourth GI endoscopy physician for CarolinaEast to start upon completion of the relocation of CarolinaEast.

**CarolinaEast: Projected Utilization- Not Including 4<sup>th</sup> Physician**

|                                  | SFY23 | SFY24 | SFY25 | SFY26 | SFY27 | SFY28 | 4-year CAGR |
|----------------------------------|-------|-------|-------|-------|-------|-------|-------------|
| GI Endo Procedures               | 2,516 | 2,570 | 2,626 | 2,683 | 2,741 | 2,801 | 2.2%        |
| Existing GI endo Physicians      | 3     | 3     | 3     | 3     | 3     | 3     |             |
| Average Procedures per Physician | 839   | 857   | 875   | 894   | 914   | 934   |             |

**CarolinaEast: Projected Utilization- Including 4<sup>th</sup> Physician**

|  | SFY23 | SFY24 | SFY25 | SFY26 | SFY27 | SFY28 | 4-year CAGR |
|--|-------|-------|-------|-------|-------|-------|-------------|
| GI Endoscopy Procedures  | 2,516 | 2,570 | 2,626 | 2,683 | 2,741 | 2,801 | 2.2%        |
| Existing GI endoscopy Physicians   | 3     | 3     | 4     | 4     | 4     | 4     |             |
| Additional GI endoscopy procedures associated with 4 <sup>th</sup> Physician | na    | na    | 657*  | 894   | 914   | 934   |             |
| Average Procedures per Physician   | 2,516 | 2,570 | 3,283 | 3,578 | 3,655 | 3,735 |             |

\*Based on start date of the second quarter

The applicant states that the projections are based on the historic growth rate of CarolinaEast of 2.2% plus the addition of a fourth physician.

The applicant considers the projected number of GI endoscopy procedures to be conservative based on:

- \*The impact of the COVID pandemic.
- \*The physical constraints of the existing facility, specifically the outer door being added which created space constraints and thus reduced patient throughput impacting volumes.

In addition, the quick ramp-up time of the fourth physician is considered reasonable as the new physician is being recruited specifically to help the other physicians meet demand at the clinic, hospital and the ASF.

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 CarolinaEast’s historical utilization growth rate of 2.2%
- The applicant states that the projected growth rate is conservative given the space constraints at the existing facility combined with the impact of the COVID-19 pandemic has held down the historic growth rate at CarolinaEast with the new location addressing the space constraints and volumes continuing to return after the COVID-19 pandemic.
- CarolinaEast will be adding a fourth GI endoscopy physician to address existing demand at the clinic, hospital and ASF.

**Access to Medically Underserved Groups**

In Section C, page 46, the applicant states,

*“Patients of CarolinaEast Health System have many rights, including the right to receive medical and nursing services without discrimination based on age, race, ethnicity, color, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, gender identity, national origin, or source of payment (see Patient Rights and Responsibilities Policy, Exhibit C.6).”*

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

| Medically Underserved Groups | Percentage of Total Patients<br>(3 <sup>rd</sup> FFY: 7/1/27 – 6/30/28) |
|------------------------------|---|
| Low-income persons           |   |
| Racial and ethnic minorities | 26.7%   |
| Women                        | 53.0%   |
| Persons with Disabilities    |   |
| Persons 65 and older         | 43.2%   |
| Medicare beneficiaries       | 17.9%   |
| Medicaid recipients          | 4.5%  |

Source: Table on page 46 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.

### **C**

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

In Section D, page 51, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 51, the applicant states:

*“The proposed site is located within two miles and a six-minute drive from the existing facility. As such, the proposed relocation will have no material impact on the ability of existing patients to access the proposed services. Further ... the relocation will*

*maintain the co-location of the GI endoscopy ASF and a GI clinic, ensuring convenient access for patients and providers.”*

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

- The two locations are less than 2.0 miles away from each other, according to Google Maps. Thus, the GI endoscopy services will still be accessible to the same population at the new location.

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

In Section D, page 52, the applicant states:

*“CarolinaEast Health System has historically provided services to all persons in need of medical care, regardless of age, race, ethnicity, color, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, gender identity, national origin, or source of payment and will continue to do so following completion of the proposed project. In addition, the relocated GI endoscopy ASF will be on the first floor, ensuring easy access for elderly patients and people with disabilities.”*

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

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

## CA

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

In Section E, page 56, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

Relocate the GI endoscopy ASF to a Different Location- The applicant determined that other locations were less effective as the proposed new location is an existing, recently vacated, MOB owned by the applicant where the GI practice is being relocated to. Locating the GI endoscopy ASF in a different location than the GI practice would negatively impact efficient staffing and reduce access to patients and providers. Therefore, the applicant determined that relocating to a different location would be more costly and less effective.

On page 56, the applicant states that its proposal is the most effective alternative because the applicant owns the recently vacated MOB where the GI endoscopy ASF is proposed to be relocated to, the GI practice that supports CarolinaEast is being relocated to the MOB, the MOB is within approximately two miles of the current location so existing patients would continue to be served with no interruption.

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. CarolinaEast Health System (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**



2. **The certificate holder shall relocate the existing ASF with three GI endoscopy rooms from 2604 Dr. M. L.K. Jr Boulevard, New Bern to 640 McCarthy Boulevard, New Bern.**
  3. **Upon completion of the project, CarolinaEast Gastroenterology shall be licensed for no more than three GI endoscopy rooms.**
  4. **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.**
  5. **Progress Reports:**
    - a. **Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
    - b. **The certificate holder shall complete all sections of the Progress Report form.**
    - c. **The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
    - d. **The first progress report shall be due on November 1, 2024.**
  6. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

## C

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

### **Capital and Working Capital Costs**

In Section Q, Form F.1a, page 100, the applicant projects the total capital cost of the project, as shown in the table below.

|                    |                    |
|--------------------|--------------------|
| Site Preparation   | \$16,699           |
| Construction Costs | \$2,783,118        |
| Medical Equipment  | \$764,248          |
| Contingency Costs  | \$366,077          |
| <b>Total</b>       | <b>\$3,930,142</b> |

In Section F.1, page 57, Section Q, Form F.1a, pages 100-101, 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 site preparation, landscaping and construction costs are based on the project architects experience with similar projects.
- The experience of CarolinaEast Health System with other similar projects was relied upon for projected costs for non-medical equipment, medical equipment, fees for consultants, architects and engineers
- The applicant included a contingency fee of 9.3% as part of projected capital costs.

In Section F.3, pages 59-60, the applicant states there will be no start-up costs or initial operating expenses because CarolinaEast is an existing facility.

**Availability of Funds**

In Section F.2, page 57, the applicant states that the capital cost will be funded, as shown in the table below.

**Sources of Capital Cost Financing**

| Type  | CarolinaEast Health System | Total              |
|---|----------------------------|--------------------|
| Loans   | \$                         | \$                 |
| Cash and Cash Equivalents, Accumulated Reserves or OE * | \$3,930,142                | \$3,930,142        |
| Bonds   | \$                         | \$                 |
| Other (Specify)   | \$                         | \$                 |
| <b>Total Financing</b>                                  | <b>\$3,930,142</b>         | <b>\$3,930,142</b> |

\* OE = Owner's Equity

Exhibit F.2-1 contains a letter dated February 15, 2024, from the Chief Financial Officer for CarolinaEast Health System, documenting the availability of enough accumulated reserves for the capital needs of the proposed project. Exhibit F.2-2 contains the audited financial statements of CarolinaEast Health System that show that as of June 30, 2022, CarolinaEast Health System had \$15.79 million in cash and cash equivalents and a total net position of \$634.9 million.

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, page 104, the applicant projects that revenues will not exceed operating expenses in any of the first three full fiscal years following completion of the project, as shown in the table below.

However, CarolinaEast Gastroenterology is part of the CarolinaEast Health System. The applicant also provided pro forma financial statements for the CarolinaEast Health System for the first three full fiscal years of operation following completion of the project. In Form F.2b, page 105, the applicant projects that revenues will exceed operating expenses in each of the first three full fiscal years following completion of the project, as shown in the table below.

**CarolinaEast**

|   | <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                        | 3,578                                   | 3,655                                  | 3,735                                  |
| Total Gross Revenues (Charges)          | \$7,090,115                             | \$7,461,378                            | \$7,852,081                            |
| Total Net Revenue                       | \$2,716,568                             | \$2,858,817                            | \$3,008,514                            |
| Average Net Revenue per Procedure       | \$759                                   | \$782                                  | \$805                                  |
| Total Operating Expenses (Costs)        | \$3,322,549                             | \$3,433,303                            | \$3,548,331                            |
| Average Operating Expense per Procedure | \$929                                   | \$939                                  | \$950                                  |
| Net Income                              | (\$605,981)                             | (\$574,486)                            | (\$539,817)                            |

\*1<sup>st</sup> Full Fiscal Year: 7/1/2025-10/30/2026

**CarolinaEast Health System**

|                                  | <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 Gross Revenues (Charges)   | \$1,892,412,452                         | \$1,956,782,943                        | \$2,023,343,797                        |
| Total Net Revenue                | \$612,914,511                           | \$633,628,533                          | \$655,043,358                          |
| Total Operating Expenses (Costs) | \$603,671,077                           | \$624,108,828                          | \$645,239,373                          |
| Net Income                       | \$9,243,435                             | \$9,519,705                            | \$9,803,985                            |

\*1<sup>st</sup> Full Fiscal Year: 7/1/2025-10/30/2026

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- 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 relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

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 2024 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.*” CarolinaEast is currently located in Craven County and, with this application, is proposing to relocate to another location also within 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 2024 SMFP, Table 6D Endoscopy Room Inventory, page 84, 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 |
|---|----------------------|----------------------|-----------------|----------------------|
| Carolina East Internal Medicine (a/k/a CarolinaEast Gastroenterology) * | 3                    | 0                    | 2,495           | 2,500                |
| CarolinaEast Medical Center   | 2                    | 0                    | 2,098           | 3,145                |
| CCHC Endoscopy Center   | 3                    | 1                    | 5,853           | 8,709                |

\*This is the facility which the applicant seeks to relocate within Craven County.

In Section G, page 67, 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:

*“The proposed project involves the relocation of an existing, licenses GI endoscopy ASF and will not result in the addition or elimination of GI endoscopy rooms in Craven County. Further, the proposed site is located within two miles and a six-minute drive from the existing location and, as such, will have no material impact on the ability of existing patients to access the proposed services. As a result, CarolinaEast Health system expects the GI endoscopy ASF will continue to serve the same subset of patients. Thus, there will be no duplication of services.”*

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:

- The proposal would not result in an increase in GI endoscopy rooms in Craven County.
- The applicant adequately demonstrates that the proposed relocation of the ASF with two GI endoscopy rooms 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.

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

In Section Q, Form H, the applicant provides both the current and projected staffing for CarolinaEast through the first three operating years of the project.

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 Section Q, Form F.3b, page 108. In Sections H.2 and H.3, pages 69-70, the applicant describes the methods to be used to recruit or fill new positions and its proposed 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:

- Staffing is based on the historical staffing at CarolinaEast with the assumption that only one additional Full Time Employee (FTE) (gastroenterologist) will be needed.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## **C**

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

### **Ancillary and Support Services**

In Section I.1, page 71, the applicant identifies the necessary ancillary and support services for the proposed services. On page 71-72, and in Exhibit I.1, the applicant explains how each ancillary and support service is or will be made available. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on

the fact that CarolinaEast is an existing GI endo ASF facility and currently provides all necessary ancillary and support services for its GI endo services.

### **Coordination**

In Section I, pages 72, 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:

- CarolinaEast is an GI endo ASF facility with extensive existing relationships with other local health care and social service providers.
- The applicant provides letters of support in Exhibit I.2.

### **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 stated above.

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

- (i) would be available under a contract of at least 5 years duration;
- (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
- (iii) would cost no more than if the services were provided by the HMO; and
- (iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

C

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

In Section K, page 81, the applicant states that the project involves renovate 6,167 square feet in an existing MOB. Line drawings are provided in Exhibit C.1-2.

On pages 75-76, 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 based on renovating existing space in an MOB which is less expensive than constructing new space.
- The GI endoscopy ASF will be co-located with the GI practice which will promote operational efficiencies while maintaining convenience for providers and patients.

On page 76, 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:

- CarolinaEast Health System *“benefits from significant cost savings measures through the consolidation of multiple services, economies of scale, and focus on providing care in the lowest cost setting as appropriate.”*
- The applicant states that it will not have to increase costs or charges to pay for the project as it has set aside excess revenues from previous years to enable it to pay for this proposed project.



On page 76, 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 79, the applicant provides the historical payor mix for CarolinaEast during the last full fiscal year (7/1/2022-6/30/2023) for the proposed services, as shown in the table below.

| <b>Payor Category</b>            | <b>Percentage of Total Patients Served</b> |
|----------------------------------|--|
| Self-Pay                         | 1.5%                                       |
| Medicare*                        | 17.9%                                      |
| Medicaid*                        | 4.5%                                       |
| Insurance*                       | 62.4%                                      |
| Other (TRICARE and other payors) | 13.7%                                      |
| <b>Total</b>                     | <b>100.0%</b>                              |

Source: Table on page 79 of the application.

\*Including any managed care plans.

In Section L, page 80, 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                              | 53.0%   | 50.1%  |
| Male                                | 46.9%   | 49.9%  |
| Unknown                             | 0.1%  |  |
| 64 and Younger                      | 56.8%   | 79.1%  |
| 65 and Older                        | 43.2%   | 20.9%  |
| American Indian                     | 0.1%  | 0.7%   |
| Asian                               | 0.9%  | 3.1%   |
| Black or African American           | 22.1%   | 20.8%  |
| Native Hawaiian or Pacific Islander | 0.1%  | 0.2%   |
| White or Caucasian                  | 72.5%   | 71.9%  |
| Other Race                          | 3.5%  | 3.3%   |
| Declined / Unavailable              | 0.8%  |  |

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 81, the applicant states:

*“Carolina Health System has no obligation to provide a specific uncompensated care amount, community service, or access to care by minorities or persons with disabilities.”*

In Section L, page 82, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against the licensed 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 79, the applicant provides the projected payor mix for CarolinaEast during the third full fiscal year (7/1/2027-6/30/2028) of operation for the proposed services, as shown in the table below.

| <b>Payor Category</b>            | <b>Percentage of Total Patients Served</b> |
|----------------------------------|--|
| Self-Pay                         | 1.5%                                       |
| Medicare*                        | 17.9%                                      |
| Medicaid*                        | 4.5%                                       |
| Insurance*                       | 62.4%                                      |
| Other (TRICARE and other payors) | 13.7%                                      |
| <b>Total</b>                     | <b>100.0%</b>                              |

Source: Table on page 82 of the application.

\*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.5% of total inpatient GI endo services will be provided to self-pay patients, 17.9% to Medicare patients and 4.5% to Medicaid patients.

In Section Q, page 110, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is based on the FY 2023 actual (historic) payor mix for the existing GI endoscopy ASF to be relocated within two miles of its current location. The projected payor mix is reasonable and adequately supported.

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

**C**

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 away in an existing MOB.

In Section M, page 85, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area have access to the facility for training purposes based on the following:

- The applicant provided a list of clinical programs that utilize CarolinaEast Health Systems for their student rotations in Exhibit M.1.

**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.

- (15) Repealed effective July 1, 1987.  
(16) Repealed effective July 1, 1987.  
(17) Repealed effective July 1, 1987.

- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

**C**

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast, to a new location less than 2.0 miles away in an existing MOB.

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 2024 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.” CarolinaEast is currently located in Craven County and, with this application, is proposing to relocate to another location also within 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.

**Craven County Endoscopy Facilities and Rooms**

| Existing Facilities   | # of Endoscopy Rooms | Adjustments for CONS | Endoscopy Cases | Endoscopy Procedures |
|---|----------------------|----------------------|-----------------|----------------------|
| Carolina East Internal Medicine (a/k/a CarolinaEast Gastroenterology) * | 3                    | 0                    | 2,495           | 2,500                |
| CarolinaEast Medical Center   | 2                    | 0                    | 2,098           | 3,145                |
| CCHC Endoscopy Center   | 3                    | 1                    | 5,853           | 8,709                |

\*This is the facility which the applicant seeks to relocate within Craven County.

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 86, the applicant states:

*“The proposed project is expected to enhance competition in the service area by promoting cost effectiveness, quality, and access to GI endoscopy services in Craven County. Approval of the proposed project will ensure that CarolinaEast Health System can continue to compete for patients in Craven Count for ambulatory GI endoscopy services in a non-hospital setting.”*

Regarding the impact of the proposal on cost effectiveness, in Section N, pages 86-87, the applicant states:

*“CarolinaEast Health System will renovate space in an existing MOB to accommodate the relocated GI endoscopy ASF. The design and means of the proposed renovation were developed to minimize the cost of the project by renovating existing space rather than construct new space. ... the continued co-location of the GI endoscopy ASF and the GI practice will minimize fragmentation, promote operational efficiencies, and maintain convenience for patients and providers...”*

...

*While the GI endoscopy ASF is and will remain accredited, and while it is and will be licensed as an ASF by the State, CarolinaEast Health System has not pursued the ASF billing as a Medicare-certified Ambulatory Surgical Center (ASC), and thus does not bill a facility fee.”*

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

Regarding the impact of the proposal on quality, in Section N, page 87, the applicant states:

*“It is in CarolinaEast Health System’s mission statement to ‘deliver compassionate, quality care.’ The proposed project is motivated, in part, by the need to continue to provide high quality, efficient service. ... the proposed relocation of the GI endoscopy ASF will enhance patient throughput, patient privacy, and overall patient experience.... CarolinaEast Health System is committed to providing the highest quality of care possible.”*

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 87, the applicant states:

*“Medically underserved groups will continue to have access to the GI endoscopy ASF following the proposed project. ... Patients of CarolinaEast Health System have many rights,, including a right to receive medical and nursing services without discrimination based on age, race, ethnicity, color, religion, culture, language, physical or mental disability, socioeconomic status, sex, sexual orientation, gender identity, national origin, or source of payment (see Patient Rights and Responsibilities Policy, Exhibit C.6). Further, the proposed site will be located on the first floor of the building, which will ensure easy access for elderly patients and people with disabilities.”*

See also Sections C and L 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**

In Section Q Form O, page 116, the applicant identifies the hospitals and ASFs located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one other related facility located in North Carolina.

In Section O, page 91, the applicant states that, during the 18 months immediately preceding the submittal of the application, none of the facilities listed on Form O have had a situation resulting in a finding of immediate jeopardy. 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 in none of these facilities. 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 both facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.

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.

**NA**

The applicant proposes to relocate its licensed, three-room GI endoscopy ASF, CarolinaEast Gastroenterology, to a new location less than 2.0 miles away. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3900, are not applicable to this review because the applicant does not propose to develop a new GI endoscopy room in a licensed health service facility.