

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 3, 2023

Findings Date: July 3, 2023

Project Analyst: Julie M. Faenza

Co-Signer: Micheala Mitchell

Project ID #: F-12315-23

Facility: Carolina Digestive Endoscopy Center-Concord

FID #: 230124

County: Cabarrus

Applicants: Carolina Digestive Health Associates P.A.

Carolina Digestive Endoscopy Center-Concord

Project: Develop a new ASF with no more than one GI endoscopy room

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

Carolina Digestive Health Associates P.A. and Carolina Digestive Endoscopy Center-Concord (hereinafter referred to as “the applicant”), propose to develop a new ambulatory surgical facility (ASF), Carolina Digestive Endoscopy Center-Concord (CDEC-Concord), with no more than one gastrointestinal endoscopy (GI) procedure room upon project completion.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2023 State Medical Facilities Plan (SMFP),

- acquire any medical equipment for which there is a need determination in the 2023 SMFP, or
- offer a new institutional health service for which there are any policies in the 2023 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- (2) Repealed effective July 1, 1987.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 develop a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

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 2023 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 facility will be developed in Cabarrus County. Thus, the service area for the proposed facility is Cabarrus County. Facilities may also serve residents of counties not included in their service area.

CDEC-Concord is not an existing facility and thus has no historical patient origin. The following table illustrates projected patient origin.

CDEC-Concord Projected Patient Origin						
	FFY 2026		FFY 2027		FFY 2028	
	# Patients	% of Total	# Patients	% of Total	# Patients	% of Total
Alamance	1	0.06%	1	0.06%	1	0.06%
Anson	139	7.43%	143	7.43%	148	7.43%
Cabarrus	445	23.75%	458	23.75%	472	23.75%
Forsyth	3	0.18%	3	0.18%	4	0.18%
Rowan	110	5.86%	113	5.86%	116	5.86%
Stanly	327	17.46%	337	17.46%	347	17.46%
Union	844	45.08%	869	45.08%	895	45.08%
Wake	3	0.18%	3	0.18%	4	0.18%
Total	1,872	100.00%	1,928	100.00%	1,986	100.00%

Source: Section C, page 37

Note: Federal Fiscal Year (FFY) = October 1 through September 30.

In clarifying information requested by the Agency, the applicant states it used FFYs for patient origin because that was the information available at the time the application was submitted.

In Section C, page 37, the applicant provides assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin for the proposed facility based on historical patient origin for its existing patients who live in counties to the east of Mecklenburg County.
- The applicant projects patient origin based on the historical growth in volume of patients who reside east of Mecklenburg County.

Analysis of Need

In Section C, pages 38-39, the applicant explains why it believes the population projected to be served by the proposed project needs the proposed services, summarized as follows:

- The applicant currently operates an ASF, Carolina Digestive Endoscopy Center (CDEC), with two GI endoscopy procedure rooms in Mecklenburg County, which completed more than 4,000 cases in each procedure room during the last fiscal year.
- Wait times to schedule a procedure are averaging 3-4 weeks.
- There is increased demand for endoscopy procedures because of an increase in the prevalence of inflammatory bowel diseases between 2001 and 2018 and a decrease in the recommended age (from age 50 to age 45) for people with average risk to begin screenings for colorectal cancers.

- CDEC has inadequate parking, waiting areas, and pre- and post-procedure bays to accommodate the increasing number of procedures. The existing facility cannot be expanded, and the facility is located in a high traffic area.
- The last four years of patient origin data show that approximately 19% of CDEC patients live in counties east of Mecklenburg County and developing a facility east of Mecklenburg County will help alleviate some of the capacity issues.

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

- The applicant relies on its own historical patient origin to determine how many patients originate from counties east of Mecklenburg County.
- The applicant cites statistics on the frequency of inflammatory bowel diseases and changes to national guidelines affecting the need for endoscopy procedures.
- The applicant explains why it cannot make changes at its existing facility to manage the volume of patients.

Projected Utilization

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

CDEC-Concord Projected Utilization			
	FY 1 (CY 2025)	FY 2 (CY 2026)	FY 3 (CY 2027)
# GI Endoscopy Rooms	1	1	1
# Procedures	2,071	2,133	2,197
# Procedures/Room*	1.38	1.42	1.46

*The applicant has divided the number of procedures in the applicable performance standard by the total number of procedures projected.

In Section Q, and in Exhibit F, the applicant provides the assumptions and methodology used to project utilization, as summarized below:

- The applicant states it relied on historical data from CDEC to project utilization.
- The average increase in procedures between 2019-2022 was 7.14% and the average increase in patient volume during the same period was 8.53%.
- The applicant states that, according to the North Carolina Office of State Budget and Management, the population of Cabarrus County is increasing at an average rate of 1.69% per year and population growth among residents of Cabarrus County aged 45 and older is increasing at an average rate of 2.17% per year.

- The applicant states that variability in annual patients and procedures made it unreasonable to use the average change in procedures and patients to project growth, so it projected growth in procedures at 3% per year based on the projected population increases in Cabarrus County.
- The average percentage of patients at CDEC who lived in counties east of Mecklenburg County was 19% between 2019 and 2022. The applicant assumed that percentage would be consistent, and those patients would be served at CDEC-Concord instead of CDEC.
- The average ratio of procedures to patients between 2019 and 2022 is 1.13 procedures per patient. The applicant used a projected ratio of 1.12 procedures per patient to calculate the number of procedures based on the increase in the number of patients.
- The applicant projects the facility will open in January 2025 and shifts 19% of patients from CDEC to CDEC-Concord at that time.

The applicant’s utilization projections are summarized in the table below.

CDEC-Concord Projected Utilization – Historical Data for Projections (CDEC)					
	CY 2019	CY 2020	CY 2021	CY 2022	Averages*
# Procedures	8,472	8,408	10,261	10,274	
# Patients	7,432	7,066	10,159	8,813	
Ratio of Procedures to Patients	1.14	1.19	1.01	1.17	1.13
Yearly % Change – Procedures	--	-0.76%	22.04%	0.13%	7.14%
Yearly % Change – Patients	--	-4.92%	43.77%	-13.25%	8.53%

*Calculated by the Project Analyst

CDEC-Concord Projected Utilization					
	Interim		Projected		
	CY 2023	CY 2024	CY 2025	CY 2026	CY 2027
CDEC # Patients (3% annual growth)	9,077	9,350	7,796	8,030	8,270
CDEC # Procedures (1.12 ratio to pts)	10,582	10,900	9,156	9,430	9,713
CDEC-Concord # Patients (3% annual growth)	--	--	1,835	1,890	1,946
CDEC-Concord # Procedures (1.12 ratio to pts)	--	--	2,071	2,133	2,197

Note: The numbers in the table above, provided by the applicant, are slightly different than those calculated by the Project Analyst; these differences do not meaningfully impact the outcome of this criterion.

As shown in the table above, the applicant projects to perform 2,197 GI endoscopy procedures in a single GI endoscopy procedure room during the third full fiscal year following project completion. This meets the performance standard promulgated in 10A NCAC 14C. 3903(4), requiring the applicant to 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 any existing, approved, and proposed GI endoscopy procedure rooms owned or operated by the applicant or a related entity in the proposed service area. The applicant does not own or operate any existing or approved GI endoscopy procedure rooms in Cabarrus County.

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

- Projected utilization is based on the applicant’s historical experience with the patient population and the applicant provides data to support its historical experience.
- The applicant uses projected growth rates for patients that are consistent with the applicant’s historical average.
- The applicant uses a projected procedure to patient ratio that is consistent with its historical average.

Access to Medically Underserved Groups

In Section C, page 42, the applicant states:

“The proposed new GI endoscopy facility...will accept any patient who meets our admission criteria. Corporate policies state that the center shall provide the highest quality care and serve as a resource for referring physicians in the community for the diagnosis, treatment and management of gastrointestinal diseases without regard to race, color, religion, sex, age, national origin, disability, or socioeconomic class.”

On page 42, the applicant provides the estimated percentage for each medically underserved group for the third full fiscal year, as shown in the following table.

Medically Underserved Groups	% of Total Patients
Low income persons	5.58%
Racial and ethnic minorities	19.35%
Women	55.00%
Persons 65 and older	27.00%
Medicare beneficiaries	28.95%
Medicaid recipients	4.47%

On page 42, the applicant states it does not have data on persons with disabilities and considers low-income persons to be those using self-pay, charity care, or Medicaid.

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 based on the following:

- The applicant provides a statement which says it will provide access to the proposed services for underserved groups.
- The applicant projects access for certain underserved groups, such as Medicare beneficiaries, based on its historical experience.
- The applicant provides a copy of its Charity Care policy in Exhibit L.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 proposes to develop a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

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.

NC

The applicant proposes to develop a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

In Section E, page 48, 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 maintaining the status quo would require expanding the existing facility and parking lot, but the existing leased facility does not allow for expansion of the building or parking lot; therefore, this was not an effective alternative.

- Develop at a Different Site - The applicant states other sites that were considered did not have adequate parking or adequate space for the office and endoscopy center, and sites in Mecklenburg County would be more expensive and not closer to the patients living east of Mecklenburg County; therefore, this was not an effective alternative.

However, the applicant does not adequately demonstrate that the alternative proposed in this application is the most effective alternative to meet the need based on the following:

- The applicant uses assumptions to project initial operating costs that are not reasonable and adequately supported. The discussions regarding projection of initial operating costs found in Criterion (5) are incorporated herein by reference. An application that cannot demonstrate its projected initial operating costs are based on reasonable and adequately supported assumptions cannot be an effective alternative to meet the need.
- The applicant does not adequately demonstrate the availability of funds for the projected working capital costs. The discussion regarding availability of funds for working capital costs found in Criterion (5) is incorporated herein by reference. An application that cannot demonstrate the availability of funding for the project it proposes to develop cannot be an effective alternative to meet the need.
- The application is not conforming to all statutory and regulatory review criteria. An application that cannot be approved cannot be an effective alternative to meet the need.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is not conforming to this criterion for the reasons stated above. Therefore, the application is denied.

- (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.

NC

The applicant proposes to develop a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

Capital and Working Capital Costs

On Form F.1a, the applicant provides the projected capital costs, as shown in the table below.

Construction/Renovation Contracts	\$1,040,000
Architect/Engineering Fees	\$80,000
Medical Equipment	\$311,320
Non-Medical Equipment/Furniture	\$50,000
Miscellaneous Costs (signage, décor, etc.)	\$130,000
Consultant Fees (CON, licensure, certs)	\$60,000
Financing Costs	\$4,850
Interest During Construction	\$60,000
CON & License Application Fees	\$9,500
Contingency	\$224,000
Total	\$1,969,670

The applicant provides the assumptions and methodology used to project capital costs in Section Q. The applicant demonstrate that projected capital costs are reasonable and adequately supported based on the following:

- The applicant states costs like medical equipment, non-medical equipment, furniture, and miscellaneous costs were based on current costs inflated by 5%.
- The applicant relied on its bank for projections about financing costs and interest.
- In Exhibit F, the applicant provides a letter dated February 3, 2023 from an architectural firm, quoting an architect/engineering fee of \$80,000 based on a construction contract cost of \$1,040,000.

In Section F, page 51, the applicant projects that start-up costs will be \$75,000 and there will be no initial operating expenses for a total working capital cost of \$75,000. On page 51 and in Exhibit F, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

However, the applicant does not adequately demonstrate that the projected working capital needs of the project are based on reasonable and adequately supported assumptions because the applicant projects no initial operating period or initial operating expenses for a new facility that does not yet exist. The applicant states it projects no initial operating expenses because it projects total cash inflow will be more than total cash outflow. However, the applicant does not explain how a new facility which does not yet exist will have total cash inflow greater than total cash inflow on the day that it opens.

Availability of Funds

In Section F, page 49, the applicant states that the capital cost will be funded as shown in the following table:

Cash & Cash Equivalents, Accumulated Reserves, or Owner’s Equity	\$75,000
Lease Upfit Allowance	\$394,670
Line of Credit	\$1,500,000
Total	\$1,969,670

On page 49, the applicant states the costs will be incurred by Carolina Digestive Health Associates. In Exhibit F, the applicant provides the following documentation:

- A letter dated February 8, 2023 from a Senior Vice President of Private Banking at South State Bank, stating that Carolina Digestive Health Associates is an existing client with a deposit and lending relationship with the bank. The letter states Carolina Digestive Health Associates has requested a “loan facility” to use to construct a new endoscopy center in their Concord office.
- A letter dated February 7, 2023 from Narwan Gobar, the CEO of Carolina Digestive Health Associates, committing \$75,000 in company cash or accumulated reserves to fund that portion of the capital cost of the project.
- A profit/loss report for Carolina Digestive Health Associates P.A. for calendar year 2021, showing net income of \$2,171,574.66 for calendar year 2021.

In Exhibit K, the applicant provides a draft copy of a proposed lease. On page 6 of the lease document, a provision lists an “improvement allowance” of \$394,670.

In Section F, page 50, the applicant states that the working capital needs of the project will be funded entirely by cash and cash equivalents from Carolina Digestive Health Associates. In Exhibit F, the applicant provides the following documentation:

- A letter dated February 7, 2023 from Narwan Gobar, the CEO of Carolina Digestive Health Associates, committing \$75,000 in company cash or accumulated reserves to fund the projected working capital costs of the project.
- A profit/loss report for Carolina Digestive Health Associates P.A. for calendar year 2021, showing net income of \$2,171,574.66 for calendar year 2021.

However, the applicant does not adequately demonstrate availability of sufficient funds for the working capital needs of the project because it does not adequately demonstrate that projected working capital costs are reasonable and adequately supported. Without reasonable and adequately supported projected working capital costs, it is impossible to determine how much funding is necessary for working capital costs and therefore

impossible to determine whether the applicant can demonstrate availability of sufficient funds for the working capital costs.

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 year following project completion, as shown in the following table:

CDEC-Concord Projected Revenues & Operating Expenses			
	FY 1 CY 2025	FY 2 CY 2026	FY 3 CY 2027
Total Procedures	2,071	2,133	2,197
Total Gross Revenues (Charges)	\$739,088	\$761,261	\$784,099
Total Net Revenue	\$739,088	\$761,261	\$784,099
Average Net Revenue / Procedure	\$357	\$357	\$357
Total Operating Expenses (Costs)	\$653,327	\$676,191	\$700,024
Average Operating Expense / Procedure	\$315	\$317	\$319
Net Income	\$85,761	\$85,070	\$84,075

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:

- The applicant relied on its historical experience in providing the same services to project future costs and revenues.
- The applicant appropriately adjusted its projections to account for the difference in facility size and population served.
- The applicant included explanations about projections and inflation factored into the projections.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

Based on that review, the Agency concludes that the application is not conforming to this criterion for the following reasons:

- The applicant does not adequately demonstrate that the working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant does not adequately demonstrate availability of sufficient funds for the working capital needs of the proposal 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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

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 2023 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 facility will be developed in Cabarrus County. Thus, the service area for this facility is Cabarrus County. Facilities may also serve residents of counties not included in their service area.

According to Table 6F on pages 83-84 of the 2023 SMFP, there are four existing or approved facilities with GI endoscopy procedure rooms in Cabarrus County. Information on the four facilities is shown in the table below.

Facilities with GI Endoscopy Procedure Rooms – Cabarrus County				
Facility	Existing Rooms	Approved Rooms	Cases*	Procedures*
Northeast Digestive Health Center – Poplar Tent	0	1	0	0
Atrium Health Cabarrus	6	0	2,614	3,666
Gateway Surgery Center	2	0	4,157	6,261
Northeast Digestive Health Center**	3	-1	5,725	7,931
Total	11	0	12,496	17,858

*During FFY 2021 as reported on 2022 License Renewal Applications

**One GI endoscopy procedure room is being relocated to develop Northeast Digestive Health Center – Poplar Tent

In Section G, page 55, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Cabarrus County. The applicant states:

“Patients are currently out-migrating from the area to obtain endoscopy procedures. This is evidenced by the fact that a 4-year average of 19% of all Carolina Digestive Endoscopy Center patients come from counties east of Mecklenburg County.

We are already performing more than 1500 cases per year for patients residing in counties east of Mecklenburg. Further, we are already seeing patients in the gastroenterology office located in the proposed building.”

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

- The applicant is already serving the patients it proposes to serve in a different location.
- The applicant adequately demonstrates that the proposed GI endoscopy procedure room is needed in addition to the existing or approved GI endoscopy procedure rooms in the proposed service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments
- 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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

On Form H in Section Q, the applicant projects full-time equivalent (FTE) staffing for the proposed services for each of the three project years, as illustrated in the following table:

CDEC-Concord Projected Staffing (FTEs)			
	FY 1 (CY 2025)	FY 2 (CY 2026)	FY 3 (CY 2027)
Registered Nurses	2.00	2.00	2.00
Nurse Manager	0.25	0.25	0.25
Endoscopy Technicians	2.00	2.00	2.00
Receptionist	1.00	1.00	1.00
Total	5.25	5.25	5.25

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 F.3b. In Section H, pages 56-57, 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:

- The applicant has an established process in place to recruit, interview, and hire new employees.
- The applicant has an existing training and continuing education program at its other locations that it plans to use for this location.
- The applicant will encourage employees to attend regional and national conferences.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

Ancillary and Support Services

In Section I, page 58, the applicant identifies the necessary ancillary and support services for the proposed GI endoscopy services. On pages 58-59, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant has an existing corporate structure in place to provide the necessary ancillary and support services.
- In Exhibit I, the applicant includes proposed contracts for the types of ancillary and support services it proposes to provide.

Coordination

In Section I, page 59, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the applicant's established relationships with local health care and social service providers that the applicant says will continue following the completion of the proposed facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

In Section K, page 61, the applicant states that the project involves renovating 3,649 square feet of existing space in an existing medical office building. Line drawings showing the areas to be renovated are provided in Exhibit K.

In Section K, pages 62-63, the applicant identifies the proposed site and provides information about the zoning and special use permits, and the availability of water, sewer and waste disposal, and power at the site. Supporting documentation is provided in Exhibit K. The site appears to be suitable for the proposed GI endoscopy facility based on the applicant's representations and supporting documentation.

In Section K, page 61, 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 it will lease space and it is the most reasonable alternative because purchasing land and constructing a new building is not required.
- The applicant states the building already exists and they will be able to design the facility in the existing space.

- The applicant has an existing office in the same building.

In Section K, pages 61-62, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed GI endoscopy services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the space is designed to be efficient and accessible without unnecessary extra space.
- The applicant states freestanding GI endoscopy centers are a low-cost alternative for outpatient GI endoscopy services.
- The applicant states they benefit from cost saving measures based on economies of scale with their existing facilities elsewhere.
- The applicant states the procedure fee schedule will remain the same as it is now after the facility opens.

In Section K, page 62, 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
- Written comments
- Responses to comments

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;

NA

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

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and persons with disabilities to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

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

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

C

In Section L, page 67, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following project completion, as shown in the following table:

CDEC-Concord Projected Payor Mix – FY 3 (CY 2027)	
Payor Category	% of Total Patients
Self-Pay	1.02%
Charity Care	0.09%
Medicare*	28.95%
Medicaid*	4.47%
Insurance*	64.46%
TRICARE	0.26%
Other (VA)	0.75%
Total	100.00%

*Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.02% of total services will be provided to self-pay patients, 0.09% to charity care patients, 28.95% to Medicare patients, and 4.47% to Medicaid patients.

On page 96, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project

completion and provides supporting documentation in Exhibit L. The projected payor mix is reasonable and adequately supported because it is based on a four-year average of the applicant's historical payor mix at its existing facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

In Section M, page 69, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- The applicant describes the historical access of health professional training programs at its other facilities.
- The applicant describes how interested individuals can have access to the facility to observe procedures.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Written comments
- Responses to comments

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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

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 2023 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 facility will be developed in Cabarrus County. Thus, the service area for this facility is Cabarrus County. Facilities may also serve residents of counties not included in their service area.

According to Table 6F on pages 83-84 of the 2023 SMFP, there are four existing or approved facilities with GI endoscopy procedure rooms in Cabarrus County. Information on the four facilities is shown in the table below.

Facilities with GI Endoscopy Procedure Rooms – Cabarrus County				
Facility	Existing Rooms	Approved Rooms	Cases*	Procedures*
Northeast Digestive Health Center – Poplar Tent	0	1	0	0
Atrium Health Cabarrus	6	0	2,614	3,666
Gateway Surgery Center	2	0	4,157	6,261
Northeast Digestive Health Center**	3	-1	5,725	7,931
Total	11	0	12,496	17,858

*During FFY 2021 as reported on 2022 License Renewal Applications

**One GI endoscopy procedure room is being relocated to develop Northeast Digestive Health Center – Poplar Tent

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 70, the applicant states:

“We do not expect an impact on competition with this proposal for a one room GI endoscopy center in Cabarrus County as we have an existing patient population that would be served by the creation of the proposed center.”

The lower recommended age for beginning colorectal cancer screening, the increasing population in Concord, and the increasing prevalence of inflammatory bowel diseases has increased demand for endoscopy facilities in the area.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 70, the applicant states:

“The proposal will allow for more efficient patient flow and throughput resulting in greater cost efficiency with the addition of pre and post procedure bays. We anticipate no changes in cost per procedure and the same fee schedule will be used that [the applicant] is currently using. Low cost is a critical factor to help ensure the highest level of patient compliance with recommended colorectal cancer screening via GI endoscopy procedures. Patients are more likely to comply with screening guidelines and undergo a GI endoscopy procedure if their out-of-pocket cost is low.”

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 70, the applicant states:

“The quality of services provided at our center is enhanced with our preparation and successful achievement of AAAHC accreditation. The new location will be included as a satellite site in our next AAAHC survey.”

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, pages 70-71, the applicant states:

“We currently provide medical care to all patients regardless of ability to pay, insurance coverage type, race, ethnicity, or gender including the medically underserved. We participate with most private health insurance plans and government health programs including Medicare and Medicaid. The proposed new facility will have no impact on the ability of the medically underserved to obtain services provided by our organization.”

See also Sections C and L of the application and any referenced 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
- Written comments
- Responses to comments
- 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 a new ASF, CDEC-Concord, with no more than one GI endoscopy procedure room upon project completion.

In Section O, page 72, and on Form O in Section Q, the applicant identifies the licensed facilities with GI endoscopy procedure rooms located in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies a total of five of this type of facility located in two counties in North Carolina.

In Section O, page 73, the applicant states that, during the 18 months immediately preceding the submission of the application, all the facilities included in Form O have provided quality care. 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, there were no incidents related to quality of care that occurred in any of these facilities. After reviewing and considering the information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided, 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 Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903, are applicable to this review.

**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- 10A NCAC 14C .3901(6) defines “service area” as “*the county where the proposed GI endoscopy facility will be developed.*” The applicant proposes to build a new facility in Cabarrus County; therefore, the service area for this project is Cabarrus County.

The applicant proposes to serve patients from eight counties east of Mecklenburg County that have historically utilized the applicant’s facility in Mecklenburg 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- On Form O in Section Q, the applicant does not identify any GI endoscopy facilities owned or operated by the applicant or a related entity located in Cabarrus County.

(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- On Form C.3b in Section Q, the applicant provides projected utilization for the proposed new GI endoscopy procedure room for the first three full fiscal years of operation following completion of the project.

(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- On Form C.3b in Section Q, 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 completion of the project.

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

-C- In Section Q and Exhibit F, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.