

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: August 2, 2019
Findings Date: August 2, 2019

Project Analyst: Celia C. Inman
Team Leader: Gloria C. Hale

Project ID #: J-11709-19
Facility: Duke GI at Green Level
FID #: 190215
County: Wake
Applicant: Private Diagnostic Clinic, PLLC
Project: Develop a new ambulatory surgical facility with four GI endoscopy rooms

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. 131E-183(a) The Agency 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

The applicant, Private Diagnostic Clinic, PLLC (PDC), proposes to develop a new ambulatory surgical facility (ASF) with four new gastrointestinal endoscopy (GI endo) rooms. The facility, Duke GI at Green Level (Duke GI GL), will be located in Cary in Wake County.

PDC is the physician practice of Duke Health and is not owned or operated by Duke University Health System (DUHS).

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 2019 State Medical Facilities Plan (SMFP).

Policies

The proposed capital cost is greater than \$2 million, but less than \$5 million; therefore, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 31 of the 2019 SMFP is applicable to this review. Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities states:

“Any person proposing a capital expenditure greater than \$2 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.”

In Section B.4, pages 13-14, the applicant discusses the project’s plan to assure improved energy efficiency and water conservation, stating:

“PDC will ensure the proposed new facility will be developed in physical spaces that are designed to be in compliance with all applicable federal, state, and local building codes, and requirements for energy efficiency and water conservation, including 2019 SMFP Policy GEN-4.”

In Section K.4(c), page 86, the applicant makes further references to its plan to assure improved energy efficiency and water conservation.

Conclusion

The Agency reviewed the:

- application, and
- 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 does not propose to develop any new beds or services, or acquire any equipment for which there is a need determination in the 2019 SMFP, and
- the applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 for the following reasons:
 - the capital cost of the proposed project is greater than \$2 million and less than \$5 million, and
 - the applicant provides a written statement in the application 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, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a new ASF with four GI endoscopy rooms.

Patient Origin

The 2019 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3901(6) defines the service area "*as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*" In Section C.3, pages 18-19, the applicant identifies its primary service area as Wake County. Facilities may also serve residents of counties not included in their service area.

Duke GI at Green Level is not an existing ASF. For information purposes, the applicant provides the last full fiscal year (FY), FY2018, patient origin for the endoscopy services at Duke GI at Brier Creek (Duke GI BC) in Section C.2, page 17.

In Section C.3, page 18, the applicant provides the projected patient origin for the first three full fiscal years following the completion of the project, as summarized in the following table:

Duke GI at Green Level Projected Patient Origin						
	CY2023		CY2024		CY2025	
County or State	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Wake	2,928	80.0%	3,701	75.0%	4,183	75.0%
Harnett	151	4.1%	255	5.2%	288	5.2%
Johnston	142	3.9%	239	4.9%	271	4.9%
Franklin	131	3.6%	221	4.5%	250	4.5%
Other Counties/ States*	307	8.4%	518	10.5%	586	10.5%
Total	3,660	100.0%	4,934	100.0%	5,577	100.0%

Totals may not sum due to rounding

Source: Table in Section C.3, page 18 of the application.

*Other includes less than one percent of patients from each of the remaining counties in North Carolina and some counties in other states.

On page 19, the applicant describes the assumptions and methodology used to project patient origin. The applicant states that in-migration was determined proportional to the Wake County endoscopy providers’ patient origin, per the Agency’s FY2017 GI endoscopy patient origin/destination report (Exhibit 13). However, PDC states that to remain conservative, it does not project a significant number of Durham County patients will utilize Duke GI GL, but rather will continue to utilize Duke GI BC and the proposed Duke GI at North Durham (Project ID #J-11708-19). The applicant’s projected patient origin is reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 20-40, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 20, the applicant states that the need for the project is supported by the following factors:

- Increasing service area population (page 35).
- Aging service area population 50 and older (page 36).
- Screening recommendations and cancer incidence increases with age (pages 24 – 29 and page 36).
- Encouragement of outpatient care by third-party payors as a lower-cost option (pages 29 – 30).
- Historical utilization of existing PDC GI endoscopy services in Wake County (pages 37-38).

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

- The population of Wake County is projected to grow 2.0% annually over the next six years, compared to a projected statewide growth rate of 1.1% during the same time period.
- Wake County population 50 and older is projected to increase at approximately 3.5% annually, which the applicant states is consistent with the ongoing demand for GI endo services in the service area.
- The American Cancer Society (ACS) recommends early screening for detection of colorectal cancer as of the utmost importance. North Carolina has committed 80 organizations to sign the shared pledge goal of reaching an 80% screening level for colorectal cancer for adults ages 50-75.
- PDC’s proposed new freestanding GI endoscopy center will expand access to lower cost outpatient GI endoscopy services compared to hospital-based GI endoscopy services in Wake County.
- PDC’s four existing GI endoscopy rooms located at Duke GI at Brier Creek are well utilized, operating at 121% capacity, based on the performance standard of 1,500 procedures per GI endoscopy room.

Projected Utilization

Duke GI at Green Level is not an existing facility. In Section Q, Form C, the applicant provides the projected utilization as summarized in the following table.

Duke GI at Green Level Projected Utilization				
	Interim Months April through December 2022	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
# GI-Endo Rooms	4	4	4	4
Outpatient GI Procedures	2,275	4,573	6,165	6,969
GI Procedures / GI Room	569	1,143	1,541	1,742
Percent Capacity*	38%	76%	103%	116%

*Based on the performance standard in 10A NCAC 14C .3903(b): 1,500 GI endo procedures per GI endo room

In Section Q, pages 117-129, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

Assumptions:

- The first three full fiscal years of the project will be CY2023 – CY2025. (page 117)
- Wake County population will increase at a compound annual growth rate (CAGR) of 2.0% per the North Carolina Office of State Budget & Management (NCOSBM). (page 118)
- Wake County FY2017 GI endoscopy patient use rate was 52.05 per 1,000 population based on DHSR Healthcare Planning Section FY2017 patient origin data. (page 118)

- Wake County GI endoscopy patients had 1.25 GI endoscopy procedures per patient based on data from the 2019 SMFP Table 6F and the DHSR Healthcare Planning Section FY2017 patient origin data. (page 120)
- 72.65% of the endo patients served in Wake County were residents of Wake County based on DHSR Healthcare Planning Section FY2017 patient origin/destination data. (page 119)
- Duke GI at Brier Creek is well utilized with 3-year, 4-year, and 5-year CAGRs exceeding 10% and rebounding from a slight decline in FY2018 to a stable growth pattern as of April 2019, with a FY2019 annualized volume of 7,565. (pages 121-122)
- PDC projects GI endo procedures at Duke GI BC to increase 3.5% annually through 2025. (page 122)
- Duke GI BC projected FY volume is converted to CY volume prior to shifting utilization to Duke GI GL: $CY2024 = (.75 \times FY2024) + (.25 \times FY2025) = 9,064$. (page 122)
- Of the GI procedures performed at Duke GI BC, 21.8% are performed on Wake County residents. (page 123)
- PDC anticipates a shift of the Wake County GI endo patients from Duke GI BC to Duke GI GL, beginning with 25% in CY2022, increasing 5% per year through CY2025. (pages 123-124)
- In addition to the shift from Duke GI BC, PDC assumes that Duke GI GL will achieve an additional 3%, 4%, 5%, and 5.5% market share of the projected total Wake County procedures in CY2022-CY2025, respectively. (page 125)
- Based on PDC experience in GI endoscopy services, PDC projects in-migration at Duke GI GL will gradually increase from 10% of total procedures in CY 2022 to 25% of total procedures in CY2024. Conversely, Wake County procedures represent 90% and 80% of total procedures in CY2022 and CY2023, respectively, and 75% of total procedures in CY2024 and 2025. The applicant states that this is conservative at less than half the actual in-migration for Duke GI BC. (pages 126-127)

Methodology Applying the above Assumptions:

Step 1: Service Area Population (page 118)

	2019	2020	2021	2022	2023	2024	2025	CAGR
Wake County Population	1,093,987	1,116,912	1,139,953	1,163,066	1,186,223	1,209,408	1,232,612	2.00%

Steps 2 and 3: Apply the Wake County GI Patient Use Rate (52.05 per 1,000) to Project GI Endo Patients (page 119)

	2019	2020	2021	2022	2023	2024	2025
Wake County GI Endo Patients	56,938	58,132	59,331	60,534	61,739	62,946	64,153

Step 4: Project GI Endo Procedures using an endoscopy procedure to patient ratio (pages 119-120)

	2019	2020	2021	2022	2023	2024	2025
Wake County GI Endo Procedures per page 120 (1.258 procedures per patient) *	71,645	73,147	74,656	76,169	77,686	79,204	80,724
Wake County GI Endo Procedures per methodology Step 4 (1.25 procedures per patient) **	71,173	72,665	74,164	75,668	77,174	78,683	80,191

Rounding of percentages results in two different outcomes in the table above, resulting in a difference of 533 procedures (0.07%)

* Per page 120 of application, applicant states using a ratio of 1.25, but actually uses 1.258 procedures per patient in its calculation

**Per Analyst calculation using the applicant’s assumption of 1.25 procedures per patient ($84,077/67,287= 1.25$) on page 120. Step 7 below uses these procedure numbers in the calculation for incremental market share.

Step 5: Project GI Endo Procedures to Shift from Duke GI at Brier Creek to Duke GI at Green Level (pages 121-124)

Following its stated assumptions, the applicant projects an increase in procedures of 3.5% annually and then converts Duke GI BC projected procedures from fiscal year to calendar year, as summarized below.

	2022	2023	2024	2025	2026
Duke GI BC GI Endo Procedures - FY	8,388	8,681	8,985	9,299	9,625
Duke GI BC GI Endo Procedures - CY	8,461	8,757	9,064	9,381	
Duke GI BC Procedures Performed on Wake County Residents (21.8%)	1,844	1,908	1,975	2,044	
Percentage Shift of Duke GI BC Wake County Procedures to Duke GI GL	25%	30%	35%	40%	
Duke GI BC Wake County Procedures to Shift to Duke GI at Green Level	461	573	691	818	
Remaining Duke GI at Brier Creek Procedures After Shift to Duke GI GL	8,000	8,185	8,372	8,563	

In addition to the Wake County procedures proposed to be shifted to Duke GI at Green Level, the applicant provides a projection of the Orange and Durham County procedures that will shift to the proposed Duke GI at North Durham (page 129) in companion application, Project ID #J-11708-19 and the remaining GI endo procedures at Duke GI at Brier Creek, as summarized in the table below.

Duke GI at Green Level
 Project I.D. #J-11709-19
 Page 8

	2022	2023	2024	2025
Duke GI at Brier Creek GI Endo Procedures Before Shifts	8,461	8,757	9,064	9,381
Wake County Procedures to Shift to Green Level	461	573	691	818
Durham County Procedures to Shift to North Durham	924	1,275	1,649	1,707
Orange County Procedures to Shift to North Durham	275	380	491	508
Duke GI at Brier Creek Remaining GI Endoscopy Procedures	6,801	6,530	6,232	6,348

Steps 6 and 7: Service Area GI Endo Procedures based on Existing and Incremental Market Share (pages 125-126)

	CY2022	CY2023	CY2024	CY2025
Wake County Procedures Shifted from Duke GI BC to Duke GI GL	461	573	691	818
Wake County Procedures based on Incremental Market Share*	2,269	3,086	3,933	4,409
Wake County GI Endo Procedures at Duke GI at Green Level	2,730	3,658	4,624	5,227

*Calculation of Wake County Market Share at Duke GI GL

	2022	2023	2024	2025
Total Wake County GI Endo Procedures ^	75,668	77,174	78,683	80,191
Duke GI GL Market Share of Wake County Procedures	3%	4%	5%	5.5%
Wake County Procedures at Duke GI GL^^	2,269	3,086	3,933	4,409

^Procedures, as calculated by Analyst in Step 4, using applicant's methodology yields the applicant's Incremental Market Share as provided by the applicant in Step 7, on page 126 and above.

^^Rounding of percentages may cause totals to be insignificantly different

Step 8: In-Migration (pages 126-127)

	CY2022	CY2023	CY2024	CY2025
Wake County GI Endo Procedures at Duke GI at Green Level	2,730	3,658	4,624	5,227
Wake County Procedures as a % of Total Procedures	90%	80%	75%	75%
Total GI Endo Procedures	3,033	4,573	6,165	6,969
In-migration as % of Total	10%	20%	25%	25%
In-migration	303	915	1,541	1,742

Step 9: Duke GI at Green Level Projected GI Endo Procedures (page 128)

	CY2022*	CY2023	CY2024	CY2025
Total GI Endo Procedures	2,275	4,573	6,165	6,969

*Operations begin April 1, 2022, resulting in a nine-month partial year

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

- the applicant projects volume of procedures for Wake County residents based upon NCOSBM population estimates, the Wake County GI endo patient use rate, and the Wake County procedure to patient ratio,
- the applicant projects total Duke GI at Brier Creek procedures based upon historical procedures and a conservative growth rate, as compared to facility historical rates and Wake County rates,
- the applicant projects a shift of Wake County procedures from Duke GI at Brier Creek to Duke GI at Green Level based on expanded access to outpatient services, physicians seeking privileges at Duke GI GL, and convenience to patients in location and timely access to services,
- the applicant bases projected incremental market share upon referral relationships with local providers and its physician recruitment initiative, the need for increased access to outpatient services, capacity constraints at Duke GI at Brier Creek, population growth and aging of Wake County residents, and physician letters of support,
- the applicant projects in-migration at Duke GI at Green Level proportional to the collective experience of Wake County GI endo providers, which is less than half the in-migration percentage of Duke GI at Brier Creek, and
- the applicant does not project a significant number (less than 1% of patient origin) of Durham County residents, anticipating they will continue to utilize the existing Duke GI at Brier Creek facility and the proposed new Duke GI at North Durham (Project ID #J-11708-19).

Access

In Section C.8, page 44, the applicant states that all area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly and other underserved groups, will have access to the proposed new ASF, as clinically appropriate. The applicant further states that it does not discriminate on the bases of race, ethnicity, age, gender, or disability. The applicant states that Duke GI at Green Level will provide access to Medicare, Medicaid, and uninsured patients. The applicant provides supporting documentation in Exhibit 5.

In Section L.3, page 98, the applicant projects payor mix during the second full fiscal year of operation following completion of the project, as summarized in the following table.

Duke GI at Green Level Projected Payor Mix CY2024	
Payor Category	GI Endo Services as Percent of Total
Self-Pay/Charity Care	1.50%
Medicare*	27.60%
Medicaid*	0.02%
Insurance*	69.90%
Other	1.00%
Total	100.00%

Totals may not sum due to rounding

Source: Section L, page 98

* Including any managed care plans

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information publicly available during the review and used by the Agency.

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

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.

- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.
- (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

The applicant proposes to develop a new ASF with four new GI endoscopy rooms. The proposed project does not involve a reduction or elimination of a facility or a service.

- (4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

The applicant proposes to develop a new ASF with four GI endoscopy rooms.

In Section E, pages 56-60, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective to meet the need than the alternative proposed in this application. The alternatives considered were:

- Maintain the Status Quo – the applicant states that population growth and aging continue to drive demand for outpatient GI endoscopy services in Wake County; therefore, the status quo would not ensure adequate access for PDC’s patients and thus is ineffective.
- Develop Incremental GI Endoscopy Rooms at Duke GI at Brier Creek – the applicant states that this alternative does not afford the benefit of enhanced geographic access and is therefore less effective.
- Relocate a Portion of the GI Endoscopy Rooms from Duke GI at Brier Creek to a New Facility – the applicant states that this alternative does not satisfy the need for additional capacity and is therefore less effective.
- Develop a Facility in Another Geographic Location – the applicant states that developing the new facility in any other geographic location in Wake County would not afford the opportunity to coordinate with Duke Health’s ongoing development of Duke Health at Green Level and is therefore less effective.

- Develop a Different Complement of GI Endoscopy Rooms at Duke GI at Green Level – the applicant states that any other complement of GI endoscopy rooms would be a less effective number to serve the projected population.

On page 58, the applicant states:

“The proposed new GI endoscopy facility will provide expanded access to freestanding GI endoscopy services in Wake County, decompress capacity constraints at Duke GI at Brier Creek and facilitate continued growth in utilization of GI endoscopy procedures performed by PDC physicians and non-PDC physicians in Wake County.”

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the identified need for the following reasons:

- It will increase overall patient access to outpatient GI endoscopy services.
- It will meet the growing GI endoscopy demand at Duke GI at Brier Creek and in Wake County.
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- application, and
- 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. Private Diagnostic Clinic, PLLC shall materially comply with all representations made in the certificate of need application.**
- 2. Private Diagnostic Clinic, PLLC shall develop a new ambulatory surgery facility with four new gastrointestinal endoscopy rooms.**
- 3. Upon completion of the project, Private Diagnostic Clinic, PLLC shall be licensed for no more than four gastrointestinal endoscopy rooms at Duke GI at Green Level.**
- 4. Private Diagnostic Clinic, PLLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation**

Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.

- 5. Private Diagnostic Clinic, PLLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application or that would otherwise require a certificate of need.**
 - 6. For the first three years of operation following completion of the project, Private Diagnostic Clinic, PLLC 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.**
 - 7. No later than three months after the last day of each of the first three full fiscal years of operation following initiation of the services authorized by this certificate of need, Private Diagnostic Clinic, PLLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.****
 - 8. Private Diagnostic Clinic, PLLC shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new ASF with four GI endoscopy rooms.

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

Duke GI at Green Level Projected Capital Cost	
Construction / Renovation	\$1,750,000
Architect/Engineering	\$180,000
Medical Equipment	\$1,425,797
Non-Medical Equipment	\$132,525
Consultant Fees	\$60,000
Contingency	\$5,000
Total	\$3,553,322

In Section F, page 61, the applicant provides the assumptions used to project the capital cost and provides supporting documentation in Exhibits 7, 9, 10 and 11.

In Section F, pages 63-64, the applicant projects start-up costs of \$225,000 and initial operating expenses of \$150,000 for a total working capital of \$375,000. The total working capital of \$375,000 conservatively exceeds the working capital calculated in Assumption 10 in Section Q Financial Assumptions to allow for contingencies.

Availability of Funds

In Section F, page 62, the applicant states that the capital cost will be funded as shown in the table below.

Type	Private Diagnostic Clinic, PLLC
Loans	
Accumulated reserves or OE*	\$65,000
Bonds	
Other (Equipment Lease)	\$1,558,322
Other (Facility Lease)	\$1,930,000
Total Financing	\$3,553,322

* OE = Owner's Equity

In Section F, page 65, the applicant states that the working capital cost will be funded as shown in the table below.

Type	Private Diagnostic Clinic, PLLC
Loans	
Accumulated reserves or OE*	\$375,000
Bonds	
Other (Equipment Lease)	
Other (Facility Lease)	
Total Financing	\$375,000

* OE = Owner's Equity

Exhibit 11 contains a letter from PDC's CFO indicating availability and commitment of the necessary cash reserves of \$440,000 to fund \$65,000 capital cost and \$375,000 working capital. Exhibit 11 also contains letters from First Citizens Bank confirming PDC has adequate funds to meet the commitment, and documentation of the lease agreements.

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as summarized below in the following table.

Duke GI at Green Level GI-Endo Procedure Rooms			
	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
Total Procedures	4,573	6,165	6,969
Total Gross Revenues (Charges)	\$13,380,098	\$18,039,319	\$20,390,523
Total Contractual Adjustments*	\$7,667,605	\$10,337,620	\$11,685,002
Total Net Revenue	\$5,712,493	\$7,701,699	\$8,705,521
Average Net Revenue per Procedure	\$1,249	\$1,249	\$1,249
Total Operating Expenses (Costs)	\$3,264,452	\$4,146,577	\$4,700,724
Average Operating Expense per Procedure	\$714	\$673	\$675
Net Income	\$2,448,041	\$3,555,121	\$4,004,797

Totals may not sum due to rounding

*Includes charity care and bad debt

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
 - The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a new ASF with four GI endoscopy rooms.

The 2019 SMFP does not define the service area for GI endo procedure rooms, however, the applicant defines its primary service area as Wake County, in compliance with Administrative Rule 10A NCAC 14C .3901(6). Facilities may also serve residents of counties not included in their service area.

In Section G, pages 70-71, the applicant identifies the existing GI endo services in Wake County and the number of GI endo procedures performed during FY2018, as provided in the providers' 2019 License Renewal Applications (LRAs). The following table summarizes the data in the 2019 SMFP and the data provided by the applicant from the 2019 LRAs.

**Wake County GI Endoscopy Utilization
 FY2018**

Facility	# GI Endo Rooms	#GI Procedures FY2017 per 2019 SMFP	# GI Procedures FY2018 per 2019 LRAs	% of Capacity FY2018 per 2019 LRAs
Center for Digestive Diseases & Cary Endoscopy Center	3	2,390	2,320	51.56%
Duke GI at Brier Creek	4	8,352	7,255	120.92%
Duke Raleigh Hospital	3	3,761	4,564	101.42%
GastroIntestinal Healthcare	2	1,631	1,721	57.37%
Kurt Vernon, MD PA	1	2,767	2,834	188.93%
Raleigh Endoscopy Center	4	12,312	13,361	224.35%
Raleigh Endoscopy Center - Cary	4	11,546	11,892	198.20%
Raleigh Endoscopy Center - North	3	7,000	5,383	119.62%
Rex Hospital	4	5,841	6,565	109.42%
Triangle Gastroenterology	2	4,311	4,090	136.33%
W.F. Endoscopy Center*	2	4,030	3,751	125.03%
Wake Endoscopy Center	4	11,810	10,782	239.60%
WakeMed	6	5,712	7,255	80.61%
WakeMed Cary Hospital	4	2,614	2,755	45.92%

Source: 2019 SMFP for facilities and # of GI endo rooms; 2019 LRAs for FY2018 procedures

*2019 SMFP shows an adjustment for CONs of 1, which agrees with the applicant’s table on page 71; W.F. Endoscopy Center’s 2019 LRA shows it is licensed for 2 GI endo rooms.

As the table above shows, Duke GI at Brier Creek is operating at 121% of capacity in FY2018 (7,255 / (1,500*4)) based on the performance standard of 1,500 procedures per GI endoscopy room, as set forth in 10A NCAC 14C .3900, Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities. In fact, ten of the 14 Wake County facilities operated above 100% of capacity in FY2018.

In Section G, pages 72-73, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI Endo services in its primary service area of Wake County. The applicant states:

“The proposed project is needed to expand access to PDC’s well-utilized GI endoscopy services. As described in Section C.4, PDC demonstrates the need the population has for the proposed new GI endoscopy facility based on demographic data specific to the defined service area, historical GI endoscopy utilization, and qualitative benefits, including enhanced geographic access and access to a new freestanding facility with non-HOPD [non-hospital outpatient department] charges.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed GI endoscopy ASF is needed in addition to the existing or approved GI Endoscopy ASF facilities.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

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

- (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 Section Q, Form H, the applicant provides the projected staffing in full-time equivalent (FTE) positions for the proposed services as illustrated in the following table.

Duke GI at Green Level Projected Staffing FTEs			
	1st Full FY CY2023	2nd Full FY CY2024	3rd Full FY CY2025
RNs	10.0	13.0	15.0
Technicians	6.0	7.0	8.0
CMA	1.0	1.0	1.5
Administrator	1.0	1.0	1.0
Assistant Administrator	0.0	1.0	1.0
Medical Records Manager	1.0	1.0	1.0
Clerical	2.0	3.0	3.5
Total	21.0	27.0	31.0

Totals may not sum due to rounding
Source: Form H in Section Q of the application

The assumptions and methodology used to project staffing are provided in Sections H and Q. The applicant states that the proposed staffing is based on PDC's experience operating Duke GI at Brier Creek. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H, pages 75-76, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 77, the applicant identifies M. Stanley Branch, M.D., the current medical director at Duke GI at Brier Creek, as the proposed facility's medical director. Exhibit 2 confirms Dr. Branch's commitment to serve in this role. In Section H, page 77, the applicant describes its physician recruitment plan.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (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 I, the applicant discusses the necessary ancillary and support services and how the services will be made available. The necessary ancillary and support services for the proposed services, as listed by the applicant on pages 79-80, include:

- physicians with privileges at Duke GI at Green Level,
- anesthesiology,
- administrative services,
- patient scheduling, HR/payroll, accounting/billing, information technology, quality and performance improvement, staff education, and infection control,
- reception and medical records,
- pharmacy and pathology,
- linen and housekeeping,
- medical supplies, and
- dietary/light nourishment/snacks.

In Section I, page 80, the applicant describes its existing and proposed relationships with other local health care and social service providers. Physician support letters are provided in Exhibit 12.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that 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

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.

C

In Section K, page 84, the applicant states that the project involves upfit of 8,200 square feet of planned medical office building space to be constructed by DUHS. Line drawings are provided in Exhibit 10.

On page 85, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 10. The applicant states:

“PDC’s architect based the projected Duke GI at Green Level design and upfit cost on a detailed review of the project, and upon actual costs of similar GI endoscopy projects, published construction costing data, and the architect’s design experience.”

On page 85, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services, stating:

“The upfit of existing spaces is economical, and the space design is efficient. PDC will obtain competitive market quotes from equipment vendors.

The project is financially feasible and will offer residents a convenient location for obtaining outpatient GI endoscopy services. The project will improve convenience and time efficiency for patients, with a location in growing western Wake County.

...

This project will not increase the charges to the public, which largely are set by the government or negotiated with payors.”

The applicant identifies the applicable energy saving features that will be incorporated into the proposed renovation plans on page 86 of the application.

Conclusion

The Agency reviewed the:

- application, and

- exhibits to the application.

Based on that review, the Agency concludes that 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

Duke GI at Green Level is not an existing facility; therefore, it has no historical payor mix. In Section L, page 97, the applicant provides the following comparison, based upon patients served by PDC physicians at Duke GI BC during CY2018.

	Percentage of Total Outpatients Served by PDC during the Last Full FY	Percentage of the Population of the Service Area
Female	56.4%	51.3%
Male	43.6%	48.7%
Unknown	0.0%	0.0%
64 and Younger	74.4%	88.8%
65 and Older	25.6%	11.2%
American Indian	*	0.8%
Asian	*	7.2%
Black or African-American	*	21.1%
Native Hawaiian or Pacific Islander	*	0.1%
White or Caucasian	*	60.6%
Other Race	*	10.2%
Declined / Unavailable	*	0.0%

*PDC does not track racial and ethnic minority data on its patients.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately documents the extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved. Therefore, the application is conforming to this criterion.

- (b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, pages 97-98, the applicant states:

“PDC has no obligation under federal regulations to provide uncompensated care or community service, or access by minorities and handicapped persons. However, PDC does not discriminate based on race, ethnicity, creed, color, sex, age, religion, national origin, handicap, or ability to pay. Please see Exhibit 5.”

Exhibit 5 contains Duke Health's Notice of Nondiscrimination and other financial policies.

In Section L, page 98, the applicant states that during the last five years, no patient civil rights equal access complaints have been filed against PDC.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section L, page 98, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown below in the table.

Duke GI at Green Level Projected Payor Mix CY2024	
Payor Category	GI Endo Services as Percent of Total
Self-Pay/ Charity Care	1.50%
Medicare*	27.60%
Medicaid*	0.02%
Insurance*	69.90%
Other	1.00%
Total	100.00%

Source: Section L, page 98

The applicant does not identify "Other"

* Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1.5% of total services will be provided to self-pay/charity care patients, 27.6% to Medicare patients and 0.02% to Medicaid patients.

The applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project in Section Q. In Section L, page 99, the applicant states that the projected payor mix is based on the FY2018 payor mix of outpatient GI endoscopy procedures at Duke GI at Brier Creek. The applicant provides data on page 100 that supports the payor mix at Duke GI at Brier Creek as being comparable to the combined average payor mix for the 10 freestanding GI endoscopy centers located in Wake County. The projected payor mix is reasonable and adequately supported. The applicant assumes the proposed project will not have a significant impact on the Wake County payor mix, thus the projected payor mix will closely resemble the existing providers' average payor mix.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L.5, page 102, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- 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

In Section M, page 103, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and states that PDC has existing relationships with health professional training programs, functioning as a faculty practice plan for Duke University School of Medicine. Exhibit 6 contains an affiliation agreement with Miller-Motte College of Raleigh and Durham Technical Community College. The applicant states that PDC facilities, including Duke GI at Green Level, will continue to be available for students training in clinical health services, as needed.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to 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 applicant proposes to develop a new ASF with four GI endoscopy rooms.

The 2019 SMFP does not define the service area for GI endo procedure rooms, however, the applicant defines its primary service area as Wake County, in compliance with Administrative Rule 10A NCAC 14C .3901(6). Facilities may also serve residents of counties not included in their service area.

In Section G, pages 70-71, the applicant identifies the existing GI endo services in Wake County and the number of GI endo procedures performed during FY2018, as provided in the providers' 2019 LRAs. The following table summarizes the data in the 2019 SMFP and the data provided by the applicant from the 2019 LRAs.

**Wake County GI Endoscopy Utilization
 FY2018**

Facility	# GI Endo Rooms	#GI Procedures FY2017 per 2019 SMFP	# GI Procedures FY2018 per 2019 LRAs	% of Capacity FY2018 per 2019 LRAs
Center for Digestive Diseases & Cary Endoscopy Center	3	2,390	2,320	51.56%
Duke GI at Brier Creek	4	8,352	7,255	120.92%
Duke Raleigh Hospital	3	3,761	4,564	101.42%
GastroIntestinal Healthcare	2	1,631	1,721	57.37%
Kurt Vernon, MD PA	1	2,767	2,834	188.93%
Raleigh Endoscopy Center	4	12,312	13,361	224.35%
Raleigh Endoscopy Center - Cary	4	11,546	11,892	198.20%
Raleigh Endoscopy Center - North	3	7,000	5,383	119.62%
Rex Hospital	4	5,841	6,565	109.42%
Triangle Gastroenterology	2	4,311	4,090	136.33%
W.F. Endoscopy Center*	2	4,030	3,751	125.03%
Wake Endoscopy Center	4	11,810	10,782	239.60%
WakeMed	6	5,712	7,255	80.61%
WakeMed Cary Hospital	4	2,614	2,755	45.92%

Source: 2019 SMFP for facilities and # of GI endo rooms; 2019 LRAs for FY2018 procedures

* The applicant's table on page 71 shows 3 rooms; the 2019 SMFP shows a CON adjustment of 1 for 3 rooms; W.F. Endoscopy Center's 2019 LRA shows it is still licensed for only 2 GI endo rooms.

As illustrated in the table above, in FY2017 and FY2018 Duke GI at Brier Creek was operating in excess of 100% of the state threshold utilization capacity of 1,500 procedures per room, as were nine of the other 13 Wake County facilities.

In Section N, pages 104-109, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 104-105, the applicant states:

“With this proposed project, PDC will offer GI endoscopy services at a convenient location in western Wake County in order to improve patient access to quality, cost-effective GI endoscopy care. As a new site, Duke GI at Green level will have a positive effect on competition in the service area. The proposed project will promote cost effective, high quality GI endoscopy services that will be broadly accessible by residents, as described in Section N.2 below. The project will enable PDC to better meet the needs of PDC’s existing patient population, and to ensure more timely provision of and convenient access to outpatient GI endoscopy services for all area residents. PDC assumes no adverse effect on current providers of such services in Wake County, as PDC physicians have been longtime existing providers of these medical services in Wake County.

...

Developing the proposed outpatient GI endoscopy services will contribute to cost-effective patient care because the services will have a charge structure different from hospital-based services, typically less costly. PDC’s proposal is consistent with the SMFP Basic Principle of promoting cost effective healthcare approaches.

...

PDC will maintain the highest standards and quality of care, consistent with the standards that it has sustained throughout its many years of providing patient care in Wake and Durham counties.”

On page 108, the applicant states:

“The proposed project will increase access to non-hospital-based GI endoscopy services to underserved groups.

...

GI endoscopy services at the Green Level facility will be available to and accessible by any patient having a clinical need for those services.

PDC will continue to serve the medically indigent through charitable care.”

The applicant provides supporting documentation of its commitment to the community in Exhibits 3, 4, 5 and 12.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any referenced exhibits).
- Quality services will be provided (see Section O of the application and any referenced exhibits).
- Access will be provided to underserved groups (see Section L of the application and any referenced exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- information which was publicly available during the review and used by the Agency.

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

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

C

In Section O, page 113, the applicant states that Duke GI at Green Level is not an existing facility. The applicant further states that the only GI endoscopy facility it operates is Duke GI at Brier Creek in Raleigh.

In Section O, page 113, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care have not occurred at Duke GI at Brier Creek, the only existing PDC related facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred at the Brier Creek facility. After reviewing and considering information provided by the applicant and considering the quality of care provided at its existing 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.
- (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 applicant proposes to develop a new ASF with four new GI endoscopy rooms. Therefore, the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900 are applicable to this review.

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

.3903 PERFORMANCE STANDARDS

- (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.*
- NA- The proposed facility, Duke GI at Green Level, is not proposing any operating rooms. However, on page 46, the applicant states that the proposed GI endo rooms will be available for use 250 days per year, five days per week, 52 weeks per year, excluding 10 days for holidays.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI-Endo procedures only per GI-Endo 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- The applicant projects to perform 6,165 GI endo procedures in four GI endo rooms at the proposed Duke GI at Green Level facility during the second year of operation following completion of the project, which is an average of 1,541 GI endo procedures per room. Duke GI at Brier Creek is projected to perform 6,232 GI endo procedures in four rooms, for an average of 1,558 procedures per room, during the second year of operation. Both PDC facilities are projected to exceed the performance requirement of 1,500 procedures per room. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall demonstrate that at least the following types of GI-Endo procedures will be provided in the proposed facility or GI-Endo room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section C, page 47, the applicant states:
- “Consistent with the outpatient GI endoscopy procedures currently performed at Duke GI at Brier Creek, Duke GI at Green Level will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.”*
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo 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-Endo 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-Endo 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-Endo 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- In Section C, page 47, the applicant states that PDC does not own or operate any surgical operating rooms in the service area (Wake County).
- (e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop an additional GI-Endo 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 Q, pages 117-129, the applicant provides the assumptions and methodology used to project GI endo procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.