

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 4, 2022

Findings Date: January 4, 2022

Project Analyst: Kim Meymandi

Co-Signer: Gloria C. Hale

Project ID #: F-12109-21

Facility: Northeast Digestive Health Center

FID #: 070514

County: Cabarrus

Applicant(s): Cabarrus Gastroenterology Associates, PLLC

Project: Develop an ambulatory surgical facility by relocating one existing 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

Cabarrus Gastroenterology Associates, PLLC (hereinafter referred to as CGA or “the applicant”), proposes to obtain an ambulatory surgical facility (ASF) license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms, Northeast Digestive Health Center – Vinehaven Drive (NDHC-Vinehaven) to a new location at Northeast Digestive Health Center – Poplar Tent (NDHC - Poplar Tent), approximately 12 miles away.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2021 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There are no policies in the 2021 SMFP which are applicable to this project.

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 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- (2) Repealed effective July 1, 1987.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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms, NDHC-Vinehaven, to a new location on the first floor of leased space in an existing building on Poplar Tent Road in Concord, approximately 12 miles away.

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 2021 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 geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” Both NDHC-Vinehaven and NDHC-Poplar Tent are located in Cabarrus County and in Section C.3, page 27, the applicant projects that 63.5% of its patients will originate from Cabarrus County, with the next largest percentage of patients originating from Rowan County. Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates NDHC-Vinehaven’s historical (FFY2020) patient origin for GI endoscopy services.

NDHC's Historical Patient Origin GI Endoscopy Rooms		
County	10/1/2019-9/30/2020	
	# of Patients	% of Total
Alamance	1	0.02%
Anson	16	0.32%
Ashe	1	0.02%
Brunswick	4	0.08%
Cabarrus	3575	72.5%
Catawba	6	0.12%
Cleveland	3	0.06%
Davidson	88	1.78%
Davie	3	0.06%
Forsyth	1	0.02%
Gaston	9	0.18%
Guilford	1	0.02%
Haywood	1	0.02%
Hoke	1	0.02%
Iredell	82	1.66%
Johnston	2	0.04%
Mecklenburg	66	1.34%
Montgomery	38	0.77%
Moore	1	0.02%
Pender	1	0.02%
Polk	1	0.02%
Randolph	1	0.02%
Rowan	598	12.13%
Stanley	389	7.89%
Transylvania	1	0.02%
Union	8	0.16%
Wilkes	1	0.02%
South Carolina	17	0.34%
Virginia	5	0.10%
Other States	10	0.20%
Total	4,931	100.00%

Source: Section C.2, page 26

The following table shows NDHC – Poplar Tent’s projected patient origin for GI endoscopy services for the first three full fiscal years of operation (FFY2021-FFY2023).

NDHC – Poplar Tent Projected Patient Origin GI Endoscopy Rooms						
County	1st Full FY 10/1/2022-9/30/2023		2nd Full FY 10/1/2023-9/30/2024		3rd Full FY 10/1/2024-9/30/2025	
	# of Patients	% of Total	# of Patients	% of Total	# of Patients	% of Total
Alamance	2	0.04%	2	0.04%	2	0.04%
Anson	13	0.24%	13	0.24%	13	0.24%
Ashe	1	0.02%	1	0.02%	1	0.02%
Brunswick	3	0.05%	3	0.05%	3	0.05%
Cabarrus	3493	63.5%	3493	63.5%	3493	63.5%
Catawba	5	0.09%	5	0.09%	5	0.09%
Cleveland	1	0.02%	1	0.02%	1	0.02%
Davidson	37	0.68%	37	0.68%	37	0.68%
Davie	2	0.03%	2	0.03%	2	0.03%
Forsyth	2	0.03%	2	0.03%	2	0.03%
Franklin	1	0.01%	1	0.01%	1	0.01%
Gaston	9	0.17%	9	0.17%	9	0.17%
Guilford	3	0.05%	3	0.05%	3	0.05%
Haywood	1	0.01%	1	0.01%	1	0.01%
Hoke	1	0.01%	1	0.01%	1	0.01%
Iredell	76	1.38%	76	1.38%	76	1.38%
Lee	1	0.01%	1	0.01%	1	0.01%
Lincoln	6	0.10%	6	0.10%	6	0.10%
Mecklenburg	289	5.25%	289	5.25%	289	5.25%
Montgomery	18	0.33%	18	0.33%	18	0.33%
Moore	1	0.02%	1	0.02%	1	0.02%
New Hanover	1	0.02%	1	0.02%	1	0.02%
Pender	1	0.01%	1	0.01%	1	0.01%
Polk	1	0.01%	1	0.01%	1	0.01%
Orange	1	0.01%	1	0.01%	1	0.01%
Randolph	2	0.03%	2	0.03%	2	0.03%
Richmond	16	0.29%	16	0.29%	16	0.29%
Rockingham	1	0.01%	1	0.01%	1	0.01%
Rowan	846	15.38%	846	15.38%	846	15.38%
Stanley	615	11.18%	615	11.18%	615	11.18%
Stokes	1	0.02%	1	0.02%	1	0.02%
Transylvania	1	0.01%	1	0.01%	1	0.01%
Union	17	0.30%	17	0.30%	17	0.30%
Wake	2	0.03%	2	0.03%	2	0.03%
Watauga	1	0.02%	1	0.02%	1	0.02%
Wilkes	1	0.01%	1	0.01%	1	0.01%
Georgia	1	0.01%	1	0.01%	1	0.01%
South Carolina	18	0.32%	18	0.32%	18	0.32%
Virginia	5	0.09%	5	0.09%	5	0.09%
Other States	12	0.22%	12	0.22%	12	0.22%

Total Patients	5,500	100.00%	5,500	100.00%	5,500	1000.0%
Vinehaven	4,500		4,500		4,500	
Poplar Tent	1,000		1,000		1,000	

Source: Section C.3, pages 27-28

Totals may not sum due to rounding

In Section C.3, pages 26-27, the applicant provides the assumptions and methodology used to project its patient origin. The applicant states projected patient origin is based on NDHC-Vinehaven’s average historical patient origin over the past four years for GI endoscopy services and provides the information in Exhibit C.3. The applicant’s assumptions are reasonable and adequately supported based on the following:

- The applicant projects patient origin at NDHC-Poplar Tent based on the patient origin of NDHC - Vinehaven.
- NDHC Poplar Tent is 12 miles from NDHC-Vinehaven in the city of Concord.
- The applicant conservatively increases the number of projected future patients based on the four-year historical average number of patients and the number of patients in the current year annualized.

Analysis of Need

In Section C.4, the applicant explains why it believes the population projected to utilize the proposed services needs the services that have been relocated. On pages 29-30, the applicant states:

- Using data from the last four and current calendar years, the applicant calculates that the three GI endoscopy rooms at NDHC – Vinehaven serve an average of 5,417 patients and perform an average of 6,610 procedures.
- The applicant states they are unable to use the third GI endoscopy room at NDHC-Vinehaven due to inadequate space for the endoscopy waiting area, cleaning scopes, pre/post procedure bays and parking. The applicant also states that NDHC-Vinehaven does not allow for expansion to correct the space issues and due to ongoing road construction, patients experience delays in getting to appointments.
- On page 30, the applicant states that prior to the COVID pandemic, procedure volumes increased an average of 11.3% annually. In supplemental information requested by the Agency, the applicant states that the 11.3% average annual increase was calculated by averaging the procedure volume percent increases as calculated from data submitted on License Renewal Applications (LRAs) for FY2017 through FY2021.
- In Section Q, page 61, the applicant calculated the five-year average percent change in procedure volume for CY2017 through CY2021 as 4.8%.

The information is reasonable and adequately supported for the following reasons:

- The applicant provides data regarding the current and historical utilization of GI endoscopy services by the proposed service area population.

- The applicant provides current and historical data demonstrating that the three GI endoscopy rooms have met and continue to meet the performance standards promulgated in 10A NCAC 14C .3903(b) and N.C.G.S. 131E-182(a). In CY2020, 6,666 procedures were performed in 3 GI endoscopy rooms which equates to operating at 148.1% of capacity [6,666 / 4,500 = 148.1%].
- The applicant provides statements regarding inadequate space, parking and traffic congestion at the current location, which along with the projected increase in utilization, supports the need for having relocated the third GI endoscopy room to an alternate location in the service area.

Projected Utilization

In Section Q, Form C, the applicant provides the historical and projected utilization for GI endoscopy rooms at NDHC-Vinehaven and NDHC-Poplar Tent through the first three full fiscal years of operation, as illustrated in the following table.

NDHC Historical Utilization

	Prior				Interim		5 Year Average 2017-2021
	CY2017	CY2018	CY2019	CY2020	CY2021	CY2022	
NDHC-Vinehaven							
GI Endoscopy Rooms	3	3	3	3	2	2	
Outpatient GI Endoscopy Procedures	6,391	6,303	6,444	6,600	6,248	6,473	
Total GI Endoscopy Procedures	6,391	6,303	6,444	6,600	6,248	6,473	
Average # of Procedures/Room			2,148	2,200	3,124	3,237	
Need for GI Endoscopy Rooms*			1.43	1.47	2.08	2.16	
NDHC-Poplar Tent							
GI Endoscopy Rooms			0	0	1	1	
Outpatient GI Endoscopy Procedures			0	66	1,000	1,500	
Total GI Endoscopy Procedures			0	66	1,000	1,500	
Average # of Procedures/Room			0	66	1,000	1,500	
Need for GI Endoscopy Rooms*			0	0.04	0.67	1.00	
Totals for both Locations							
Total GI Endoscopy Procedures	6,391	6,303	6,444	6,666	7,248	7,973	6,610
Annual Percent Change	---	-1.38	2.24	3.45	8.73 [8.8]	10.00 [9.9]	4.80 [5.15]

*Need for GI Endoscopy rooms is based on 1,500 procedures per room

[] Calculations performed by Project Analyst

NDHC Projected Utilization

	FY1 CY2023	FY2 CY2024	FY3 CY2025
NDHC-Vinehaven			
GI Endoscopy Rooms	2	2	2
Outpatient GI Endoscopy Procedures	6,872	7,290	7,730
Total GI Endoscopy Procedures	6,872	7,290	7,730
Average # of Procedures/Room	3,436	3,645	3,865
Need for GI Endoscopy Rooms*	2.29	2.43	2.58
NDHC-Poplar Tent			
GI Endoscopy Rooms	1	1	1
Outpatient GI Endoscopy Procedures	1,500	1,500	1,500
Total GI Endoscopy Procedures	1,500	1,500	1,500
Average # of Procedures/Room	1,500	1,500	1,500
Need for GI Endoscopy Rooms*	1.00	1.00	1.00

*Need for GI Endoscopy rooms is based on 1,500 procedures per room

As shown in the tables above, the applicant projects that it will perform a total of 6,872 total GI endoscopy procedures in two GI endoscopy rooms at NDHC-Vinehaven and a total of 1,500 total GI endoscopy procedures in one GI endoscopy room at NDHC-Poplar Tent in the first full operating year. During the second full operating year, the applicant projects a total of 7,290 GI endoscopy procedures to be performed at NDHC-Vinehaven and a total of 1,500 GI endoscopy procedures at NDHC-Poplar Tent. Based on projections by the applicant, in the second full operating year, NDHC-Vinehaven will perform an average of 3,645 procedures per room [7,290 procedures / 2 rooms = 3,645 procedures per room] and NDHC-Poplar Tent will perform an average of 1,500 procedures per room [1,500 / 1 room = 1,500 procedures per room], both of which meet the utilization threshold of 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

In Section Q, pages 60-61, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- CY2023-CY2025 are the first three full fiscal years following the completion of the project.
- The applicant calculates the total number of GI endoscopy procedures for the first interim year, CY2021, by annualizing seven months of data from CY2021. In supplemental information requested by the Agency, the applicant states a total of 4,231 GI endoscopy procedures were performed at both locations in the first seven months of CY2021. The procedure volume at Vinehaven was 520 procedures/month and Poplar Tent was 84/month for a total of 604/month. Using this data, the applicant projects a total of 7,248 GI endoscopy procedures at both locations (6,240 at Vinehaven and 1,008 at Poplar Tent) in CY2021.
- The applicant calculates the average number of GI endoscopy procedures completed in the last five years to include the current interim year projections as 6,610.
- The applicant projects a 9% increase in GI endoscopy procedures post COVID-19 for CY2021.

- The applicant calculates the average annual increase in procedure volumes for the last five calendar years (2017-2021) to include the current interim year as 4.8% per year.
- The applicant projects a 5% increase in the total number of procedures for the first three full fiscal years following project completion.
- In supplemental information requested by the Agency, the applicant states that they utilized 5% rather than 11.3% (average percent volume change by fiscal year) to project increases in procedure volumes because there was less variation from year to year in the calendar year volume percentage changes versus the percentage change for the fiscal years.

Projected utilization is reasonable and adequately supported for the following reasons:

- Projected utilization is based on the most recent GI endoscopy procedure data annualized.
- The applicant's projected growth rates in GI endoscopy procedures are conservative and supported by the growth rate post COVID-19 and the historical five-year average.
- The applicant demonstrates that the projected utilization exceeds the required 1,500 procedures per GI endoscopy room.

Access to Medically Underserved Groups

In Section C.6, pages 31-32, the applicant states its services are accessible to all residents in need of GI endoscopy services, regardless of race, color, religion, national origin, sex, age, disability, or socioeconomic class. On page 32, the applicant projects the patient percentages of underserved groups seeking GI endoscopy services at NDHC – Poplar Tent during the third year of operation (CY2025) following completion of the project, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	1%
Racial and ethnic minorities	28%
Women	58%
Persons with Disabilities	Not available
The elderly	30%
Medicare beneficiaries	27%
Medicaid recipients	1%

Source: Table on page 32 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 based on the following:

- The applicant provides an estimate for each medically underserved group it proposes to serve.

- The applicant provides written statements about offering access to all residents of the state, including underserved groups.

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.

- (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, CGA, proposes to obtain a license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms, NDHC-Vinehaven, to a new location on the first floor of leased space in an existing building.

The applicant does not propose to reduce or eliminate any existing GI endoscopy room services; rather, the applicant has relocated a GI endoscopy room from NDHC-Vinehaven located at 1070 Vinehaven Drive, NE in Concord in Cabarrus County to 9965 Poplar Tent Road in Concord in Cabarrus County and seeks to obtain a license for the relocated GI endoscopy room. The two buildings are approximately 12 miles and 15 minutes driving time from each other, according to Google Maps. Thus, the GI endoscopy services will still be accessible to the same population at the new location.

In Section D.2, the applicant explains why it believes the needs of the population presently utilizing the services at NDHC - Vinehaven will be adequately met following completion of the project. On page 36, the applicant states:

“Since we are currently using 2 of the 3 GI endoscopy procedure rooms at the Vinehaven location, the impact on patients will be minimal with the relocation of the third room. The needs of the patients currently utilizing the GI endoscopy center at Northeast Digestive Health Center-Vinehaven will continue to be met. We do not anticipate that the relocation will negatively impact any existing patients. Further, the new location will be more geographically convenient due to reduced traffic and limited construction causing delays in reaching the center on Vinehaven Drive and will be

more convenient for those living in the western part of Concord and Cabarrus County.
 ”

In Section Q, Form C, the applicant provides projected utilization, as illustrated in the following table.

NDHC Projected Utilization

	FY1 CY2023	FY2 CY2024	FY3 CY2025
NDHC-Vinehaven			
GI Endoscopy Rooms	2	2	2
Outpatient GI Endoscopy Procedures	6,872	7,290	7,730
Total GI Endoscopy Procedures	6,872	7,290	7,730
Average # of Procedures/Room	3,436	3,645	3,865
Need for GI Endoscopy Rooms*	2.29	2.43	2.58
NDHC-Poplar Tent			
GI Endoscopy Rooms	1	1	1
Outpatient GI Endoscopy Procedures	1,500	1,500	1,500
Total GI Endoscopy Procedures	1,500	1,500	1,500
Average # of Procedures/Room	1,500	1,500	1,500
Need for GI Endoscopy Rooms*	1.00	1.00	1.00

*Need for GI Endoscopy rooms is based on 1,500 procedures per room

In Section Q, pages 60-61, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- CY2023-CY2025 are the first three full fiscal years following the completion of the project.
- The applicant calculates the total number of GI endoscopy procedures for the first interim year, CY2021 by annualizing seven months of data from CY2021. In supplemental information requested by the Agency, the applicant states a total of 4,231 GI endoscopy procedures were performed at both locations in the first seven months of CY2021. The procedure volume at Vinehaven was 520 procedures/month and Poplar Tent was 84/month for a total of 604/month. Using this data, the applicant projects a total of 7,248 GI endoscopy procedures at both locations (6,240 at Vinehaven and 1,008 at Poplar Tent) in CY2021.
- The applicant calculates the average number of GI endoscopy procedures completed in the last five years to include the current interim year projections as 6,610.
- The applicant projects a 9% increase in GI endoscopy procedures post COVID-19.
- The applicant calculates the average annual increase in procedures for the last five years to include the current interim year as 4.8% per year.
- The applicant projects a 5% increase in the total number of procedures for the first three full fiscal years following project completion.

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

- Projected utilization is based on the most recent GI endoscopy procedure data annualized.
- The applicant's projected growth rates in GI endoscopy procedures are conservative and supported by the growth rate post COVID-19 and the historical five-year average.
- The applicant demonstrates that the projected utilization exceeds the required 1,500 procedures per GI endoscopy room.

Access to Medically Underserved Groups

In Section D.2, page 36, the applicant states:

“The proposed relocation will have no impact on the ability of the groups listed above to obtain the services provided by the facility. Access for low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups will not be negatively affected by the proposed relocation. A second endoscopy center location in Concord will allow for needed health care closer to home for many residents of western Cabarrus County. Public transportation is available at both locations.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use the GI endoscopy rooms at NDHC – Vinehaven will be adequately met following completion of the project for the following reasons:

- The needs of the population currently using the services, which have been relocated, can be adequately met at the new location.
- The applicant has relocated the GI endoscopy procedure room within the same county.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.
- The applicant provides written statements about offering access to all residents of the service area, including underserved groups.

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 the following reasons:

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or 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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed, three-room GI endoscopy ASF, Northeast Digestive Health Center – Vinehaven Drive (NDHC-Vinehaven) to a new location on the first floor of leased space in an existing building on Poplar Tent Road in Concord, approximately 12 miles away.

In Section E, page 38, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states that this alternative is not feasible because the increase in procedure volume would necessitate the addition of at least two pre/post procedure bays and expansion of the scope cleaning room. They would also need to increase the endoscopy waiting area and number of parking spaces. The applicant states that the current facility site does not allow for expansion and there is not available land at the site. Furthermore, the applicant cites an increase in traffic and construction causing delays in accessing NDHC-Vinehaven as well as scheduling difficulties due to the projected increase in volume. For these reasons, this alternative was not determined to be an effective alternative.
- Relocate the existing facility to a different site – the applicant states that other sites that were considered were not as convenient, would not offer ample parking, or would not provide adequate space for both the office and GI endoscopy center. Thus, this alternative was rejected.

On page 38, the applicant states that its proposal is the most effective alternative because the new location will allow for operational efficiencies to meet the increasing demands of growing procedure volumes, provide additional prep and recovery bays, ample parking, and access to GI endoscopy procedures in a timely manner.

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. Cabarrus Gastroenterology Associates, PLLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application and any supplemental responses. If representations conflict, the certificate holder shall materially comply with the last made representation.**
- 2. The certificate holder shall be eligible to obtain an ambulatory surgical facility license for no more than one existing gastrointestinal endoscopy room relocated from 1070 Vinehaven Drive NE, Concord to 9965 Poplar Tent Road, Concord for a total of no more than one gastrointestinal endoscopy room upon project completion.**
- 3. Upon completion of the project, Northeast Digestive Health Center at 9965 Poplar Tent Road shall be licensed for no more than one GI endoscopy room.**
- 4. Upon completion of the project, the certificate holder shall take the steps necessary to delicense one GI endoscopy room at Northeast Digestive Health at 1070 Vinehaven Drive, NE, Concord for a total of no more than two licensed gastrointestinal endoscopy rooms.**
- 5. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.**
- 6. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 7. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Sections F and Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 8. 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. Progress reports shall be due on the first day of every third month. The first progress report shall be due on April 1, 2022. The second progress report shall be due on July 1, 2022 and so forth.
9. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
- a. Payor mix for the services authorized in this certificate of need.
 - b. Utilization of the services authorized in this certificate of need.
 - c. Revenues and operating costs for the services authorized in this certificate of need.
 - d. Average gross revenue per unit of service.
 - e. Average net revenue per unit of service.
 - f. Average operating cost per unit of service.
10. 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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms, NDHC-Vinehaven, to a new location on the first floor of leased space in an existing building on Poplar Tent Road in Concord, approximately 12 miles away.

Capital and Working Capital Costs

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

	NDHC Poplar Tent Endoscopy
Site Costs	\$0
Medical Equipment	\$219,860
Construction Costs	\$996,476
Miscellaneous Costs	\$168,541
Total	\$1,384,876

*Total may not foot due to rounding

In Section Q, page 65 the applicant provides the assumptions and methodology used to calculate the capital costs of the project. The applicant adequately demonstrates that the capital cost is based on reasonable and adequately supported assumptions based on the following:

- The applicant provides actual costs that were incurred in 2020 for the upfit of leased space at NDHC-Poplar Tent for a medical office and GI endoscopy center which opened on November 30, 2020.
- In calculating the total capital cost for NDHC-Poplar Tent, the applicant allocates the total cost of medical equipment to the GI endoscopy center.
- The applicant calculates the percentage of space occupied by the GI endoscopy center [$4,909 / 12,100 = 0.4057$] and applies this to the remaining total costs for the office [$\$3,091,479 - 219,860 = \$2,871,619 \times 0.4057 = \$1,165,016$] and then adds back the cost of medical equipment [$\$1,165,016 + \$219,860 = \$1,384,876$]

In Section F, page 40, the applicant states that the relocation project does not involve start-up costs or initial operating expenses.

Availability of Funds

In Section F, page 39, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing	
Type	CGA
Loans	\$996,469
Accumulated reserves or OE *	\$388,407
Bonds	\$0
Other	\$0
Total Financing	\$ 1,384,876

* OE = Owner's Equity

The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project based on the following:

- Exhibit F contains a promissory note from Pinnacle Bank to CGA in the amount of \$2,456,173.
- In Exhibit F.2.c, pages 21-22 the applicant provides a letter from the accountant and the Financial Officer for CGA documenting adequate accumulated reserves to fund the amount committed to the capital costs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In supplemental information requested by the Agency, the applicant projects on Form F.2b, that revenues will exceed operating expenses in the third full fiscal years following completion of the project, as shown in the table below.

NDHC-Poplar Tent Projected Revenues & Expenses for GI Endoscopy Services			
FYs 1-3 (CYs 2023-2025)			
	1st Full Fiscal Year CY2023	2nd Full Fiscal Year CY2024	3rd Full Fiscal Year CY2025
Total Procedures	1,575	1,654	1,737
Total Gross Revenues	\$1,406,349	\$1,476,890	\$1,550,734
Total Net Revenue	\$679,267	\$713,338	\$749,005
Average Net Revenue per Procedure	\$431	\$431	\$431
Total Operating Expenses	\$702,229	\$725,212	\$736,412
Average Operating Expense per Procedure	\$446	\$438	\$423
Net Income	-\$22,962	-\$11,874	\$12,593

In supplemental information requested by the Agency, the applicant provides on Form F.2b the assumptions and methodology used in preparation of the pro forma financial statements. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant bases revenues and expense for NDHC-Poplar Tent on historical revenues and expenses for NDHC-Vinehaven.
- The applicant accounts for projected operating expenses, such as salaries, consistent with projections elsewhere in the application.
- 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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms to a new location approximately 12 miles away.

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 2021 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 geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” The facility is located in Cabarrus County and in Section C.3, page 27, the applicant projects that 63.5% of its patients will originate from Cabarrus County, with the next largest percentage of patients originating from Rowan County. Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

The 2021 SMFP shows there are 11 existing or approved GI endoscopy rooms in three facilities in Cabarrus County, as shown below.

Cabarrus County GI Endoscopy Services – FY2019 Data			
Existing Facilities	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Atrium Health Cabarrus	6	2,859	4,441
Gateway Surgery Center	2	4,028	4,028
Northeast Digestive Health Center	3	5,059	10,114
Total	11	11,946	18,583

Source: Table 6F: Endoscopy Room Inventory (page 84 of the 2021 SMFP)

In Section G.2, page 42, 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:

“The proposed project will not result in any unnecessary duplication of the existing or approved facilities that provide the same services and are in the service area because the existing facility has consistently completed the highest number of GI endoscopy procedures in the service area as seen in the last 3 annual State Medical Facilities Plans. For the last 4 years in the current interim year, the facility has completed an average of 6,610 procedures annually at the existing facility. We are projecting that 1,500 procedures would be completed at the proposed site in years 2023-2025. “

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 Cabarrus County.
- The applicant adequately demonstrates that the relocation of the existing GI endoscopy room and the subsequent licensing of the facility it has been relocated to as an ASF is needed in order to better meet the needs of the population being served.

Conclusion

The Agency reviewed the:

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

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

- (7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms to a new location approximately 12 miles away.

In supplemental information requested by the Agency, the applicant provides in Section Q, Form H, current and projected staffing for the proposed services by full-time equivalent (FTE) position, as illustrated in the following table.

NDHC-Poplar Tent Current & Projected Staffing by FTE Position				
Position	Current FTE as of 6/30/21	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
Registered Nurse	0.5	1.0	1.0	1.0
Licensed Practical Nurse	0.5	0.8	0.8	0.8
GI Technicians	1.0	1.5	1.5	1.5
Clerical	0.5	1.0	1.0	1.0
Total	2.5	4.3	4.3	4.3

In supplemental information requested by the Agency, the applicant provides in Section Q, Form H the assumptions and methodology used to project staffing. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and Section H.3, page 43, the applicant describes the methods to be used to recruit or fill new positions and its 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 projects an increase in the clinical FTE positions as the second location increases the days of operation.
- Annual salary per FTE position are based on the current salary per FTE inflated 3.0% annually.

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 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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms to a new location approximately 12 miles away.

Ancillary and Support Services

In Section I, page 44, the applicant identifies the necessary ancillary and support services for the proposed services. On page 44, the applicant explains that all ancillary and support services required for NDHC are provided by CGA and in Exhibit I.b provides operating agreements that CGA currently has in place with contractors to provide anesthesiology and pathology services. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant specifically identifies the existing providers of the ancillary and support services.
- The applicant provides documentation in Exhibit I.b that the necessary ancillary and support services will continue to be provided.

Coordination

In Section I, page 45, the applicant describes its existing and proposed relationships with other local health care providers and provides supporting documentation in Exhibit I.b. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- The applicant states that the facility has established relationships with other local healthcare providers.
- The applicant provides supporting documentation in Exhibit I.b.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed

services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered.

- (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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms to a new location on the first floor of leased space in an existing building on Poplar Tent Road in Concord.

In Section K, page 47, the applicant states that the project involved the renovation of 4,909 square feet in leased space and did not include the construction of new space. Line drawings and the lease are provided in Exhibit K.2.

On page 47, 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 upfit for the leased space did not involve the purchase of land or the construction of new space.

- The applicant was able to design the GI endoscopy center and office within the existing space to provide efficient and accessible patient and staff experience, without undue excess space.

On pages 47 and 48, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services based on the following:

- The applicant states that NDHC-Poplar Tent, as a freestanding ASF, represents a low-cost alternative for the provision of outpatient GI endoscopy services.
- NDHC benefits from the significant cost savings measures through the large economies of scale provided by CGA.

On page 48, the applicant identifies any applicable energy saving features that were 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.1, page 50, the applicant provides the historical payor mix during 10/1/2019 to 9/30/2020 at NDHC-Vinehaven, as summarized in the table below.

Payment Source	Percent of Total GI Endoscopy Patients
Self-Pay	0.7%
Charity Care	0.1%
Medicare*	27.0%
Medicaid*	0.2%
Insurance*	72.0%
Other	0.0%
Total**	100.0%

Source: Table on page 50 of the application.

*Includes managed care plans.

Totals may not sum due to rounding

In Section L.1, page 50, the applicant provides the following comparison of its patient population to the Cabarrus County service area population.

	% of Total Patients Served at NDHC 10/2019-9/2020	% of the Population of Cabarrus County
Female	58.0%	51.0%
Male	42.0%	49.0%
Unknown	0.0%	0.0%
64 and Younger	70.0%	87.0%
65 and Older	30.0%	13.0%
American Indian	0.0%	0.7%
Asian	2.0%	4.7%
Black or African-American	10.0%	19.6%
Native Hawaiian or Pacific Islander	0.0%	0.1%
White or Caucasian	85.0%	72.4%
Other Race	0.0%	2.4%
Declined / Unavailable	3.0%	0.1%

Source: Section L.1, page 50 of application

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

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.2, page 51, the applicant states that the facility has no obligation under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and handicapped persons.

In Section L.2, page 51, the applicant states that during the last 18 months it has not been notified of any patient civil rights equal access complaints filed against the applicant or a related entity and located in North Carolina.

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.

- (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.3, page 52, the applicant projects the following payor mix for NDHC-Poplar Tent and GI endoscopy services during the third year of operation (CY2025) following completion of the project, as shown in the following table.

Payment Source	Percent of Total Patients
Self-Pay	0.7%
Charity Care	0.1%
Medicare*	27.0%
Medicaid*	0.2%
Insurance*	72.0%
Other	0.0%
Total**	100.0%

Source: Table on page 52 of the application.

*Includes managed care plans.

**Totals may not foot due to rounding.

As shown in the table above, during the third full fiscal year of operation, the applicant projects 0.7 percent of GI endoscopy services will be provided to self-pay patients, 27.0 percent to Medicare patients, and 0.2 percent to Medicaid patients.

In Section L.3, page 51, the applicant provides the assumptions and methodology used to project payor mix following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical payor mix.

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.

- (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.5, page 53, 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

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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms, to a new location approximately 12 miles away.

In Exhibit M.2, page 74, 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 states that health professional training students utilize the office for training.
- The applicant provides the policies and procedures for observing procedures performed at NDHC.

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, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed ASF with three GI endoscopy rooms, to a new location approximately 12 miles away.

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 2021 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 geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.” The facility is located in Cabarrus County and in Section C.3, page 27, the applicant projects that 63.5% of its patients will originate from Cabarrus County, with the next largest percentage of patients originating from Rowan County. Thus, the service area for this facility consists of Cabarrus County. Facilities may also serve residents of counties not included in their service area.

The 2021 SMFP shows there are 11 existing or approved GI endoscopy rooms in three facilities in Cabarrus County, as shown below.

Cabarrus County GI Endoscopy Services – FY2019 Data			
Existing Facilities	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Atrium Health Cabarrus	6	2,859	4,441
Gateway Surgery Center	2	4,028	4,028
Northeast Digestive Health Center	3	5,059	10,114
Total	11	11,946	18,583

Source: Table 6F: Endoscopy Room Inventory (page 84 of the 2021 SMFP)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 55, the applicant states:

“We do not expect an impact on competition with this proposed relocation since we are currently providing services in the existing location and our current center is the primary provider of GI endoscopy procedures among the existing hospital facilities and ambulatory surgery facilities according to the 2020 and 2021 State Medical Facilities Plans. We met with the administrative staff and owners of the local ambulatory surgery facility, Gateway Surgery Center, and gained agreement with the proposal to move one GI endoscopy procedure room to the new location.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 55, the applicant states:

“The relocation proposal will allow for more efficient patient flow and throughput resulting in greater cost efficiency with the addition of pre and post procedure bays, a

larger scope cleaning room, and additional storage space. We anticipate no changes in cost per procedure and the same fee schedule will be used at both locations.”

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 55, 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 on Poplar Tent Road will be included as a satellite site in our upcoming AAAHC survey that is scheduled for September 2021.

....

We believe this will remain the case as we prepare to comply with the ASC licensure rules and Medicare conditions of coverage for the new location and continue to comply at the current location.”

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 55, 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 medical underserved. We participate with most private health insurance plans and government health programs including Medicare and Medicaid. The proposed relocation of one room will have no impact on the ability of the medically underserved to obtain services provided by our organization. The new location has access to public transportation as does the current center.”

See also Sections L, D and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion for 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 A.6, page 21, the applicant states they own, operate or manage one existing and approved facility of the same type (ASF) in North Carolina.

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 did not occur in the facility. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at NDHC, there is 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 Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903, 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. Rather the applicant, CGA, proposes to obtain an ASF license for one existing GI endoscopy room that has been relocated from a licensed, three-room GI endoscopy ASF, to a new location approximately 12 miles away.