REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conforming as Conditioned
NC = Nonconforming
NA = Not Applicable

Decision Date: August 29, 2023 Findings Date: September 1, 2023

Project Analyst: Terris Riley Co-Signer: Lisa Pittman

Project ID #: F-12387-23 Facility: CGH-Rea Farms

FID #: 070703 County: Mecklenburg

Applicants: Charlotte Gastroenterology & Hepatology, PLLC

CGH Properties, LLC

Project: Relocate the facility and develop no more than three new GI endoscopy rooms

for a total of no more than five GI endoscopy rooms upon project completion

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.

 \mathbf{C}

Charlotte Gastroenterology & Hepatology, PLLC and CGH Properties, LLC (hereinafter referred to as "the applicant" or "CGH"), propose to develop a new ambulatory surgical facility (ASF), by relocating two gastrointestinal endoscopy (GI Endo) rooms and one unlicensed procedure room from Charlotte Gastroenterology of Hepatology (CGH-Ballantyne) and developing three new GI Endo rooms at CGH-Rea Farms, for a total of no more than five GI Endo procedure rooms upon project completion.

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 2023 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

One Policy in Chapter 4 of the 2023 SMFP, *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities* is applicable to this review. On pages 30-31, the policy states:

"Any person proposing a capital expenditure greater than \$4 million to develop, replace, renovate or add to a health service facility pursuant to G.S. § 131E-178 shall include in its certificate of need application a written statement describing the project's plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. § 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. § 131E-184 is required to submit a plan for energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant's representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control."

The proposed capital expenditure for this project is greater than \$4 million. In Section B, page 26, the applicant describes the project's plan to improve energy efficiency and indicates it will "accept a condition requiring CGH to submit an Energy Efficiency and Sustainability Plan to the Agency's Construction Section that conforms to or exceeds energy efficiency and water conservation..." The applicant adequately demonstrates that the application includes a written statement in Exhibit B.2., describing the project's plan to ensure improved energy efficiency.

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 because the applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.

- (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.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI Endo rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI Endo rooms for a total of no more than five GI Endo procedure rooms upon project completion.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, "Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility." The 2023 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "the county where the proposed GI endoscopy room will be developed."

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

In Section C, page 31, the applicant states CGH Rea Farms is not an existing facility and thus has no patient origin. The applicant proposes to relocate existing GI endoscopy procedure rooms from the CGH-Ballantyne Endoscopy Center and has provided historical patient origin information for the CGH Ballantyne facility.

See the following table from pages 31 and 33 that illustrate patient origin from the last full fiscal year (FY) and the projections for the third FY of operation, CY 2028:

CGH-Ballantyne Endoscopy Center - HISTORICAL and Projected Patient Origin

| | Historical for FY 2022 | | Projected f | or FY 2028 |
|-------------|------------------------|------------|-------------|------------|
| County | # Pts. | % of Total | # Pts. | % of Total |
| Cabarrus | 82 | 1.4% | 203 | 1.4% |
| Gaston | 78 | 1.3% | 189 | 1.3% |
| Mecklenburg | 3,142 | 52.9% | 7,671 | 52.9% |
| Stanly | 55 | 1.0% | 145 | 1.0% |
| Union | 1,414 | 23.8% | 3,451 | 23.8% |
| Other** | 1,173 | 19.8% | 2,871 | 19.8% |
| Total | 5,944 | 100.0% | 14,500 | 100.0% |

^{*}The applicant lists the North Carolina counties included in "other", as well as other states on pages 33 and 35.

In Section C, pages 32-33, the applicant provides the assumptions and methodology to project patient origin. The applicant's assumptions are reasonable and adequately based on the following:

- The projections are based on the historical patient origin for the licensed GI Endoscopy room at CGH-Ballantyne as reported in the 2023 License Renewal Application from October 2021 through September 2022.
- The patients currently being served at CGH-Ballantyne are expected to continue being served at the new location, CGH-Rea Farms.
- CGH-Rea Farms is in close proximity to CGH Ballantyne (6-7 miles), which is still generally considered the Ballantyne/Providence Crossing area of Charlotte, North Carolina.
- The applicant also considers the increasing demand for GI Endoscopy services in the proposed service area as well as projected population growth.

Analysis of Need

In Section C, page 35, the applicant summarizes the need for the project as follows:

"CGH has a need to relocate to CGH-Rea Farms to have a site from which it can meet the needs of the population for Endoscopy services.

...CGH's lease on this space is coming to an end, requiring it to find an alternate location from which it can meet the needs of the patients it serves.

Without approval of this project, CGH would be without a site to take the place of its highly utilized CH-Ballantyne location..."

In Section C, pages 35-47, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below:

- The applicant states that the primary factor is the need to relocate to an available site with sufficient capacity to meet the current and increasing demand for endoscopy services.
- The applicant performed 6,973 procedures in its two licensed GI endoscopy rooms and 2,826 in its unlicensed room for a total of 9,799 procedures in SFY 2022.
- The applicant operates two licensed GI endoscopy rooms and averages 3,486.5 procedures per year per room which is more than the Performance Standards for five license GI endoscopy rooms as proposed in this application.
- The proposed facility will allow operational changes to enhance efficiencies and allow CGH to co-locate more physician offices at the same site.
- The applicant projects utilization for the proposed facility based on historical patient origin for its existing patients who are currently serviced in the CGH-Ballantyne facility as these patients are expected to continue service as the proposed location. Specifically, the applicant's ability to license all rooms at the proposed facility increases their ability to serve more patients regardless of payor source.

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

- Projected population growth in the service area, particularly among the 65+ population.
- Lowering of the recommended age to begin screening from age 50 to age 45.
- The historical growth in GI endoscopy procedures performed at CGH-Ballantyne.

Projected Utilization

In Section Q, Forms C.3a and C.3b the applicant provides projected utilization, as illustrated in the following tables.

| CGH Ballentyne (Will be CGH Rea Farms) | Interim Year FFY 2022 | Interim Year FFY 2023 | FFY 2024 | Interim Half Year FFY 2025 10/1/24-3/31-25 |
|-------------------------------------------|--------------------------|--------------------------|----------|--------------------------------------------------|
| # Procedures GI Endo Rooms | 6,973 | 6,980 | 6,990 | 3,500 |
| # GI Endo Rooms | 2 | 2 | 2 | 2 |
| Procedures per Room | 3,486 | 3,490 | 3,495 | 1,750 |

| CGH-Rea Farms (Previously CGH-Ballentyne | Interim Half Year FFY 2025 04/01/2025 – 9/30/2025* | FFY 2026 | FFY 2027 | FFY 2028 |
|---------------------------------------------|----------------------------------------------------------|----------|----------|----------|
| # Procedures | 8,000 | 14,000 | 14,250 | 14,500 |
| # GI Endo Rooms | 5 | 5 | 5 | 5 |
| Procedures/Room | 1,600 | 2,800 | 2,850 | 2,900 |

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

Step 1: Examine CGH-Ballentyne's Existing Volumes

Current High Utilization of CGH-Ballentyne

- During FFY 2022 CGH performed 3,487 procedures per licensed room and 2,826 procedures in the un-licensed room for a total of 9,799 procedures or 3,266 procedures per room.
- Current utilization is over twice the 1,500 procedures per room required by the Performance Standards in NCAC 14C .3903(4).

Expanding Procedure Volumes/Facility Constraints

• Despite the limitations on capacity, procedure volumes have increased by a CAGR of 1.63% from FFY2020-2022

Three-Month Patient Waiting List

- The first appointment available at CGH-Ballentyne is often 3 months from the date of the request.
- The facility constraints are resulting in delayed patient access to care despite utilizing the rooms at near-maximum capacity each working day.

Step Two: Examine Population Growth and Aging/New American Cancer Society Guidelines/New CGH Physicians

Overall Population Growth

- The applicant states that CGH-Ballantyne draws the most patients from Mecklenburg and Union Counties
- Per NCOSBM population growth from 2020-2030 is projected to grow 16.6% or a CAGR of 1.55% in Mecklenburg County and 22.5% or a CAGR of 2.05% in Union County

New American Cancer Society Age-45 Screening Guideline

- The applicant states that the American Cancer Society's newest guidelines recommend beginning colorectal cancer screenings at age 45 instead of at age 50.
- Further, the applicant states that the 45+ age group will now be highly likely to use the proposed services.
- The applicant states that it is hiring three new physicians in the summer of 2023 and two or three in the summer of 2024. These new physicians are expected to be at full potential in terms of referrals when the new facility opens April1, 2025.

Step 3: Determine GI Endoscopy Use Trends – Mecklenburg Facilities

• Based on the 2020-2023 SMFP's, the applicant states that endoscopy procedures in Mecklenburg County increases at a CAGR of 6.83% from October 1, 2017, through September 30, 2020.

Step 4: Calculate Overall Procedure Volumes – Mecklenburg Facilities

• Using the CAGR of 6.83%, the applicant projects Mecklenburg County volume through March 31, 2025 (See Step 4 in Section Q

<u>Step 5: Determine Historical CGH-Ballentyne Market Share/Hold "Constant" for Interim Years</u>

• The applicant states it will keep procedure volumes "close to flat" during the interim years, even though market share will decrease as total procedures in Mecklenburg County increase.

Step 6: Project CGH-Rea Farms Market Share

• The applicant projects to increase market share from its current percentage of approximately 6%, with 2 licensed GI endoscopy rooms and one un-licensed procedure room to 99% to 10% with a total of 5 licensed GI endoscopy rooms at CGH Rea Farms. Additionally, the applicant anticipates a ramping-up in cases as it will be able to schedule the "pent-up" demand. CGH-Rea is projected to open April 1, 2025.

As shown in the tables above, the applicant projects to perform 2,900 GI endoscopy procedures per GI endoscopy procedure room by the third full fiscal year following project completion. This meets the performance standard promulgated in 10A NCAC 14C. 3903(4), requiring the applicant to project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in any existing, approved, and proposed GI endoscopy procedure rooms owned or operated by the applicant or a related entity in the proposed service area.

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

• Projected utilization is based on actual historical utilization of GI endoscopy rooms owned or operated by CGH-Ballantyne.

- The applicant's projected growth rate in GI endoscopy procedures is supported by the historical growth rate as well as projected population growth in Mecklenburg County and surrounding areas.
- 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, page 52, the applicant provides the estimated percentage for each medically underserved group during the third full FY, as shown in the following table:

| Medically Underserved | Percentage of |
|------------------------------|-----------------------|
| Groups | Total Patients |
| Low-income persons | Not tracked |
| Racial and ethnic minorities | Not tracked |
| Women | 56.6% |
| Persons with Disabilities | Not tracked |
| Persons 65 and older | 27.0% |
| Medicare beneficiaries | 27.0% |
| Medicaid recipients | 2.2% |

In Section C, page 52, the applicant states:

"The Applicant does not maintain data on certain groups (as indicated above) and therefore does not have a reasonable basis to estimate percentage of service to individuals in these groups; however, the Applicant does not discriminate or deny access to individuals in these groups."

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

In Section D, page 58, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. The applicant states:

"The proposed project will not result in any reduction in access to these services. CGH-Rea Farms will serve the patients currently utilizing these services at CGH-Ballantyne as the rooms located at CGH-Ballantyne will be relocated to CGH-Rea Farms. These locations are both within Mecklenburg County and in the same zip code. As a result of the relocation and the proposed addition of rooms, patients will have access to a larger facility with expanded spaces for prep and recovery and other benefits of a new modern facility which will promote the efficient delivery of quality care."

Access to Medically Underserved Groups

In Section D, page 59, the applicant states:

"The proposed relocation/addition project is not expected to have any impact on the ability of these groups to obtain the services proposed as [at] CGH-Rea Farms will continue to serve the patient population following project completion."

The applicant adequately demonstrates that the needs of medically underserved groups that have used GI endoscopy services at CGH-Ballantyne, will be adequately served because the applicant is not proposing to reduce access to these services, as it will continue to serve the patients currently utilizing these services at CGH-Ballantyne, at the new location, CGH-Rea Farms.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be 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.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

In Section E, page 63, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo The applicant states maintaining the status quo is not an option because its lease ends soon; therefore, this was not an effective alternative.
- Delay Development of the Project The applicant states that it believes current legislative initiatives "are poised" to remove CON restrictions on the development of new single specialty licensed ASCs located in "higher population" counties, as early as two years from this summer. Delaying this project two more years would not meet their ability to meet the high demands of the patient population.
- Relocate CGH-Ballantyne to an Alternate Location The applicant considered other sites but determined that they were not suitable based on several factors: insufficient parking, inadequate space for the medical office and the endoscopy center, less desirable features, and pricing. Rea Farms was selected because it can accommodate a building large enough to house both the medical office and the endoscopy center. Rea Farms is also in close proximity to its partner, Novant Ballantyne Medical Center—giving physicians greater accessibility for patients to be treated at the hospital as well.

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's proposal will provide a more cost-effective and efficient setting for GI endoscopy services.
- 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. Charlotte Gastroenterology & Hepatology, PLLC and CGH Properties, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.
- 2. The certificate holder proposes to develop a new ASF, by relocating two GI endoscopy rooms and one un-licensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms at CGH-Rea Farms upon project completion.

3. Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: https://info.ncdhhs.gov/dhsr/coneed/progressreport.html.
- b. The certificate holder shall complete all sections of the Progress Report form.
- c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should

include documentation to substantiate each step taken as available.

- d. The first progress report shall be due on January 1, 2024.
- 4. 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.
- 5. 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 Section 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.
- 6. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

Capital and Working Capital Costs

In Section Q, on Form F.1a, the applicant provides the projected capital costs, as shown in the table below:

| Construction/Renovation Contracts | \$2,649,000 |
|-----------------------------------|-------------|
| Architect/Engineering Fees | \$134,450 |
| Medical Equipment | \$750,000 |
| Non-Medical Equipment | \$150,000 |
| Miscellaneous | \$340,782 |
| Total | \$4,022,232 |

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

- The applicant states that construction and renovation costs are based on the experience of the General Contractor and supporting documentation is provided in Exhibit B.2.
- In calculating costs for medical equipment and non-medical equipment, the applicant assumes that the medical equipment can be relocated from CGH-Ballantyne facility to the proposed facility. Other medical equipment will be purchased, and all projected costs are based on the applicant's experience.
- Applicant states that the financing costs were built into the loan package and the estimated interest during construction is based on lender input.
- In Exhibit B.2, the applicant provides a letter dated May 9, 2023, from M.A. Mock Enterprises, Inc., a general contracting firm, quoting an architect/engineering fee of \$134,450 based on a construction contract cost of \$2,649,000.

In Section F, page 67, the applicant there will be no start-up costs or initial operating expenses for the proposed project because, "CGH-Ballantyne is a "going concern" and operates with revenues exceeding its expense. CGH-Ballantyne will continue in operation until the opening of CGH-Rea Farms. Staff will transition from CGH-Ballantyne to CGH-Rea Farms." On pages 67-68, the applicant states that since CGH-Ballantyne will transition into a fully operational CGH-Rea Farms, the applicant does not anticipate a start-up budget or the need for initial operation funds.

Availability of Funds

In Section F, page 66, the applicant states that the capital cost will be funded as shown in the following table:

| Charlotte Gastroenterology & Hepatology, PLLC. | | |
|------------------------------------------------------------------|-------------|--|
| Loans | \$4,022,232 | |
| Cash & Cash Equivalents, Accumulated Reserves, or Owner's Equity | \$0 | |
| Bonds | \$0 | |
| Other | \$0 | |
| Total | \$4,022,232 | |

On page 65, the applicant states the capital expenditure costs will be incurred by Charlotte Gastroenterology & Hepatology, PLLC. In Exhibit F, the applicant provides the following documentation:

• A letter dated May 10, 2023, signed by a Senior Vice President of Mecklenburg Commercial Banking at First Citizens Bank, stating that Charlotte Gastroenterology & Hepatology, PLLC is an existing client with a long business relationship with the bank.

The letter affirms their interest in providing financing for the capital needs for the proposed CGH-Rea Farms project.

Exhibit D.1 contains facility and line drawings depicting construction overview. The exhibit also includes a document from Polaris 3G Parcel Ownership and GIS Summary confirming land property owned by the applicant, CGH Properties, LLC. Also contained in Exhibit D.1 is a Special Warranty Deed granting conveyance of the property from Charlotte Gastroenterology & Hepatology, PLLC. To CGH Properties, LLC.

The applicant adequately demonstrates availability of sufficient funds for the capital needs of the project because the explanation of the funding is reasonable and adequately supported.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2a, the applicant projects that revenues will exceed operating expenses in the first three full fiscal year following project completion, as shown in the following table:

| CGH-Rea Farms Projected Revenues & Operating Expenses | | | |
|-------------------------------------------------------|----------------------|----------------------|----------------------|
| | 1 st Full | 2 nd Full | 3 rd Full |
| | FY 2025 | FY 2026 | FY 2027 |
| Total Procedures | 14,000 | 14,250 | 14,500 |
| Total Gross Revenues (Charges) | \$24,514,000 | \$24,951,750 | \$25,389,500 |
| Total Net Revenue | \$7,844,480 | \$7,984,560 | \$8,124,640 |
| Average Net Revenue / Procedure | \$560 | \$560 | \$560 |
| Total Operating Expenses (Costs) | \$4,962,511 | \$5,323,598 | \$5,707,903 |
| Average Operating Expense / Procedure | \$354 | \$374 | \$394 |
| Net Income | \$2,881,969 | \$2,660,962 | \$2,416,737 |

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

- The applicant relied on its historical experience in providing the same services to project future costs and revenues.
- The applicant appropriately adjusted its projections to account for the difference in the increased number of GI endoscopy rooms and number of patients to be served.

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 because the applicant adequately demonstrates that capital costs are based on reasonable and adequately supported assumptions 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.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

N.C. Gen. Stat. §131E-176 (24a) states, "Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility." The 2023 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "...the county where the proposed GI endoscopy room will be developed." The facility will be developed in Mecklenburg County. Thus, the service area for this facility is Mecklenburg County. Facilities may also serve residents of counties not included in their service area.

According to Table 6F on pages 88-89 of the 2023 SMFP, there are 19 existing or approved facilities with GI endoscopy procedure rooms in Mecklenburg County. Information on these facilities is shown in the table below.

| Facilities with GI Endoscopy Procedure Rooms – Mecklenburg County | | | | | |
|-------------------------------------------------------------------|-------------------|-------------------|--------|------------|--|
| Facility | Existing Rooms | Approved Rooms | Cases | Procedures | |
| Novant Health Ballantyne Medical Center* | 0 | 1 | 0 | 0 | |
| Carolina Digestive Endoscopy Center | 2 | 0 | 9,528 | 9,670 | |
| Carolina Endoscopy Center-Huntersville | 2 | 0 | 4,569 | 4,589 | |
| Carolina Endoscopy Center-Pineville | 2 | 0 | 4,034 | 4,110 | |
| Carolina Endoscopy Center-University | 2 | 0 | 4,062 | 4,090 | |
| Atrium Health Endoscopy Center Ballantyne | 4 | 0 | 8,995 | 14,577 | |
| Atrium Health Endoscopy Center Kenilworth | 2 | 0 | 4,167 | 5,430 | |
| Atrium Health Pineville | 2 | 0 | 3,004 | 4,285 | |
| Atrium Health University City | 1 | 0 | 1,208 | 1,866 | |
| Carolinas Medical Center/Center for Mental Health | 12 | 0 | 10,942 | 16,357 | |
| Charlotte Gastroenterology & Hepatology, PLLC-Endo Div | 4 | 0 | 6,178 | 7,338 | |
| Charlotte Gastroenterology & Hepatology, PLLC-Endo Div | 2 | 0 | 5,873 | 6,820 | |
| Endoscopy Center of Lake Norman | 2 | 0 | 3,697 | 4,296 | |
| Novant Health Ballantyne Outpatient Surgery | 1 | 0 | 554 | 554 | |
| Novant Health Huntersville Medical Center | 3 | 0 | 2,015 | 2,065 | |
| Novant Health Matthews Medical Center | 3 | 0 | 1,439 | 1,497 | |
| Novant Health Mint Hill Medical Center | 1 | 0 | 138 | 143 | |
| Novant Health Presbyterian Medical Center | 9 | -1 | 2,794 | 2,875 | |
| Tryon Endoscopy Center | 4 | 0 | 8,478 | 9,906 | |
| Total | 58 | 0 | 81,675 | 100,468 | |

^{*}During FFY 2021 as reported on 2022 License Renewal Applications

In Section G, page 75, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Mecklenburg County. The applicant states:

"The services proposed by CGH will not duplicate existing services but will relocate and add capacity for a service offering that is highly sought-after in the area based on population growth and aging. Screening recommendations call for residents aged 45 years and over, as well as patients with specific needs to access regular endoscopy services. As patients in these age groups come to represent a larger segment of the population in the area, demand for endoscopy services can be expected to elevate. For this reason, the Center as proposed will not duplicate but will enhance access to a much-needed service offering."

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

^{*}Certificate of Need approved facility that was under development and not licensed as of 9/30/2021

- The applicant is already serving the patients it proposes to serve in a different location close to the current location.
- The applicant adequately demonstrates that the proposal to develop a new ASF by relocating two GI endoscopy rooms and one un-licensed procedure room and developing three new GI endoscopy rooms is needed in addition to the existing or approved GI endoscopy procedure rooms in the proposed service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

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

| Projected Staffing (FTEs) | | | | | |
|---------------------------|-------------------------------------------------------------------------------|-------|-------|--|--|
| | 1 st Full Year 2 nd Full Year 3 rd Full Year | | | | |
| Registered Nurses | 10.00 | 11.00 | 12.00 | | |
| Nurse Manager | 1.00 | 1.00 | 1.00 | | |
| Endoscopy Technicians | 9.00 | 10.00 | 11.00 | | |
| Front Desk | 2.00 | 2.00 | 2.00 | | |
| Total | 22.00 | 24.00 | 26.00 | | |

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in Form F.3b, in Section Q. In Section H, pages 76-77, the applicant describes the methods to be used to recruit or fill new positions and its proposed training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant has an established process in place to recruit new employees.
- To aid in attracting and retaining excellent staff, CGH offers attractive salary and benefit packages, including group health, life insurance, dental coverage, and disability insurance.
- The applicant has an existing training and continuing education program.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a new ASF, by relocating two GI endo rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

Ancillary and Support Services

In Section I, page 79, the applicant identifies the necessary ancillary and support services for the proposed GI endoscopy services. On pages 77-78, the applicant explains how each ancillary and support service will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available based on the following:

- The applicant currently provides all necessary ancillary and support services and states it will continue these capabilities at the new location.
- In Exhibit I, the applicant includes a statement from its Chief Executive Officer, confirming the availability for the types of ancillary and support services it will continue to provide.

Coordination

In Section I, page 79, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the applicant's established relationships with local health care and social service providers that the applicant says will continue following the completion of the proposed facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

NA

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

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
 - (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and

(iv) would be available in a manner which is administratively feasible to the HMO.

NA

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

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

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

In Section K, page 82, the applicant states that the project involves renovating 13,245 square feet of existing space in an existing medical office building. Line drawings showing the areas to be renovated are provided in Exhibit D.1.

In Section K, pages 82-84, the applicant identifies the proposed site and provides information about the zoning and special use permits, and the availability of water, sewer and waste disposal, and power at the site. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed GI endoscopy facility based on the applicant's representations and supporting documentation.

In Section K, page 82-83, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states the cost, design, means of construction for the proposed project is the most reasonable alternative because:
 - o upfitting space is a cost-effective solution,
 - o the present site offers no viable mechanism for increasing the number of GI Endoscopy spaces; and
 - o proposed site will be modern with up-to-date features, which will maximize efficiencies in the delivery of care.

• The medical business office will also be located at the proposed site which will maximize the efficiency of operations.

In Section K, pages 82-83, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed GI endoscopy services or the costs and charges to the public for the proposed services based on the following:

- The applicant states the space is designed to be efficient and accessible with sufficient extra space.
- The applicant states that as a freestanding GI endoscopy center, the project will be a low-cost alternative for outpatient GI endoscopy services.
- The applicant states they benefit from cost saving measures based on economies of scale.

In Section K, page 83, the applicant identifies applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and persons with disabilities, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
 - (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved.

In Section L, page 86, the applicant provides the historical payor mix during calendar year (FY) 2022 for the GI endoscopy services performed at CGH-Ballantyne, the facility from which the GI endoscopy rooms will be relocated, as shown in the following table:

| CGH-Ballantyne Historical Payor Mix 10/01/2021-09/30/2022 | | |
|--------------------------------------------------------------|---------------------|--|
| Payor | Percentage of Total | |
| Category Patients Served | | |
| Self-Pay | 1% | |
| Charity 1% | | |
| Medicare* 27.0% | | |
| Medicaid* 2.2% | | |
| Insurance* 68.8% | | |
| Other 4.8% | | |
| Total 100.0% | | |

^{*}Including any managed care plans.

In Section L, page 87, the applicant provides the following comparison.

| CGH-Ballantyne | Percentage of Total Patients Served by the Facility or Campus during the Last Full FY | Percentage of the Population of the Service Area |
|-------------------------------------|---------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Female | 56.6% | 51.7% |
| Male | 43.4% | 48.3% |
| 64 and Younger | 73.0% | 88.1% |
| 65 and Older | 27.0% | 11.9% |
| American Indian | Unknown | 0.9% |
| Asian | Unknown | 6.5% |
| Black or African-American | Unknown | 33.3% |
| Native Hawaiian or Pacific Islander | Unknown | 0.1% |
| White or Caucasian | Unknown | 56.6% |

^{*} Percentages can be found online using the United States Census Bureau's QuickFacts located at: http://www.census.gov/quickfacts/fact/table/US/PST045218. Just enter the name of the county.

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

^{*} Census data is shown for Mecklenburg County from which most patients are expected to originate

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;

 \mathbf{C}

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L.2, page 87, the applicant states that it is not obligated under any applicable federal regulations to provide uncompensated care, community service, or access by minorities and persons with disabilities.

In Section L.2, pages 87-88, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

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

 \mathbf{C}

In Section L.3, page 88, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following project completion, as shown in the following table.

| CGH-Rea Farms Projected Payor Mix – FY 3 (FFY 2028) | | |
|-----------------------------------------------------|---------------------|--|
| Payor Category | % of Total Patients | |
| Self-Pay | 1.0% | |
| Charity Care | 1.0% | |
| Medicare* | 27.0% | |
| Medicaid* | 2.2% | |
| Insurance* | 68.8% | |
| TRICARE | Included above | |
| Total | 100.0% | |

^{*}Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1% of total services will be provided to self-pay patients, 1% to charity care patients, 27% to Medicare patients, and 2.2% to Medicaid patients.

On page 88, the applicant further states, the "projected payor mix for CGH-Rea Farms is based on the historical payor mix at CGH-Ballantyne; future payor mix is expected to mirror historical experience. Because GI Endoscopy services represent the sole service component, the service component payor mix is the same as the entire facility's 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 based on the reasons stated above.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

 \mathbf{C}

In Section C.6, page 52, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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 proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

In Section M, page 90, the applicant describes the extent to which health professional training programs in the area will have access to the proposed facility for training purposes. Exhibit M.1 documents the efforts made by the applicant to establish relationships with health professional training programs. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based their correspondence with several health professional training programs regarding access to CGH-Rea Farms for training purposes.

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.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, "Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility." The 2023 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "...the county where the proposed GI endoscopy room will be developed."

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

According to Table 6F on pages 88-89 of the 2023 SMFP, there are 19 existing or approved facilities with GI endoscopy procedure rooms in Mecklenburg County. Information on the facilities is shown in the table below.

| Facilities with GI Endoscopy Procedure Rooms – Mecklenburg County | | | | |
|-------------------------------------------------------------------|-------------------|-------------------|--------|------------|
| Facility | Existing Rooms | Approved Rooms | Cases | Procedures |
| Novant Health Ballantyne Medical Center* | 0 | 1 | 0 | 0 |
| Carolina Digestive Endoscopy Center | 2 | 0 | 9,528 | 9,670 |
| Carolina Endoscopy Center-Huntersville | 2 | 0 | 4,569 | 4,589 |
| Carolina Endoscopy Center-Pineville | 2 | 0 | 4,034 | 4,110 |
| Carolina Endoscopy Center-University | 2 | 0 | 4,062 | 4,090 |
| Atrium Health Endoscopy Center Ballantyne | 4 | 0 | 8,995 | 14,577 |
| Atrium Health Endoscopy Center Kenilworth | 2 | 0 | 4,167 | 5,430 |
| Atrium Health Pineville | 2 | 0 | 3,004 | 4,285 |
| Atrium Health University City | 1 | 0 | 1,208 | 1,866 |
| Carolinas Medical Center/Center for Mental Health | 12 | 0 | 10,942 | 16,357 |
| Charlotte Gastroenterology & Hepatology, PLLC-Endo Div | 4 | 0 | 6,178 | 7,338 |
| Charlotte Gastroenterology & Hepatology, PLLC-Endo Div | 2 | 0 | 5,873 | 6,820 |
| Endoscopy Center of Lake Norman | 2 | 0 | 3,697 | 4,296 |
| Novant Health Ballantyne Outpatient Surgery | 1 | 0 | 554 | 554 |
| Novant Health Huntersville Medical Center | 3 | 0 | 2,015 | 2,065 |
| Novant Health Matthews Medical Center | 3 | 0 | 1,439 | 1,497 |
| Novant Health Mint Hill Medical Center | 1 | 0 | 138 | 143 |
| Novant Health Presbyterian Medical Center | 9 | -1 | 2,794 | 2,875 |
| Tryon Endoscopy Center | 4 | 0 | 8,478 | 9,906 |
| Total | 58 | 0 | 81,675 | 100,468 |

^{*}During FFY 2021 as reported on 2022 License Renewal Applications

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 91, the applicant states that their proposal is expected to have a positive effect on competition in the service area by "offering patients an expanded Center in a new location with increased access to quality health care services."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 91, the applicant states:

"CGH will continue its emphasis on delivery of endoscopy services in the most costeffective manner. ...By expanding access through development of a larger Center, CGH can more rapidly schedule more patients and provide more care to allow patients to benefit from early screening and treatment options. In doing so, CGH is promoting quality, cost-effective offerings A new state-of-the art center will allow CGH to maximize the number of procedures it can offer and thus, improve its perprocedure cost structure to allow it to render care most cost-effectively.

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

^{*}Certificate of Need approved facility that was under development and not licensed as of 9/30/2021

Regarding the impact of the proposal on quality, in Section N, page 91, the applicant states:

"CGH will continue to offer quality services in a cost-effective setting with improved arrangements to accommodate increasing patient demand for endoscopy services. The proposed facility will offer physical spaces designed to promote excellence in the delivery of health care services by providing patients and staff with access to larger areas in a more modern facility.

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

Regarding the impact of the proposal on access by medically underserved groups, in Section N, pages 91- 92, the applicant states:

"With a 5-room Center, CGH will increase access for all patients, including those traditionally medically underserved. CGH will continue to offer services to all patients in need and to participate in community efforts designed to increase awareness and access to services to all residents in Mecklenburg, Union, and surrounding counties."

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

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

- 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.
- 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.
- 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

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

- (19) Repealed effective July 1, 1987.
- (20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

 \mathbf{C}

The applicant proposes to develop a new ASF, by relocating two GI endoscopy rooms and one unlicensed procedure room from CGH-Ballantyne and developing three new GI endoscopy rooms for a total of no more than five GI endoscopy procedure rooms upon project completion.

In Section O, page 93, and on Form O in Section Q, the applicant identifies the GI endoscopy facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of three of this type of facility located in North Carolina. One of those facilities, Endoscopy Center of Lake Norman, is a joint venture with Novant Health.

In Section O, page 94 and Exhibit I.1, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care did not occur any of these facilities.

After reviewing and considering information provided by the applicant and considering the quality of care provided at this facility, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

The application is conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903. The specific criteria are discussed below.

SECTION .3900 – CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES .3903 PERFORMANCE STANDARDS

An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:

- (1) identify the proposed service area;
- -C- In Section C, page 53, the applicant states the service area for this project is Mecklenburg County.
- (2) identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;
- -C- On Form O, the applicant identifies three GI endoscopy facilities owned or operated by the applicant or a related entity located in Mecklenburg County.
- (3) provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;
- -C- On Form C.3b in Section Q, Form C.3b, the applicant provides projected utilization for the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms at CGH-Rea Farms.
- (4) project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and
- -C- On Form C.3b in Section Q, Form C.3b, the applicant projects to perform an average of at least an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following project completion.
- (5) provide the assumptions and methodology used to project the utilization required by this Rule.
- -C- In Section Q, following Form C.3b, the applicant provides the assumptions and methodology used to project utilization required by this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.