



**WRITTEN COMMENTS ON PROJECT ID F-012315-23
CAROLINA DIGESTIVE ENDOSCOPY CENTER - CONCORD
SUBMITTED BY NORTHEAST DIGESTIVE HEALTH CENTER**

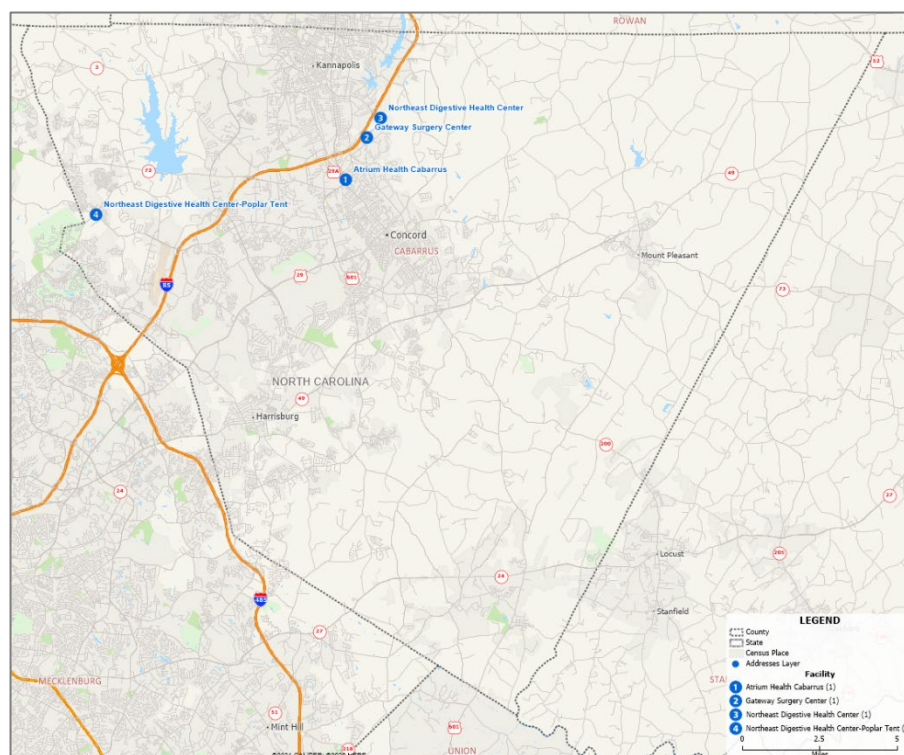
MARCH 31, 2023

Cabarrus Gastroenterology Associates, PLLC doing business as Northeast Digestive Health Center (“Northeast Digestive”) submits these comments in accordance with N.C. Gen. Stat. § 131E-185(a1)(1) to address the representations in the application submitted by Carolina Digestive Health Associates P.A. and Carolina Digestive Endoscopy Center – Concord (“the applicants”) to develop a new GI endoscopy facility with one licensed GI endoscopy room, including a discussion of the most significant issues regarding the application’s conformity with the statutory and regulatory review criteria (“the Criteria”) in N.C. Gen. Stat. §131E-183(a). Other non-conformities in the application may exist.

General Comments

Northeast Digestive is an affected party as defined in G.S. 131E-188(c). Specifically, Northeast Digestive operates licensed GI endoscopy rooms in Cabarrus County. Northeast Digestive provides GI endoscopy services to individuals residing within the service area proposed to be served by Carolina Digestive Endoscopy Center-Concord (CDECC).

CDECC proposes to develop a new GI endoscopy center with one GI endoscopy procedure room in the Gateway Medical Office Building in Concord, NC (Cabarrus County). Northeast Digestive operates a licensed GI endoscopy center with two GI endoscopy procedure rooms approximately one mile from CDECC’s proposed location. Moreover, the proposed location is in a building that is adjacent to Gateway Surgery Center, which hosts two licensed GI endoscopy procedure rooms.



As described in the following pages, the project is not needed because application lacks sufficient evidence to demonstrate conformity to multiple statutory review criteria.

Criterion 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 applicants fail to identify the population to be served by the project and adequately demonstrate the need that the population has for the proposed additional GI endoscopy room.

Population to be Served

The applicants project the following patient origin for the proposed new facility in Cabarrus County.

<GI Endoscopy Patients>	<Carolina Digestive Endoscopy Center- Concord> *					
	1 st Full FY		2 nd Full FY		3 rd Full FY	
	10/01/2025 to 09/30/2026		10/01/2026 to 09/30/2027		10/01/2027 to 09/30/2028	
County	Number of Patients **	% of Total	Number of Patients **	% of Total	Number of 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 Patients	1872	100%	1928	100%	1986	100%

Source: Application page 37

The applicants state in Exhibit C that the service area for the proposed project is Cabarrus County. However, the applicants project that Union County patients will account for over 45 percent of its patient origin during the first three project years, which is greater than any other county to be served by the proposed new GI endoscopy facility. The applicants project that Cabarrus County will account for only 23.75 percent of patient origin during the first three project years, or 472 patients during PY3.

The applicants failed to provide adequate information to demonstrate the need Cabarrus County patients have for an additional GI endoscopy procedure room as proposed in the application. While the applicants provided some demographic information for Cabarrus County in Exhibit C, the patient projections for Cabarrus County fall woefully short of the performance standard for GI endoscopy rooms. CDECC projects to serve only 472 Cabarrus County patients during the third project year, which is approximately 31 percent of the CON performance standard for GI endoscopy rooms, i.e., 1,500 procedures. It would seem the proposed project may be better suited in Union County where the applicants project to serve the highest number and percentage of patients.

Projected Utilization

The applicants provide historical patient origin information by county in Exhibit C, which indicates that the number of Cabarrus patients served by CDHA-CDEC decreased by over 12 percent from FFY2021 (448) to FFY2022 (393). See also the following table.

CDHA- CDEC Historic Patient Origin by County
Counties East of Mecklenburg

County	Oct 2018- Sept 2019		Oct 2019- Sept 2020		Oct 2020- Sept 2021		Last Full FY Oct 2021-Sept 2022		
	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total	Number of Patients	% of Total CDEC	% of Total East of Meck
Alamance	0	0.00%	0	0.00%	0	0.00%	1	0.01%	0.06%
Anson	22	0.68%	55	0.80%	130	1.36%	123	1.41%	7.43%
Brunswick	0	0.00%	0	0.00%	5	0.05%	0	0.00%	0.00%
Cabarrus	168	5.22%	240	3.49%	448	4.70%	393	4.49%	23.75%
Cumberland	0	0.00%	0	0.00%	4	0.04%	0	0.00%	0.00%
Davidson	5	0.16%	0	0.00%	4	0.04%	0	0.00%	0.00%
Davie	0	0.00%	0	0.00%	3	0.03%	0	0.00%	0.00%
Forsyth	0	0.00%	6	0.09%	2	0.02%	3	0.03%	0.18%
Guilford	5	0.16%	4	0.06%	4	0.04%	0	0.00%	0.00%
Johnston	0	0.00%	0	0.00%	1	0.01%	0	0.00%	0.00%
Montgomery	0	0.00%	4	0.06%	2	0.02%	0	0.00%	0.00%
Moore	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0.00%
Nash	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0.00%
New Hanover	0	0.00%	0	0.00%	3	0.03%	0	0.00%	0.00%
Richmond	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0.00%
Robeson	0	0.00%	0	0.00%	2	0.02%	0	0.00%	0.00%
Rockingham	0	0.00%	0	0.00%	3	0.03%	0	0.00%	0.00%
Rowan	24	0.75%	64	0.93%	142	1.49%	97	1.11%	5.86%
Scotland	0	0.00%	0	0.00%	5	0.05%	0	0.00%	0.00%
Stanly	45	1.40%	31	0.45%	66	0.69%	289	3.30%	17.46%
Union	405	12.57%	682	9.92%	1161	12.19%	746	8.52%	45.08%
Wake	0	0.00%	0	0.00%	0	0.00%	3	0.03%	0.18%
Total	674	20.93%	1086	15.80%	1991	20.90%	1655	18.91%	100.00%

Source: Application Exhibit C

The applicants project to serve 472 Cabarrus County patients during the third project year, an increase of over 20 percent compared to FFY2022. There was no information provided in the application as submitted to describe why patient utilization for the service area (Cabarrus County) recently decreased or rationale to indicate why utilization would 1) begin increase before the project is complete and 2) increase simply as a result of the project.

Form C.3b provides projected utilization for the proposed CDECC facility, a copy of which is also provided below.

Form C.3b Projected GI Endo Room Utilization upon Project Completion Carolina Digestive Endoscopy Center- Concord	1st Full CY	2nd Full CY	3rd Full CY
	F: 01/01/2025 T: 12/31/2025	F: 01/01/2026 T: 12/31/2026	F: 01/01/2027 T: 12/31/2027
GI Endoscopy Rooms			
# of Rooms	1	1	1
# of Outpatient GI Endoscopy Procedures	2071	2133	2197
Average # of Procedures per Room ⁽⁷⁾	1.38	1.42	1.46

The application does not contain the assumptions and methodology used to project the number of GI endoscopy procedures. Exhibit C contains historical patient origin data; however, there is no data available regarding the number of historical GI endoscopy procedures performed on the respective patients. Furthermore, there is no discussion of how the applicants determined the average annual number of procedures per room in Form C.3b or why the average number of procedures per room increases during each of the first three project years.

In summary, for the reasons previously described, the applicants failed to demonstrate the need the population has for the services proposed and that projected utilization is based on reasonable and adequately supported assumptions. Consequently, the application does not conform to Criterion 3.

Criterion 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.”*

The applicants are nonconforming with Criterion 3. Therefore, the applicants failed to adequately demonstrate that its proposal is an effective alternative for developing an additional GI endoscopy room in Cabarrus County. Consequently, the application is nonconforming to Criterion 4.

Additionally, the applicants did not discuss the alternative of developing a new GI endoscopy facility in Union County. The applicants project that Union County patients will account for over 45 percent of patient origin during the first three project years, which is greater than any other county to be served by the proposed new GI endoscopy facility. Carolina Digestive Health Associates owns an endoscopy center in Monroe, NC (Union County); however, the applicants failed to discuss why the Monroe facility was less effective than the project as proposed.

Criterion 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.”*

There are numerous deficiencies regarding the financial and operational projections for the project that render the application non-conforming.

- The application does not include Form F.1 Capital Cost. Therefore, the Agency cannot evaluate the reasonableness of the capital needs for the project as proposed.
- The applicants failed to include any staffing expense in the projected start-up costs. As shown on page 50, the applicants only allocate costs related to rent and medical supplies. Staffing expenses are applicable to the projected start-up costs because staff for the proposed new GI endoscopy room would need to be on-boarded and trained prior to operation.
- In Form F.2b, CDECC’s projected gross revenues are the same as projected net revenues. The applicants failed to include any adjustments to gross revenue for charity care, bad debt, and contractual adjustments.
- Form F.3b for CDECC includes annual expenses of approximately \$25,000-\$28,000 for equipment leases. As previously described, application does not include Form F.1 Capital Cost; therefore, it is uncertain whether the project capital cost includes acquisition of necessary medical equipment for the proposed GI endoscopy room.

Consequently, the application does not conform to this criterion.

Criterion 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 applicants failed to adequately demonstrate the need for the proposed services (See Criterion 3). Therefore, the applicants failed to adequately demonstrate that its proposal will not result in an unnecessary duplication of existing or approved GI endoscopy services and is nonconforming to this criterion.

The applicants failed to identify all existing and approved health service facilities that provide GI endoscopy services in the proposed service area, i.e., Cabarrus County. The response to Section G.1 identifies Gateway Surgery Center and Northeast Digestive Health Center; however, the applicants failed to identify two other health facilities with GI endoscopy rooms in Cabarrus County. As demonstrated in Table 6F of the 2023 SMFP, Northeast Digestive Health Center-Poplar Tent and Atrium Health Cabarrus is approved to develop one GI endoscopy room and Atrium Health Cabarrus operates six GI endoscopy rooms.

The proposed project unnecessarily duplicates existing GI endoscopy rooms in Cabarrus County. As previously described, CDECC projects to serve only 472 Cabarrus County during the third project year, which is approximately 31 percent of the CON performance standard for GI endoscopy rooms, i.e., 1,500 procedures. It would seem the proposed project may be better suited in Union County where the applicants project to serve the highest number and percentage of patients. Carolina Digestive Health Associates owns an endoscopy center in Monroe, NC (Union County); however, the applicants failed to discuss why the Monroe facility was less effective than the project as proposed.

Criterion 13c *“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 handicapped persons, 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:*

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”

The applicants did not provide the assumptions and methodology to project payor mix for the proposed project. The projected payor mix for the proposed new GI endoscopy room provided in Section L.3 is not consistent with the historical payor mix provided in Section L.1 as shown in the following tables.

Last Full FY before Submission of Application
10/01/2021 to 09/30/2022

<Carolina Digestive Health Associates – CDEC>	
Payor Source	Percentage of Total Patients Served
Self-Pay	3.71%
Charity Care	0.33%
Medicare *	20.87%
Medicaid *	2.28%
Insurance *	71.3%
Workers Compensation	0%
TRICARE	1.02%
Other (describe) Veterans Admin	0.49%
Total	100.0%

* Including any managed care plans.

Source: Application Section L.1, page 65

Projected Payor Mix during the 3rd Full CY
1/01/2027 to 12/31/2027

<Carolina Digestive Endoscopy Center - Concord>	
Payor Source	Percentage of Total Patients Served
Self-Pay	1.02%
Charity Care	0.09%
Medicare *	28.95%
Medicaid *	4.47%
Insurance *	64.46%
Workers Compensation	0%
TRICARE	0.26%
Other (Describe) Veterans Admin	0.75%
Total	100.0%

* Including any managed care plans.

Source: Application Section L.4, page 67

The applicants project the percentage of Medicaid patients served at the proposed new facility in Concord will be nearly two times greater than the percentage of Medicaid patients it has historically served at its existing facility. The percentage of Medicare patients served is also projected to increase from 20.87 percent to 28.95 percent. The application contains no discussion of the rationale for projecting an increase in Medicaid and Medicare payor mix for the proposed services. The applicants may not amend the application to provide additional information. Therefore, the application does not conform to this criterion.

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.”*

The applicants fail to demonstrate that the proposed health services will accommodate the clinical needs of health professional training programs in the area.

Application page 69 states, *“[l]ocal colleges have not historically used our endoscopy center for training, but health professional training students do utilize the gastroenterology office for training.”* Emphasis added. The gastroenterology office is not the subject of CON review. The applicant did not state or demonstrate that the proposed GI endoscopy service would be available to accommodate the clinical needs of health professional training programs in the area. The applicants may not amend the application to provide additional information. Therefore, the application does not conform to this criterion.

Criterion 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.”*

Based on the facts which result in the application being nonconforming with Criteria 3, 4, 5, 6, and 13c it should also be found nonconforming with Criterion 18a.

10A NCAC 14C .3903 Performance Standards for GI Endoscopy Procedure Rooms

The application does not contain the assumptions and methodology used to project the number of GI endoscopy procedures. Exhibit C contains historical patient origin data; however, there is no data available in the application regarding the number of historical GI endoscopy procedures performed on the respective patients. Furthermore, there is no discussion of how the applicants determined the average annual number of procedures per room in Form C.3b or why the average number of procedures per room increases during each of the first three project years. Consequently, the application does not conform to this rule.