



**DELIVERED VIA EMAIL**

March 31, 2023

Ms. Micheala Mitchell Chief  
Ms. Terris Riley. Project Analyst  
Certificate of Need Section  
Division of Health Service Regulation  
NC Department of Health and Human Services  
809 Ruggles Drive  
Raleigh, North Carolina 27603

**Re: Comments on Competing Applications for a Certificate of Need for an GI Endoscopy Surgery Center, Cabarrus County, Health Service Area III; CON Project ID Number F-012315-23:**

Dear Ms. Riley and Ms. Mitchell:

On behalf of Gateway Ambulatory Surgery Center, LLC, thank you for the opportunity to comment on the recently submitted Carolina Digestive Endoscopy Center – Concord Certificate of Need application.

We own and operate Gateway Surgery Center, an efficient, low-cost, freestanding ambulatory surgery center only 0.2 miles (or across the parking lot) from the proposed project. We have two GI Endoscopy Rooms in addition to six operating rooms. DHSR only recently approved significant expansions and improvements to make Gateway more responsive to our community (Project ID F-11906-20). Then, the pandemic and labor costs put significant stress on our operating budget. While we appreciate the importance of competition, we believe that this proposed project would represent unnecessary duplication. Moreover, as noted in the attached document the CDEC -Concord CON application has enough shortcomings to make it un-approvable.

We understand that state rules require only 1500 GI endoscopy procedures to justify a GI procedure room, but we believe the forecasts in this application involve some unreasonable assumptions.

Thank you for your kind consideration of these comments.

Sincerely,

Dr. F.P. Johns Langford, MD  
President of Board of Managers  
Gateway Surgery Ce

## **Comments on CON Application – Carolina Digestive Endoscopy Center - Concord / Project ID F-012315-23**

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### **OVERVIEW**

Two applicants, Carolina Digestive Health Associates, PA, and Carolina Digestive Endoscopy Center - Concord, submitted a CON application for a new GI Ambulatory Surgery Center, Carolina Digestive Endoscopy Center-Concord (“CDEC-Concord”). The proposed center would have one GI procedure room and four prep/ recovery bays (Exhibits pdf p 73). The new surgery center would be in leased space in Copperfield Medical Office building. Gateway Surgery Center is an existing, freestanding surgery center with six operating rooms and two GI endoscopy rooms. The proposed CDEC-Concord facility will be located 0.2 miles (or across the parking lot) from Gateway (see Attachment A).

Two Carolina Digestive Health Associate gastroenterologist physicians associated with CDEC-Concord, Drs. Fowler and Rothwell, currently have privileges and perform GI endoscopy procedures at Gateway. Historically, Drs. Fowler and Rothwell do approximately 800 GI endoscopy cases per year at Gateway. Their cases represent about 20 percent of Gateway’s annual 4100 cases. This is significant, and the application does not indicate how many of these cases, these physicians would transfer to the proposed new center. Gateway has capacity for these cases and no Carolina Digestive patient has been denied a surgery schedule at Gateway.

Gateway Surgery Center is an efficient, low-cost freestanding ambulatory surgery center that provides an important service to residents of Cabarrus and surrounding counties. DHSR only recently approved significant expansions and improvements to make Gateway more responsive (Project ID F-11906-20). Then, the pandemic and labor costs put significant stress on our operating budget. While we appreciate the importance of competition, we believe that this proposed project would represent unnecessary duplication. Moreover, the CDEC -Concord CON application has enough shortcomings to make it unprovable.

The following paragraphs address a few of the issues that make the proposed project un-approvable. They reference by number, statutory review Criteria in GS 131E-183.

## CON REVIEW CRITERIA

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

The application identifies counties from which CDEC-Concord proposes to attract patients and it notes a recent USPSTF change in recommended age for screening colonoscopies. However, the application provides no quantitative analysis to tie this information back to the need of the population to be served for another GI endoscopy room or GI Ambulatory Surgery Center in Concord.

The proposed patient origin on page 37 forecasts 1,986 patients from eight counties, as far away as Wake and Alamance and including 148 from Anson and 895 (or 45% of the projected patient origin) from Union County. Only 23 percent of the patients, 472, would come from Cabarrus County. The two Gastroenterologists in Concord did only 869 procedures at Gateway Surgery Center last year. So, we do not know the referral base for the other half of the patients. The application provides no information about who would do the remaining procedures. It has no letters of support from referring physicians or from patients who would use the proposed facility.

In fact, the need analysis is just a simple proposal to “shift” patients from the CDHA south Mecklenburg County ambulatory surgery center to Concord. It asserts that 19 percent of patients who have received services at CDHA Carolina Surgery Center in the past come from east of Mecklenburg County and the count will increase a rate of 3 percent annually through FY 2028. Then it asserts that all those future patients in counties east of Mecklenburg will shift to the proposed CHDA – Concord facility.

First, no provider can assume ownership of patients. Patients regularly change providers, for multiple reasons. It just assumes, that patients from eight counties, including Anson, Union, Alamance, and Wake County will voluntarily change their patterns and seek care at the one-room proposed CHDA- Concord facility in Cabarrus County. The application makes no reference to why patients sought care at CHDA Mecklenburg. Was it, for example, because of an established relationship with CDHA Mecklenburg physicians, or because they had a relative who lives in Charlotte and could provide support pre- and post- procedure? The application does not indicate if any physicians from CHDA – Mecklenburg will travel to Concord to do procedures. According to Google, the drive from CDHA – Union to Concord takes more than an hour (see Attachment B). The applicants provide no reasonable explanation why 45% of their projected patient origin would drive from Union County to northern Cabarrus County for services when there is an existing CDHA location in Union County.

For these and other reasons, the application is non-conforming to Criterion 3, demonstrating need of the population to be served for the proposed project.

**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.**

Projected Expenses in Form F.3b are inadequate to support the proposed anesthesia contract in Exhibit I. (pdf page 52). Exhibit 1 to that contract (pdf p 57) indicates that CDEC-Concord must pay the Anesthesia company the greater of \$1,000 per day or \$150 per hour plus administrative fees which would not exceed \$12,000 per year. This could amount to \$212,000 for a 200-day work year. There is no line item in F.3.b adequate to cover an amount even close to this.

The budget in form F.2b projects net earnings of only \$84,075 in the third year. The non-cash Depreciation line is only \$4,523. The project would lose significant money in the third operating year. Moreover, the proforma on Form F.3, page 84 shows the project income will be less every year. This is not a financially viable project. Hence it is non-Conforming with Criterion 5.

Year 03 Income	84,075
Year 03 Depreciation	4,523
<b>Year 03 Cash Income</b>	<b>88,598</b>
Less Anesthesia Contract	(212,000)
<b>Adjusted Cash Income</b>	<b>(133,402)</b>

The application also has underfunded start-up costs. This facility will require a new license and a new provider number. CDEC- Concord will be in Concord County, not Mecklenburg County. North Carolina Ambulatory Surgery licenses are site specific. Thus, the table on page 38 is incorrect. The project will not be part of an existing facility, it will result in a second health care facility for the applicants. Concord and Mecklenburg will not be a single health care facility.

In the start-up months, the new Concord facility will not have established provider numbers with Medicare and Medicaid, so, it will be providing services without revenue. Proformas in Form F.2a show Medicare and Medicaid revenue from Day 1. The project does not show evidence of extra sources of financing to cover a start-up period expense, which could last three to six months.

These are only a few of the weaknesses that make the project non-conforming to Criterion 5.

**6. The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.**

The application provides no discussion of other similar freestanding surgery center alternatives available to people who live in any county in its proposed service area. Hence it falls short on Criterion 6.

## PERFORMANCE STANDARDS

GS 131E-183(b), requires the applicant to meet Special Rules adopted by the Department related to the type of health service reviewed. 10A NCAC 14C. 3903 Ambulatory Surgery Performance Standards

10A NCAC 14C.3903 requires “An applicant proposing to develop a new GI Endoscopy room in a licensed health service facility shall:

1. *Identify the proposed service area;*
2. *Identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity in the proposed service area;*

CHDA, one of the applicants, is a partial owner in four GI Endoscopy Centers and sole owner of one GI Endoscopy Center in the counties the applicants are proposing to pull patients from:

- Endoscopy Center Huntersville, LLC d/b/a Carolina Endoscopy Center-Huntersville, LLC (Mecklenburg County)
- Endoscopy Center Pineville, LLC d/b/a Carolina Endoscopy Center-Pineville, LLC (Mecklenburg County)
- Endoscopy Center University, LLC d/b/a Carolina Endoscopy Center-University, LLC (Mecklenburg County)
- Endoscopy Center Monroe, LLC d/b/a Carolina Endoscopy Center-Monroe, LLC (Union County)
- Carolina Digestive Endoscopy Center (Charlotte/Mecklenburg County)

10A NCAC 14C.3903 further requires.

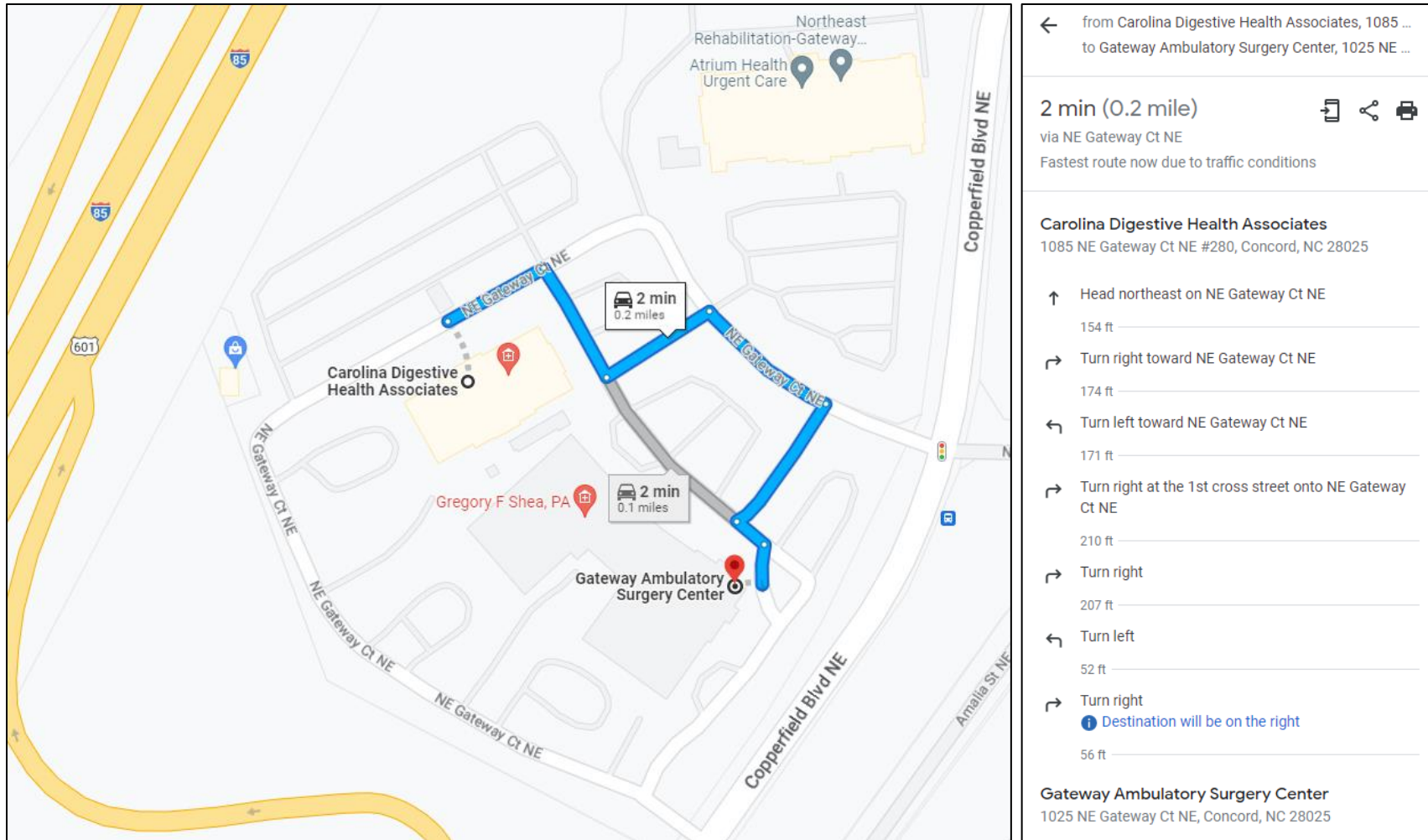
3. *Provide projected utilization for each of the first full fiscal years of operation following the completion of the project for all GI Endoscopy rooms identified in item (2) of this rule;*
4. *Project to perform an average of at least 1,500 GI endoscopy procedure per GI endoscopy room during the third full year of operation following completion of the project in the GI endoscopy rooms identified in item (2) of this rule;*
5. *Provide the assumptions and methodology used to project the utilization required by this rule.*

CDHA-Concord lists these facilities in Form O on p.108 in the application. Yet, in response to the Performance standard on page 43, the application fails to provide projected occupancy for any of these facilities. At best, it forecasts occupancy for the Carolina Digestive Endoscopy Center in the table showing patients at CDHA Carolina and CDEC-Concord combined in on pdf page 21 of the Exhibit book. Hence it is non-conforming.

For this reason alone, the project is not approvable.

### ATTACHMENT A

#### Locations of Gateway Ambulatory Surgery Center and proposed Carolina Digestive Health Associates compared.







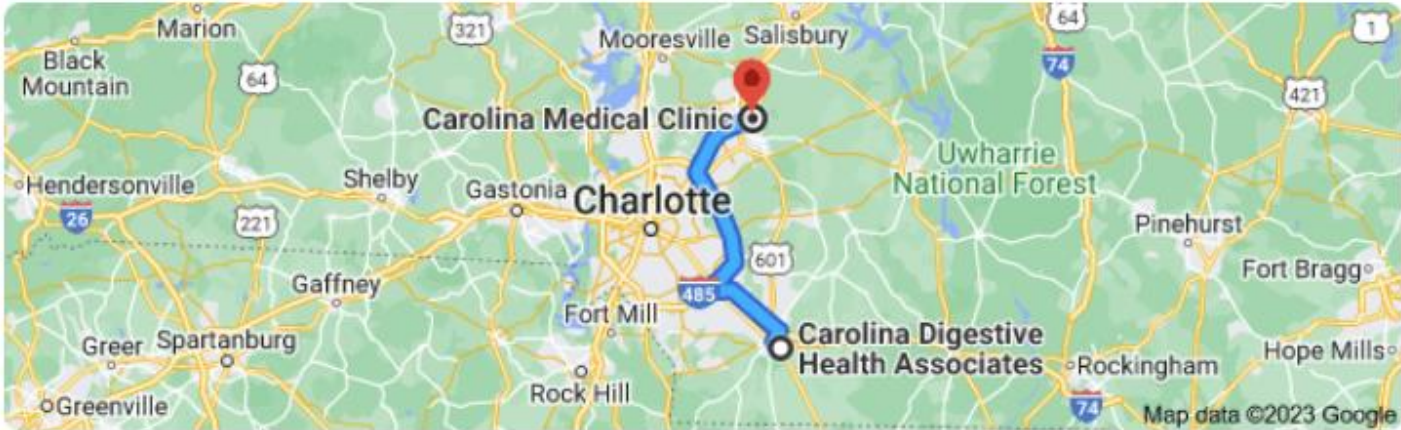


**ATTACHMENT B**


○ Carolina Digestive Health Associates, 1663 Campus Park Dr suite d, Monroe, NC 28112

○ Carolina Medical Clinic Copperfield Boulevard Northeast, Concord, NC



**49 min** (49.6 mi) via I-485 Outer

 Directions

**1 hr 14 min** (66.7 mi) via I-85 N