**ATTACHMENT - REQUIRED STATE AGENCY FINDINGS**

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

| | |
|---|---|
| Decision Date: | July 23, 2015 |
| Findings Date: | July 23, 2015 |
| Project Analyst: | Gloria C. Hale |
| Team Leader: | Lisa Pittman |
| Project ID #: | J-11031-15 |
| Facility: | Duke GI at Brier Creek |
| FID #: | 150337 |
| County: | Wake |
| Applicant: | Private Diagnostic Clinic, PLLC |
| Project: | Relocate the existing licensed facility and develop two additional GI endoscopy rooms for a total of 4 rooms upon project completion |

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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.

C

Private Diagnostic Clinic, PLLC (PDC) d/b/a Duke GI at Brier Creek (Duke GI) is an existing, licensed ambulatory surgery center with two GI endoscopy rooms and is located at 10441 Moncreiff Road, Suite 101, in the Brier Creek area of Raleigh, in Wake County. Duke GI proposes to relocate the ambulatory surgery center to leased space in a medical building located at 10207 Cerny Street in Raleigh, and to develop two additional GI endoscopy rooms for a total of four GI endoscopy rooms. The proposed, relocated site will be in the Brier Creek area in Raleigh, approximately one half mile from the current site. The total cost for the proposed project is $1,635,993.

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 2015 State Medical Facilities Plan (2015 SMFP). In addition, no policies in the 2015 SMFP are applicable to this

review, including Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, since the total projected cost of the proposal is less than two million dollars. Therefore, this criterion is not applicable in 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The 2015 SMFP does not define a service area for GI endoscopy rooms, however the applicant defines its service area as Wake and Durham counties. The applicant may also serve residents of counties not included in its service area.

Duke GI is an existing, licensed ambulatory surgery center located in Raleigh, Wake County, which operates two GI endoscopy rooms. Duke GI proposes to relocate its licensed ambulatory surgery center within a half mile from its current location and add two additional GI endoscopy rooms for a total of four GI endoscopy rooms.

**Population to be Served**

In Sections III.6 and III.7, pages 66-67, the applicant provides the current and projected patient origin for GI endoscopy services provided at Duke GI, as illustrated in the following table:

**Duke GI at Brier Creek**
**Historical and Projected Patient Origin**

| County | Historical Patient Origin, FY2014 (9/01/13 – 8/31/14) | Projected Patient Origin, CY2016-CY2017 |
|---|---|---|
| Wake | 35.9% | 35.9% |
| Durham | 33.3% | 33.3% |
| Orange | 8.2% | 8.2% |
| Granville | 6.2% | 6.2% |
| Alamance | 2.5% | 2.5% |
| Chatham | 0.7% | 0.7% |
| Person | 2.2% | 2.2% |
| Franklin | 1.4% | 1.4% |
| Cumberland | 0.4% | 0.4% |
| Virginia | 1.2% | 1.2% |
| Other* | 8.0% | 8.0% |
| **Total** | **100.0%** | **100.0%** |

*Other includes <1% patient origin from each of 53 counties in the state and other states. See pages 66-67 for complete listing.

The applicant adequately identifies the population proposed to be served.

**Analysis of Need**

In Section III.1, page 35, the applicant states that the following factors support the need to develop two additional GI endoscopy rooms at Duke GI in Wake County:

- Rapid increase in utilization of Duke GI's existing two GI endoscopy rooms,
- Steady increase in service area population,
- Projected growth of the service area population aged 55+,
- Projected increase in cancer incidence concomitant with increases in average age of population,
- Service area's large percentage of minority population who are disproportionally affected by colon/rectum cancer, and
- Pressure by third-party payors to have their subscribers use lower cost options for outpatient care.

Rapid Increase in Utilization at Duke GI

In Section III, page 51, the applicant provides a table depicting an increase in GI endoscopy procedures at Duke GI from FY2010 through FY2014, for a four-year annual Compound Annual Growth Rate (CAGR) of 11.8%, illustrated as follows:

**Duke GI Utilization**

| | FY2010 | FY2011 | FY2012 | FY2013 | FY2014 | 4-Year CAGR |
|---|---|---|---|---|---|---|
| GI Endoscopy Procedures | 2,969 | 2,861 | 3,078 | 3,686 | 4,635 | 11.8% |

The applicant states, on page 51,

> *"The most recent one-year annual increase during FY2014 was 25.7 percent. Based on the performance standard of 1,500 procedures per GI endoscopy room defined in 10A NCAC 14C .3903 (b) & (c), PDC's two existing GI endoscopy rooms operated at 155 percent (4,635/ 2 rooms/ 1,500 procedures). Based on current utilization and the performance standard of 1,500 procedures per GI endoscopy room, Duke GI at Brier Creek can already justify a third GI endoscopy room."*

Steady Increase in Service Area Population

In Section III, page 47, the applicant states that Duke GI's service area includes Wake and Durham counties which account for approximately 70 percent of the facility's patient origin and that the population of these two counties is expected to grow 5.8 percent between 2015 and 2018. By comparison, the state is projected to grow by 3.0 percent. The applicant provides a table depicting projected population for Wake and Durham counties, from 2015 to 2018, as follows:

**Total Population Projections**

| County | 2015 | 2016 | 2017 | 2018 | 3-Year CAGR |
|---|---|---|---|---|---|
| Wake | 1,004,455 | 1,024,343 | 1,044,232 | 1,064,120 | 1.9% |
| Durham | 296,492 | 301,697 | 306,899 | 312,095 | 1.7% |
| **Total Service Area** | **1,300,947** | **1,326,040** | **1,351,131** | **1,376,215** | **1.9%** |

Projected Growth of Service Area Population aged 55+

In Section III, page 48, the applicant provides a similar table depicting growth of the population in its service area aged 55+ for the same time period, and states, *"The projections by age cohort 55 and older are fundamentally representative of the relevant population identified by ACS* [American Cancer Society] *colorectal screening recommendations."*

**Age 55+ Population Projections**

| County | 2015 | 2016 | 2017 | 2018 | 3-Year CAGR |
|---|---|---|---|---|---|
| Wake | 216,309 | 227,098 | 237,859 | 248,708 | 4.8% |
| Durham | 66,713 | 69,067 | 71,427 | 73,786 | 3.4% |
| **Total Service Area** | **283,022** | **296,165** | **309,286** | **322,494** | **4.4%** |

The applicant states, on page 48, that the 3-year CAGR for the 55+ age cohort is 4.4% compared to 1.9% for the service area's population as a whole. In addition, the applicant states that the 4.4% CAGR for the 55+ age cohort is higher than the statewide 3-year CAGR for the 55+ age cohort which is 2.6%. Lastly, it states, on page 48, that as the population increases, cancer incidence will increase as well. The applicant illustrates this by providing a table, on page 48, that compares colorectal cancer incidence rates by age group in the service area, from 2008-2012, as follows:

**Colorectal Cancer Incidence Rates**
**per 100,000 persons**
**2008-2012**

| Ages | Wake County | Durham County |
|---|---|---|
| All | 34.8 | 42.9 |
| 65+ | 163.5 | 169.3 |

Significant African American Population and Higher Cancer Incidence

The applicant states, in Section III, page 49, that there is a significant African American population in the Duke GI service area and that this is important since there is a correlation between race and cancer incidence. It states, *"African American men have the highest colorectal cancer incidence and mortality rates, and have a greater percentage of cases diagnosed in the latter stages."* Tables depicting the percentages of African Americans in the Duke GI service area compared to the state as a whole, and the colon/rectal cancer incidence in African Americans compared to all races in North Carolina, are provided on page 49 and are illustrated as follows:

**African American Population**
**July 1, 2013**

| Area | Percent of Total Population |
|---|---|
| Wake County | 21.4% |
| Durham County | 38.7% |
| North Carolina | 22.0% |

**Colon/Rectum Cancer Incidence per 100,000 persons**
**North Carolina**
**2008-2012**

| Body Site | African Americans | All Races |
|---|---|---|
| Colon/Rectum | 48.6 | 39.8 |

The applicant states, on pages 49-50, that the colon/rectum cancer rate for African Americans in the state is 22 percent higher than the incidence rate for all races and that African Americans are more likely to die of cancer than other races. In addition, as stated on page 50, African American men, in particular, *"have the highest colorectal cancer incidence and mortality rates and have a greater percentage of cases diagnosed in the latter stages."*

Pressure to use Lower Cost Options for Outpatient Care

The applicant states, in Section III, page 46, that patient cost-sharing, such as out-of-pocket costs and deductibles, are a barrier to persons seeking recommended screening tests. On page 45, the applicant states that freestanding outpatient facilities provide more affordable healthcare services than hospitals and that patients typically pay less coinsurance at them than they would at hospitals for the same services. Therefore, private insurers will tend to save money if their subscribers use non-hospital based services. Due to these factors, the applicant states that cost of care is a factor in access to GI endoscopy services and that Duke GI's endoscopy services *"offers a lower cost structure compared to the existing hospital-based GI endoscopy services in Wake and Durham counties."* In addition, the applicant states, on page 47, that its GI endoscopy services are also consistent with the Affordable Care Act in that it promotes *"cost-effective and convenient local outpatient healthcare services."*

**Projected Utilization**

Step One:
The applicant provides Duke GI's historical utilization for GI endoscopy procedures for FY2010 – FY2014 in Section III, page 57, illustrated as follows:

**Duke GI Endoscopy Historical Utilization**

| | FY2010 | FY2011 | FY2012 | FY2013 | FY2014 | 4-Year CAGR |
|---|---|---|---|---|---|---|
| GI Endoscopy Procedures | 2,969 | 2,861 | 3,078 | 3,686 | 4,635 | 11.8% |
| GI Endoscopy Cases | 2,467 | 2,357 | 2,572 | 2,899 | 3,811 | 11.5% |

As illustrated in the table above, the 4-year CAGR for Duke GI's GI endoscopy procedures was 11.8% and its 4-year CAGR for its GI endoscopy cases was 11.5%. Duke GI's one-year growth rate for GI endoscopy procedures, FY2013-FY2014, was 25.8%.

In addition, the applicant states it exceeded the performance standard of 1,500 procedures per GI endoscopy room as defined in 10A NCAC 14C .3903(b) & (c). This is calculated using GI endoscopy procedure data for FY2014, as follows:

4,635 (FY2014 procedures) / 2 (# of GI endoscopy rooms) = 2,317.5 / 1,500 = 1.55 or 155% capacity

Step Two:
In Section III, page 58, the applicant converts utilization from federal fiscal year to calendar year. The proposed project is expected to be operational by January 2016, therefore the first year of operation would be CY2016. The conversion of Duke GI's FY2014 GI endoscopy data results in the following:

| | **CY2014** |
|---|---|
| # of GI Endoscopy Procedures | 4,811 |
| # of GI Endoscopy Cases | 3,949 |
| # of GI Endoscopy Patients | 3,836 |

Step Three:
In Section III, page 48, the applicant depicts the growth of the population in its service area for persons aged 55+, illustrated below.

| **County** | **2015** | **2016** | **2017** | **2018** | **3-Year CAGR** |
|---|---|---|---|---|---|
| Wake | 216,309 | 227,098 | 237,859 | 248,708 | 4.8% |
| Durham | 66,713 | 69,067 | 71,427 | 73,786 | 3.4% |
| **Total Service Area** | **283,022** | **296,165** | **309,286** | **322,494** | **4.4%** |

In Section III, page 59, the applicant applies the total service area CAGR for persons aged 55+ of 4.4% to Duke GI's CY2014 utilization data to project utilization for CY2015, as follows:

| | **CY2015** |
|---|---|
| # of GI Endoscopy Procedures | 5,025 |
| # of GI Endoscopy Cases | 4,125 |
| # of GI Endoscopy Patients | 4,007 |

The applicant states, on page 59, that its use of a 4.4% growth rate to project utilization in CY2015 is reasonable and conservative given its most recent growth rate of 25.8% from FY2013 to FY2014.

Step 4:
In Section III, pages 59-61, the applicant reviewed its historical growth trends for GI endoscopy procedures and calculated the CAGRs for various lengths of time, illustrated as follows:

| | |
|---|---|
| 4-year CAGR (FY2010-FY2014) | 11.8% |
| 3-year CAGR (FY2011-FY2014) | 17.4% |
| 2-year CAGR (FY2012-FY2014) | 22.7% |
| 1-year percent change (FY2013-FY2014) | 25.7% |

The applicant states, on page 60, that it calculated growth for the first full year of the proposed project by using 60% of its most recent 2-year CAGR, FY2012-FY2014, illustrated as follows:

Growth rate calculation for Project Year One (CY2016)
2-year CAGR (FY2012-FY2014) = 22.7%
22.7 x 0.60 = 13.6%

The applicant projected utilization for Project Years Two and Three in a similar manner, however it used 50% of its most recent 2-year CAGR, FY2012-FY2014, for Project Year Two, and 40% of its most recent 2-year CAGR, FY2012-FY2014, for Project Year Three. These calculations are illustrated as follows:

Growth rate calculation for Project Year Two (CY2017)
2-year CAGR (FY2012-FY2014) = 22.7%
22.7 x 0.50 = 11.4%

Growth rate calculation for Project Year Three (CY2018)
2-year CAGR (FY2012-FY2014) = 22.7%
22.7 x 0.40 = 9.1%

The calculation of projected utilization for Project Years One through Three using the applicant's growth rates is illustrated as follows:

| | **CY2015** | **CY2016** | **CY2018** | **CY2019** |
|---|---|---|---|---|
| # of GI Endoscopy Procedures | 5,025 | 5,710 | 6,358 | 6,936 |
| # of GI Endoscopy Cases | 4,125 | 4,687 | 5,219 | 5,693 |
| # of GI Endoscopy Patients | 4,007 | 4,553 | 5,070 | 5,530 |
| Annual Growth | 4.4% | 13.6% | 11.4% | 9.1% |

The applicant's assumptions and methodologies used to project utilization are provided in Section III, pages 48, and 57-61.

The applicant adequately demonstrates that it is reasonable to assume it will perform 6,358 GI endoscopy procedures in four GI endoscopy rooms in the second operating year, CY2018, which is an average of 1,590 procedures per room [6,358 procedures / 4 rooms = 1,590 procedures per room]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

**Access to the Proposed Services**

In Section VI.2, pages 81-82, the applicant states:

> *"PDC has historically provided care and services to medically underserved populations. As a certified provider under Title XVIII (Medicare), PDC offers its services to the elderly. Also, PDC provides services to low-income persons as a certified provider under Title XIX (Medicaid).*
>
> *Further, PDC does not discriminate based on income, race, ethnicity, creed, color, age, religion, national origin, gender, physical or mental handicap, sexual orientation, ability to pay or any other factor that would classify a patient as underserved."*

In Section VI, page 91, the applicant projects that Medicare will comprise 26.04% of its payor mix and Medicaid will comprise 0.46%. The applicant states, in Section VI, page 82, that Medicaid and self-pay, indigent, and charity care patients comprised 1.0% of Duke GI's patients, however, it notes, *"...most Medicaid-eligible residents are children, who are not typical candidates for GI endoscopy procedures."*

The applicant describes its charity and financial payment policies on pages 83-87. The applicant projects, in Section VI, page 86, that Duke GI will provide $55,303 (0.95%) in combined bad debt and charity care to GI endoscopy patients in its first year of operation.

In summary, the applicant adequately identifies the population to be served and demonstrates the need the population proposed to be served has for two additional GI endoscopy procedure rooms at Duke GI. The applicant also adequately demonstrates the extent to which all residents of the service area, in particular, the underserved, will have access to the proposed services. Consequently, the application is conforming to this criterion.

(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, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(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

In Section III.8, pages 68-69, the applicant describes the alternatives considered, which include the following:

1) Maintain the Status Quo – the applicant considered this alternative, but decided it was not an acceptable alternative because Duke GI's utilization has increased steadily over the years and the facility has exceeded its physical capacity.

2) Utilize Local Hospital-Based GI Endoscopy Rooms – the applicant states that this alternative would not be a cost-effective alternative since freestanding facilities provide surgical and procedural services at a lower cost than hospitals. The applicant states, on page 69, that *"…patients incur fewer out-of-pocket costs when they utilize such facilities."*

3) Pursue a Joint Venture – the applicant states that since it is a freestanding, existing facility that already has two GI endoscopy rooms, this would not be a realistic option.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The applicant adequately demonstrates that the proposed alternative is the most effective or least costly alternative to meet the need for additional GI endoscopy rooms at Duke GI at Brier Creek. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **Private Diagnostic Clinic, PLLC d/b/a Duke GI at Brier Creek shall materially comply with all representations made in the certificate of need application and supplemental information received. In those instances where representations conflict, Private Diagnostic Clinic, PLLC d/b/a Duke GI at Brier Creek shall materially comply with the last made representation.**

2. **Private Diagnostic Clinic, PLLC d/b/a Duke GI at Brier Creek shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **Private Diagnostic Clinic, PLLC d/b/a Duke GI at Brier Creek shall develop no more than two additional gastrointestinal endoscopy rooms and shall be licensed for a total of no more than four gastrointestinal endoscopy rooms at Duke GI at Brier Creek following project completion.**

4. **Private Diagnostic Clinic, PLLC d/b/a Duke GI at Brier Creek shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section 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

In Section VIII.1, page 103, the applicant projects the total capital cost for the project will be $1,635,993. The capital costs include $932,188 in construction costs and $703,805 in miscellaneous costs which include equipment, furniture, consultant fees, and interest during construction. In Section VIII.3, pages 105-106, the applicant states the capital costs will be financed through accumulated reserves, an equipment operating lease, and through a facility lease with the lessor. The applicant provides a letter, dated April 10, 2015 from its Chief Financial Officer, in Exhibit 15, indicating the availability of accumulated reserves, which states,

> *"PDC* [Private Diagnostic Clinic, PLLC] *will fund the $40,000 associated with the consultant and application fees through its accumulated reserves. The financial statements included in our application show that PDC has these funds currently available. Please accept this letter as confirmation of PDC's intention to use the funds for the proposed CON project."*

The applicant provides a letter dated April 14, 2015, in Exhibit 16, from the Senior Vice President of First Citizens Bank which states, in part:

> *"**LESSEE**: Private Diagnostic Clinic, PLLC ('Borrower')*
>
> ***LEASE PURPOSE**: The lease proceeds may be used by the Borrower for the sole purpose of purchasing medical equipment for GI Endoscopy rooms that will be located at 10207 Cerny Street, Raleigh, NC 27617.*
>
> ***LEASE AMOUNT:** First Citizens Bank has approved a lease line of credit of which up to $600,000.00(**Six Hundred Thousand Dollars & 00/100**) will be set aside for the purpose of purchasing specific equipment described below.*
>
> ***EQUIPMENT:** GI Endoscopy equipment."*

Lastly, the applicant provides a draft memorandum of an Office Lease between 10207 Cerny Street, LLC and Private Diagnostic Clinic, PLLC in Exhibit 13. The applicant states, in Section VIII, page 102, *"PDC will incur the tenant improvement costs via the lease agreement."* The applicant also states, on page 102, that the lease costs are operational and that the lessor, 10207 Cerny Street, LLC, will up fit the medical office building, *"...a portion of which PDC will lease."* The applicant states, in Section XI, page 121, that its assumptions used to project the facility up fit costs were based on an architect's detailed review of the

project and the architectural firm's experience. A letter provided in Exhibit 14, dated April 6, 2015, from the Studio Forty architectural firm, states that the up fit of the medical office building space will cost approximately $1,020,000.

Therefore, the proposed funding for the capital and operating needs of the project is summarized as follows:

| | |
|---|---|
| $ 40,000 | Applicant's accumulated reserves |
| $ 600,000 | First Citizen's Bank, equipment operational lease |
| $1,020,000 | 10207 Cerny Street, LLC, operational lease |
| $1,660,000 | Total projected funding |
| | |
| $1,635,993 | Applicant's total projected capital costs |

In Section IX, page 109, the applicant states there will be no start up or initial operating expenses since Duke GI is an existing facility that is already offering GI endoscopy services.

In supplemental information, the applicant provides an audited financial statement for the years ended December 31, 2013 and December 31, 2012. As of December 31, 2013, Private Diagnostic Clinic, PLLC had $265,541,462 in total net assets (total assets less total liabilities), and $591,037,879 in total assets. The applicant provides pro forma financial statements for the first three years of the project in Section XIII. The applicant projects that Duke GI's GI endoscopy services revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the following table:

| Duke GI<br>GI Endoscopy Services | Project Year 1<br>CY 2016 | Project Year 2<br>CY 2017 | Project Year 3<br>CY 2018 |
|---|---|---|---|
| Projected # of Procedures | 5,710 | 6,358 | 6,936 |
| Projected Average Charge | 2,191 | 2,246 | 2,302 |
| Gross Patient Revenue | $12,511,924 | $14,281,162 | $15,968,100 |
| Deductions from Gross Patient Revenue | $6,666,081 | $7,608,692 | $8,507,455 |
| Net Patient Revenue | $5,845,844 | $6,672,470 | $8,507,455 |
| Total Expenses | $3,430,595 | $3,723,269 | $3,976,623 |
| Net Income | $2,415,249 | $2,949,201 | $3,484,022 |

The applicant projects a positive net income for Duke GI in each of the first three operating years of the project. In Section II, page 23, the applicant provides the projected average facility charge per procedure for the 10 most common GI endoscopy procedures. In Section II, page 24, the applicant states that the following professional services are not included in the average facility charge and will be charged separately by each provider, if they are needed: anesthesiology, pathology, radiology, pre-operative laboratory services, and any emergency transportation.

The assumptions used by the applicant in preparation of the pro formas are reasonable, including projected utilization, costs and charges. See Section XIII for the pro formas of the application for the assumptions regarding costs and charges. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The 2015 SMFP does not define a service area for GI endoscopy rooms, however the applicant defines its service area as Wake and Durham counties. The applicant may also serve residents of counties not included in its service area.

The applicant, Private Diagnostic Clinic, PLLC d/b/a Duke GI at Brier Creek, operates only one GI endoscopy facility in Wake County. Duke GI is currently licensed for two GI endoscopy procedure rooms in the Brier Creek area of Raleigh, in Wake County. Duke GI proposes to relocate its facility approximately one half mile away and add two GI endoscopy procedure rooms to its facility for a total of four GI endoscopy procedure rooms. There are 14 GI endoscopy facilities in Wake County and three in Durham County. Both Wake and Durham counties are in the applicant's service area, as stated in Section III.9, page 69. The tables below list all of the providers in the applicant's service area, the number of licensed GI endoscopy rooms for each, and the number of GI procedures performed in each during

FFY2013 as reported in the 2015 SMFP. In addition, utilization is provided for all 17 facilities.

**Wake County GI Endoscopy Facilities**
**FFY2013**

| HOSPITAL BASED | # OF GI ROOMS | TOTAL # OF GI PROCEDURES PERFORMED | # OF GI PROCEDURES PER GI ROOM |
|---|---|---|---|
| Duke Raleigh Hospital | 3 | 2,973 | 991 |
| Rex Hospital | 4 | 4,489 | 1,122 |
| WakeMed Hospital | 6 | 4,395 | 733 |
| WakeMed Cary Hospital | 4 | 2,831 | 708 |
| **Subtotal** | **17** | **14,688** | |
| # of Procedures/ 1,500 | 9.8 | | |
| # of Procedures/ # of Rooms | 864 | | |
| % of Regulatory Performance Std. | 57.6% | | |
| **FREESTANDING, NON-HOSPITAL BASED** | | | |
| Center for Digestive Diseases & Cary Endoscopy Center | 3 | 2,942 | 981 |
| Duke GI at Brier Creek | 2 | 3,686 | 1,450 |
| GastroIntestinal Healthcare | 2 | 2,140 | 993 |
| Kurt G. Vernon, MD PA | 1 | 2,278 | 2,278 |
| Raleigh Endoscopy Center | 4 | 14,857 | 2,157 |
| Raleigh Endoscopy Center-Cary | 4 | 11,845 | 1,968 |
| Raleigh Endoscopy Center-North | 3 | 8,793 | 1,656 |
| Triangle Gastroenterology | 2 | 4,620 | 2,310 |
| W.F. Endoscopy Center, LLC | 2 | 2,230 | 994 |
| Wake Endoscopy Center | 4 | 9,569 | 2,111 |
| **Subtotal** | **27** | **62,960** | |
| # of Procedures / 1,500 | 42.0 | | |
| # of Procedures / # of Rooms | 2,332 | | |
| % of Regulatory Performance Std. | 155.5% | | |
| **TOTALS** | | | |
| **# of GI Endoscopy Rooms/ Procedures** | 44 | 77,648 | |
| **# of Procedures / 1,500** | 51.8 | | |
| **# of Procedures / # of Rooms** | 1,765 | | |
| **% of Regulatory Performance Std.** | 117.7% | | |

**Durham County GI Endoscopy Facilities**
**FFY2013**

| HOSPITAL BASED | # OF GI ROOMS | TOTAL # OF GI PROCEDURES PERFORMED | # OF GI PROCEDURES PER GI ROOM |
|---|---|---|---|
| Duke University Hospital | 10 | 12,926 | 1,293 |
| Duke Regional Hospital | 4 | 4,356 | 1,089 |
| **Subtotal** | **14** | **17,282** | |
| # of Procedures/ 1,500 | 11.5 | | |
| # of Procedures/ # of Rooms | 1,234 | | |
| % of Regulatory Performance Std. | 82.3% | | |
| **FREESTANDING, NON-HOSPITAL BASED** | | | |
| Triangle Endoscopy Center | 4 | 5,991 | 1,498 |
| **Subtotal** | **4** | **5,991** | |
| # of Procedures / 1,500 | 4.0 | | |
| # of Procedures / # of Rooms | 1,498 | | |
| % of Regulatory Performance Std. | 99.9% | | |
| **TOTALS** | | | |
| **# of GI Endoscopy Rooms/ Procedures** | 18 | 23,273 | |
| **# of Procedures / 1,500** | 15.5 | | |
| **# of Procedures / # of Rooms** | 1,293 | | |
| **% of Regulatory Performance Std.** | 86.2% | | |

As illustrated in the tables above, six of the 14 GI endoscopy facilities in Wake County have exceeded 1,500 procedures per GI endoscopy room in FFY2013. All of Wake County's GI endoscopy rooms combined are operating at 117.7% of capacity, exceeding the performance standard of 1,500 procedures per GI endoscopy room. In addition, two facilities, one in Wake County and one in Durham County, are close to meeting the performance standard of 1,500 procedures per GI endoscopy room. All eight of the facilities exceeding or nearing the performance standard are freestanding GI endoscopy facilities. Durham County's GI endoscopy facilities, combined, are operating at just over 86% of the performance standard.

The applicant states that the need for two additional GI endoscopy procedure rooms is based on growing demand for GI endoscopy services at Duke GI and, as stated on page 71, to *"decompress capacity constraints and improve access to PDC's outpatient GI endoscopy services."* As stated in Section III, page 57, in FY2014, Duke GI performed 4,635 GI endoscopy procedures in two GI endoscopy rooms. This equates to 2,318 GI endoscopy procedures per room and is 154% of the performance standard of 1,500 GI endoscopy procedures per GI endoscopy room. The applicant has demonstrated that two additional GI endoscopy rooms will be needed. The discussion regarding analysis of need found in Criterion 3 is incorporated herein by reference.

In summary, the applicant's proposal will not result in the unnecessary duplication of existing or approved GI endoscopy rooms in the proposed service area. Therefore, the application is conforming to this criterion.

(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

In Sections VII.1 and VII.2, pages 93-94, the applicant provides the current and proposed staffing for its GI endoscopy services for the first full fiscal year, CY2016, as illustrated in the table below:

**Duke GI's GI Endoscopy Services**
**Number of Full-Time Equivalent Positions (FTEs)**

| Position | Current Staff (FTEs) | Projected Staff Additions (FTEs) | Total Projected Staff (FTEs) Project Year 1 CY 2016 |
|---|---|---|---|
| Administrator | 1.0 | 0.0 | 1.0 |
| Registered Nurse (RN) | 7.0 | 3.0 | 10.0 |
| Endoscopy Technician | 4.0 | 3.0 | 7.0 |
| Receptionist/Scheduler | 1.0 | 0.0 | 1.0 |
| **Totals** | **13.0** | **6.0** | **19.0** |

As indicated, Duke GI will add three additional full-time Registered Nurses and three additional full-time Endoscopy Technicians to its GI endoscopy services to accommodate its proposed two additional GI endoscopy rooms. In Section VII.3, pages 94-95, the applicant states that nearly all of the non-physician staff of PDC are leased employees through an arrangement with Duke University. The applicant states that Duke University is one of the largest employers in the area and that it offers competitive salaries and benefits. Duke GI states that it will continue to utilize employees from this arrangement and does not expect any difficulty in filling the additional positions it needs for the proposed project. In Section V.3, page 76, the applicant states that Dr. M. Stanley Branch will continue to serve as the Medical Director at Duke GI. Exhibit 3 contains a letter from Dr. Branch, dated April 9, 2015, indicating his intent to continue to serve as the Medical Director of Duke GI.

The applicant adequately documents the availability of sufficient health manpower and management personnel to staff the proposed new GI endoscopy room at Duke GI. Therefore, the application is conforming to this criterion.

(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

In Section II.2, pages 9-11, the applicant discusses all of the ancillary and support services it provides and will continue to provide for the proposed GI endoscopy services. A table is provided on page 9 that lists all of the services needed and indicates the in-house staff and contracted providers who will provide each of the services. Exhibit 10 includes a letter from the Department of Pathology at Duke University Medical Center indicating the continued availability of pathology services for the proposed services. In addition, as stated in Section V, page 75, Duke GI has transfer agreements with Duke University Hospital and Duke Raleigh Hospital. Copies of these agreements are provided in Exhibit 12. In Section V, page 77, the applicant states that Duke GI is an existing provider of GI endoscopy services and as such, has ongoing working relationships with Duke University Health System and Duke Primary Care, and, as stated on page 78, *"is aware of the medical needs of the community, through its involvement with patients at its current practices and through interactions with referring physicians."* Exhibit 18 contains letters of support for the proposed project from local healthcare providers. The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

(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

(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

(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

In Section XI.5, page 119, the applicant states it proposes to renovate 8,363 square feet of a portion of one floor of the Cerny Street medical office building it plans to utilize. Duke GI's current location consists of 4,122 square feet. The applicant states, on page 120, that the 8,363 square feet includes shared square footage for the building's common areas, which was used to calculate the project capital cost. The actual footprint of the relocated Duke GI facility will be 7,139 square feet.

Exhibit 14 contains the line drawings for the proposed project. Exhibit 14 contains an April 6, 2015 letter from the architectural firm, Studio Forty, certifying the project costs of $1,020,000, inclusive of architect and engineering fees, construction, and reimbursable expenses. This estimate is equivalent to the projected project costs listed in Section VIII, page 103.

In Section XI.6, page 121, the applicant estimates the following construction costs per square foot:

| **Duke GI** | **Square Feet** | **Construction Costs per Square Feet** | **Total Cost per Square Feet** |
|---|---|---|---|
| Proposed Endoscopy Suite with four GI endoscopy rooms | 8,363 | $111 | $196 |

In Section XI.8, pages 121-122, the applicant states that the proposed medical office building it will use for the relocation and addition of two GI endoscopy rooms *"was constructed in 2007, and uses modern energy conservation practices and methods, featuring energy efficiency and water conservation."* In addition, the applicant states that the building's HVAC, electrical systems, and lighting systems meet the current industry and State standards and that water fixtures designed as low flow will be used for water conservation.

The applicant adequately demonstrates that the cost, design and means of construction represent the most reasonable alternative for the project as proposed and that the construction project will not unduly increase the costs and charges of providing health services. The discussion regarding the costs and charges found in Criterion (5) is incorporated herein by reference. Therefore, the application is conforming to this criterion.

(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 handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(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 VI.12, page 89, the applicant provides the GI endoscopy services payor mix, as a percentage of total GI endoscopy cases, during the last calendar year, CY 2014 (1/01/2014 - 12/31/2014), for Duke GI, as illustrated in the following table:

**Duke GI Payor Mix**
**CY2014**

| Payor | % of Procedures |
|---|---|
| Self Pay / Indigent / Charity | 0.3% |
| Medicare | 26.0% |
| Medicaid | 0.5% |
| Commercial | 36.8% |
| Blue Cross Blue Shield | 29.9% |
| State Employees Health Plan | 5.6% |
| Other | 0.8% |
| **Total** | **100.0%** |

In Section VI.6, page 84, the applicant states,

> *"PDC currently provides access to outpatient GI endoscopy services for uninsured and medically underserved patients. All services offered by PDC at Duke GI at Brier Creek will continue to be available to all persons who present themselves for services. PDC will continue to provide services without regard to race, color, religion, sex, age, national origin, handicap, or ability to pay."*

Sections VI.4, VI.6, and VI.8 pages 84-87, contain additional discussion of access to current and proposed services for medically underserved patients, including charity care and financial payment policies.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Wake and Durham counties and statewide.

| County | 2010 Total # of Medicaid Eligibles as % of Total Population* | 2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population* | CY 2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center)* |
|---|---|---|---|
| Wake | 9.8% | 3.3% | 18.4% |
| Durham | 15.6% | 5.7% | 20.1% |
| Statewide | 16.5% | 6.7% | 19.7% |

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the GI endoscopy services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those aged 20 and younger and 31.6% for those aged 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The Office of State Budget & Management (OSBM) maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations currently have adequate access to the GI endoscopy services offered at Duke GI. 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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Section VI.11, page 88, the applicant states it has no obligation under public regulations to provide uncompensated care, community services, or access to care by minorities and handicapped persons. However, the applicant states that it will continue to serve all underserved patients as is its current business practice and that it has designed its proposed relocated facility to comply with access requirements of the Americans with Disabilities Act.

In Section VI.10, page 88, the applicant states that there have been no civil rights access complaints filed against them during the last five years. 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 VI.14, page 91, the applicant provides the projected payor mix for Duke GI's GI endoscopy services during the second operating year (CY 2017), as illustrated in the table below:

**Duke GI**
**Projected Payor Mix**
**CY 2017**

| Payor | Percent of Total GI Endoscopy Procedures |
|---|---|
| Self Pay / Indigent / Charity | 0.3% |
| Medicare | 26.0% |
| Medicaid | 0.5% |
| Commercial | 36.8% |
| Blue Cross Blue Shield | 29.9% |
| State Employees Health Plan | 5.6% |
| Other | 0.8% |
| **Total** | **100.0%** |

In Section VI.4, page 83, the applicant states all patients will continue to have access to GI endoscopy services regardless of their ability to pay. The applicant estimates that Duke GI will provide $55,303, or 0.95% of its net revenue, in charity care, for the first year of operation and $63,123 in the second year. These totals include bad debt since PDC's accounting system combines it with charity care. Exhibit 11 contains a copy of

PDC's financial assistance policy. Section VI, pages 83-84, contains additional discussion of patient access regardless of their ability to pay, including financial payment policies.

The applicant demonstrates that medically underserved populations will continue to have adequate access to the proposed GI endoscopy services. Therefore, 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 VI.9, page 87, the applicant states that patients gain access to endoscopy services at Duke GI through referrals by physicians. This occurs through the existing relationships patients have with PDC physicians or through self-referral by presenting directly at PDC specialty clinics.

The applicant adequately demonstrates that it offers a range of means by which a person will have access to GI endoscopy services at Duke GI. Therefore, 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

In Section V.1, page 75, the applicant states that it has agreements with Durham Technical Community College and Miller-Motte College to provide clinical training opportunities in practical nursing and medical assisting, respectively. Exhibit 9 contains copies of each agreement with these educational institutions. In addition, on page 75, the applicant states that since *"PDC functions as the faculty practice plan for Duke University…all PDC practice sites and services provide opportunities for training medical students and residents."* The information provided is reasonable and supports a finding of conformity with this criterion.

(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 2015 SMFP does not define a service area for GI endoscopy rooms, however the applicant defines its service area as Wake and Durham counties. The applicant may also serve residents of counties not included in its service area.

The applicant proposes to add two GI endoscopy procedure rooms to Duke GI for a total of four GI endoscopy procedure rooms. The following table lists the current providers of GI endoscopy services in Wake and Durham counties and utilization data from FFY2013 as reported in the 2015 SMFP:

| Hospital-Based Facilities | County | # of GI Rooms | Total # of GI Cases | Total # of GI Procedures |
|---|---|---|---|---|
| WakeMed Hospital | Wake | 6 | 4,010 | 4,395 |
| WakeMed Cary Hospital | Wake | 4 | 2,328 | 2,831 |
| Rex Hospital | Wake | 4 | 3,565 | 4,489 |
| Duke Raleigh Hospital | Wake | 3 | 2,178 | 2,973 |
| Duke University Hospital | Durham | 10 | 8,402 | 12,926 |
| Duke Regional Hospital | Durham | 4 | 3,956 | 4,356 |
| **Totals for Hospital-Based Facilities** | | **31** | **24,439** | **31,970** |
| **Freestanding Facilities** | | | | |
| Triangle Endoscopy Center | Durham | 4 | 4,855 | 5,991 |
| Center for Digestive Diseases & Cary Endoscopy Center | Wake | 3 | 2,942 | 2,942 |
| Duke GI at Brier Creek | Wake | 2 | 2,899 | 3,686 |
| GatroIntestinal Healthcare | Wake | 2 | 1,985 | 2,140 |
| Kurt G. Vernon, MD PA | Wake | 1 | 2,278 | 2,278 |
| Raleigh Endoscopy Center | Wake | 4 | 8,629 | 14,857 |
| Raleigh Endoscopy Center-Cary | Wake | 4 | 7,870 | 11,845 |
| Raleigh Endoscopy Center-North | Wake | 3 | 4,967 | 8,793 |
| Triangle Gastroenterology | Wake | 2 | 4,620 | 4,620 |
| W.F. Endoscopy Center, LLC | Wake | 2 | 1,987 | 2,230 |
| Wake Endoscopy Center | Wake | 4 | 8,444 | 9,569 |
| **Totals for Freestanding Facilities** | | **31** | **51,476** | **68,957** |

In Section III.9, page 71, the applicant states that the proposed project is based on the need to address the high and growing demand for GI endoscopy services at Duke GI, to alleviate capacity constraints, and to improve access to services.

In Section V.7, pages 78-80, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and

access. The applicant states that by adding two GI endoscopy rooms for a total of four GI endoscopy rooms, and by relocating the facility, it will address capacity constraints and improve access to services. See Sections II, III, V, VI and VII of the application where the applicant discusses the impact of the project on cost effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to GI endoscopy services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need to add two GI endoscopy rooms, for a total of four GI endoscopy rooms at Duke GI and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations;

Therefore, the application is conforming to this criterion.

(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

Duke GI is accredited by The Joint Commission and is certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred at the facility within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by Duke GI in North Carolina. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

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

C

The proposal submitted by Duke GI is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900, which are discussed below.

**.3902 INFORMATION REQUIRED OF APPLICANT**

.3902(a)(1) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: (1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906.;*

-C- In Section II.11, page 18, the applicant states its proposed service area consists of Wake and Durham counties. As stated in Section III.6, page 66, 69.2% of Duke GI's patients come from Wake and Durham counties.

.3902(a)(2) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (2) with regard to services provided in the applicant's GI endoscopy rooms, identify:*

*(A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located.*

-C- In Section II.11, page 18, the applicant states that Duke GI currently has two licensed GI endoscopy rooms and proposes to develop two additional licensed GI endoscopy rooms for a total of four.

*(B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area.*

-NA- In Section II.11, page 18, the applicant states that neither PDC nor any related entity currently owns or operates any other licensed facility with existing or approved GI endoscopy rooms in the state.

*(C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months.*

-C- In Section II, page 19, the applicant provides a table depicting all of Duke GI's GI endoscopy procedures by CPT code during CY2014 for a total of 4,811 procedures.

*(D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project.*

-C- In Section II, page 20, the applicant provides a table indicating the number of GI endoscopy procedures, identified by CPT codes, projected to be performed at Duke GI in each of the first three operating years of the project.

*(E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months.*

-NA- In Section II, page 20, the applicant states that it has only performed GI endoscopy procedures in Duke GI's two licensed GI endoscopy rooms during the last 12 months.

*(F) the number of procedures by type, other than GI endoscopy procedures, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project.*

-NA- In Section II, page 21, the applicant states that it does not project to perform any non-GI endoscopy procedures in any of its licensed GI endoscopy rooms in the first three operating years of the project.

*(G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months.*

-C- In Section II, page 21, the applicant states that it served 3,836 patients at Duke GI in its two licensed GI endoscopy rooms in the last 12 months, during CY2014.

*(H) the number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project.*

-C- In Section II, page 21, the applicant projects to serve 4,553 patients in Project Year One, CY2016, 5,070 patients in Project Year Two, CY2017, and 5,530 patients in Project Year Three, CY2018.

.3902(a)(3) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (3) with regard to services provided in the applicant's operating rooms identify: (A) the number of existing operating rooms in the facility;*

-NA- In Section II, page 22, the applicant states that it does not operate any operating rooms at Duke GI or in Wake County or any other counties in the state.

*(B) the number of procedures by type performed in the operating rooms in the last 12 months; and*

-NA- The applicant states, in Section II, page 22, that it does not operate any operating rooms at Duke GI or in Wake County or any other counties in the state.

*(C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project.*

-NA- The applicant states, in Section II, page 22, that it does not operate any operating rooms at Duke GI or in Wake County or any other counties in the state.

.3902(a)(4) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located.*

-C- In Section II, page 22, the applicant states that it will continue to provide services Monday through Friday, 7:00am to 5:00pm, 52 weeks a year, excluding holidays.

*.3902(a)(5) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-C- In Section II, page 22, the applicant provides the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the last 12 months, CY2014, as follows:

| **Description** | **Average Charge*** |
|---|---|
| Colonoscopy with biopsy single/multiple | $2,298 |
| EDG transoral biopsy single/multiple | $2,041 |
| Colsc flx with removal of tumor polyp lesion snare tq | $2,447 |
| Colon CA scrn not hi risk ind/pr colonoscopy flx dx with collj spec when performed | $2,107 |
| Colorectal screen; hi risk indicated | $2,180 |
| Esophagogastroduodenoscopy transoral diagnostic | $1,564 |
| Colsc flx with directed submucosal njx any sbst | $2,372 |
| Sigmoidoscopy flexible with bx | $1,349 |
| Sigmoidoscopy flx dx with collj spec br/wa if performed | $1,058 |
| EDG removal tumor polyp/other lesion snare tech | $1,915 |

*Charges are rounded to the nearest whole dollar

.3902(a)(6) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (6) the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility.*

-C- In Section II, page 23, the applicant provides the type and average facility charge for the 10 GI endoscopy procedures it projects will be performed most often in the facility, as illustrated in the table below:

| **Description** | **Project Year 1 CY 2016*** | **Project Year 2 CY 2017*** | **Project Year 3 CY 2018*** |
|---|---|---|---|
| Colonoscopy with biopsy single/multiple | $2,298 | $2,355 | $2,414 |
| EDG transoral biopsy single/multiple | $2,041 | $2,092 | $2,144 |
| Colsc flx with removal of tumor polyp lesion snare tq | $2,447 | $2,508 | $2,571 |
| Colon CA scrn not hi risk ind/pr colonoscopy flx dx with collj spec when performed | $2,107 | $2,160 | $2,214 |
| Colorectal screen; hi risk indicated | $2,180 | $2,235 | $2,290 |
| Esophagogastroduodenoscopy transoral diagnostic | $1,564 | $1,603 | $1,643 |
| Colsc flx with directed submucosal njx any sbst | $2,372 | $2,431 | $2,492 |
| Sigmoidoscopy flexible with bx | $1,349 | $1,383 | $1,417 |
| Sigmoidoscopy flx dx with collj spec br/wa if performed | $1,058 | $1,085 | $1,112 |
| EDG removal tumor polyp/other lesion snare tech | $1,915 | $1,963 | $2,012 |

*Charges are rounded to the nearest whole dollar

.3902(a)(7) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge.*

-C- In Section II, page 23, the applicant states:

> *"GI endoscopy charges are inclusive of GI professional and technical fees, reflecting charges for procedure room and recovery room time, nursing time, administrative time, linens, medications, billable medical supplies, equipment use, and other miscellaneous fees."*

.3902(a)(8) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an*

*existing licensed health service facility shall provide the following information: ... (8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges.*

-C- In Section II, page 24, the applicant states that the following charges will be billed separately by each provider: anesthesia, pathology, radiology, pre-operative lab work, and emergency transportation.

*.3902(a)(9) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-C- In Section II, page 24, the applicant provides the average reimbursement received per procedure for each of the 10 GI endoscopy procures most commonly performed in the facility during CY2014, as illustrated below:

| **Description** | **Average Reimbursement*** |
|---|---|
| Colonoscopy with biopsy single/multiple | $1,051 |
| EDG transoral biopsy single/multiple | $841 |
| Colsc flx with removal of tumor polyp lesion snare tq | $1,224 |
| Colon CA scrn not hi risk ind/pr colonoscopy flx dx with collj spec when performed | $1,086 |
| Colorectal screen; hi risk indicated | $986 |
| Esophagogastroduodenoscopy transoral diagnostic | $658 |
| Colsc flx with directed submucosal njx any sbst | $552 |
| Sigmoidoscopy flexible with bx | $433 |
| Sigmoidoscopy flx dx with collj spec br/wa if performed | $467 |
| EDG removal tumor polyp/other lesion snare tech | $580 |

*Average reimbursement figures are rounded to the nearest whole dollar

*.3902(a)(10) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: ... (10) the average reimbursement projected to be received for each of the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.*

-C- In Section II, page 25, the applicant provides the average reimbursement projected to be received for the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility for the first three project years, as follows:

| Description | Project Year 1 CY2016 | Project Year 2 CY2017 | Project Year 3 CY2018 |
|---|---|---|---|
| Colonoscopy with biopsy single/multiple | $1,051 | $1,077 | $1,104 |
| EDG transoral biopsy single/multiple | $841 | $862 | $883 |
| Colsc flx with removal of tumor polyp lesion snare tq | $1,224 | $1,255 | $1,286 |
| Colon CA scrn not hi risk ind/pr colonoscopy flx dx with collj spec when performed | $1,086 | $1,113 | $1140 |
| Colorectal screen; hi risk indicated | $986 | $1,011 | $1,036 |
| Esophagogastroduodenoscopy transoral diagnostic | $658 | $675 | $692 |
| Colsc flx with directed submucosal njx any sbst | $552 | $565 | $580 |
| Sigmoidoscopy flexible with bx | $433 | $443 | $454 |
| Sigmoidoscopy flx dx with collj spec br/wa if performed | $467 | $479 | $491 |
| EDG removal tumor polyp/other lesion snare tech | $580 | $594 | $609 |

*.3902(b) An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information:*

*(1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay;*
*(2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility;*

*(3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay;*

*(4) a written description of patient selection criteria including referral arrangements for high-risk patients;*

*(5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility;*

*(6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern.*

-NA- Duke GI is an existing provider of GI endoscopy services and does not propose to establish a new licensed ambulatory surgical facility.

***.3903 PERFORMANCE STANDARDS***

*.3903(a) In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*

-C- The applicant does not propose to operate any surgical operating rooms. In Section II, page 27, the applicant states that Duke GI will continue to operate its GI endoscopy rooms five days a week, 7:00am to 5:00pm, 52 weeks per year, excluding holidays.

*.3903(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*

-C- In Section III, page 60, the applicant states that Duke GI projects to perform 6,358 GI endoscopy procedures during Project Year Two, CY 2017, for four GI endoscopy rooms, which is an average of 1,590 procedures per room (6,358 procedures / 4 GI endoscopy procedure rooms = 1,590 procedures per room).

In Section III, pages 57-61 of the application, the applicant provides the assumptions and methodology used to project utilization. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

*.3903(c) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*

-C- In Section II, page 20, the applicant provides a table listing the top ten GI endoscopy procedures it provides and states it will continue to provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at Duke GI, as stated in Section II, page 27.

*.3903(d) If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: (1) if the applicant or a related entity*

*performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*

-NA- The applicant states, in Section II, page 28, that it does not, nor does any related entity, own or operate any surgical operating rooms in the proposed service area.

*.3903(e) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*

-C- In Section III, pages 57-61, the applicant describes the assumptions and methodology it uses to project GI endoscopy procedures. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference.

***.3904 SUPPORT SERVICES***

*.3904(a) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services.*

-C- Exhibit 10 contains a letter, dated April 10, 2015, from the Interim Chair of the Department of Pathology at Duke University Medical Center, stating that the Department of Pathology will continue to be available to provide pathology services for patients at Duke GI upon completion of the proposed project.

*.3904(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.*

-C- Exhibit 4 contains a copy of the applicant’s clinical policies and procedures related to anesthetics, including administration of conscious sedation or any type of

anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes.

.3904(c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.*

-C- Exhibit 4 contains a copy of the applicant's clinical policies and procedures related to cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases.

.3904(d) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide:*

*(1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county.*

-C- In Section II, page 29, the applicant states that all physicians with membership in PDC must *"receive privileges at a Duke University Health System hospital for membership."* In addition, the Medical Director at Duke GI, Dr. M. Stanley Branch, is on the medical staff at Duke University Hospital and Duke Raleigh Hospital.

*(2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges.*

-C- Exhibit 12 contains a letter from PDC stating that Duke GI is able to accept Duke GI endoscopy patients referred by Duke Raleigh Hospital.

*(3) documentation of a transfer agreement with a hospital in case of an emergency.*

-C- Exhibit 12 contains a copy of Duke GI's patient transfer agreement with Duke Raleigh Hospital and Duke University Hospital.

***.3905 STAFFING AND STAFF TRAINING***

.3905(a) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas: (1) administration; (2) pre-operative; (3) post-*

*operative; (4) procedure rooms; (5) equipment cleaning, safety, and maintenance; and (6) other.*

-C- In Section VII.6, page 97, the applicant projects staffing at Duke GI, by area of operation, as shown in the following table:

| Area of Operation | Employee Category | # of FTE Positions |
|---|---|---|
| Administration | Professional Health Care Administrator | 1.0 |
| Pre-operative | RN<br>Endoscopy Technician | 2.0<br>0.5 |
| Post-operative | RN<br>Endoscopy Technician | 2.0<br>0.5 |
| GI endoscopy procedure room | RN<br>Endoscopy Technicians | 4.0<br>4.0 |
| Other | RN<br>Endoscopy Technicians*<br>Non-Health professionals and technical personnel | 2.0<br>2.0<br>1.0 |
| Totals | | 19.0 |

*Perform scope processing.

.3905(b) *The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility.*

-C- In Section II, page 31, the applicant provides a listing of 24 Board-certified gastroenterologists at PDC who also have practice privileges at Duke GI. Of these, 10 are listed on page 31 who regularly practice at Duke GI. The applicant states that it expects the same physicians to continue to practice at the facility following completion of the proposed project.

.3905(c) *The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility.*

-C- Exhibit 6 contains a copy of PDC's policy regarding Medical Staff Credentialing and Privileging Process.

.3905(d) *If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health*

*Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility:*

*(1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility;*

*(2) all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery;*

*(3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area;*

*(4) at least one registered nurse shall be employed per procedure room;*

*(5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and,*

*(6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified.*

-NA- Duke GI is accredited by The Joint Commission. See Exhibit 7 for a copy of the accreditation certificate.

***.3906 FACILITY***

*.3906(a)* *An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located.*

*(b) An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of*

*Ambulatory Surgical Facilities within one year of completion of the proposed project.*

*(c) If the facility is not accredited at the time the application is submitted, an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall:*

*(1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies.*

*(2) provide a floor plan of the proposed facility identifying the following areas: (A) receiving/registering area; (B) waiting area; (C) pre-operative area; (D) procedure room by type; and (E) recovery area.*

*(3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and,*

*(4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located.*

-NA- Duke GI is an existing freestanding facility and it is accredited by The Joint Commission. See Exhibit 7 for a copy of the accreditation certificate.