

## ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

### FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 25, 2020

Findings Date: November 25, 2020

Project Analyst: Mike McKillip

Assistant Chief: Lisa Pittman

Project ID #: J-11934-20

Facility: Duke Gastroenterology of Raleigh

FID #: 200638

County: Wake

Applicant: Private Diagnostic Clinic, PLLC

Project: Develop a new ambulatory surgical facility with four gastrointestinal (GI) endoscopy procedure 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, Duke Gastroenterology of Raleigh, with four gastrointestinal (GI) endoscopy procedure rooms.

#### **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 2020 State Medical Facilities Plan (SMFP).

#### **Policies**

There is one policy in the 2020 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

#### **Policy GEN-4**

*Policy GEN-4* 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.”*

The proposed capital expenditure for this project is greater than \$2 million but less than \$5 million. In Section B.4, page 12, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plans to assure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

#### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant does not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2020 SMFP.
  - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 for the following reason:
    - The applicant adequately demonstrates that the application includes a written statement describing the project's plan to assure improved energy efficiency and water conservation.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

## C

The applicant, PDC, proposes to develop a new ambulatory surgical facility, Duke Gastroenterology of Raleigh, with four gastrointestinal (GI) endoscopy rooms. In Section C.1, page 13, the applicant states PDC will develop the new ambulatory surgical facility (ASF) by leasing and upfitting space in an existing medical office building owned by Duke University Health System, and located on the campus of Duke Raleigh Hospital.

### **Patient Origin**

The 2020 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, page 15, the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

In Section C.3, page 15, 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:

<b>Duke Gastroenterology of Raleigh Projected Patient Origin</b>						
	<b>CY2023</b>		<b>CY2024</b>		<b>CY2025</b>	
<b>County or State</b>	<b># of Patients</b>	<b>% of Patients</b>	<b># of Patients</b>	<b>% of Patients</b>	<b># of Patients</b>	<b>% of Patients</b>
Wake	3,627	74.8%	4,612	74.8%	5,003	74.8%
Durham	243	5.0%	309	5.0%	336	5.0%
Johnston	208	4.3%	264	4.3%	286	4.3%
Harnett	202	4.2%	257	4.2%	279	4.2%
Franklin	190	3.9%	241	3.9%	262	3.9%
Orange	52	1.1%	67	1.1%	72	1.1%
Granville	43	0.9%	55	0.9%	60	0.9%
Chatham	25	0.5%	32	0.5%	34	0.5%
Other	259	5.3%	329	5.3%	357	5.3%
<b>Total</b>	<b>4,849</b>	<b>100.0%</b>	<b>6,166</b>	<b>100.0%</b>	<b>6,689</b>	<b>100.0%</b>

Totals may not sum due to rounding

Source: Table in Section C.3, page 15 of the application. The applicant states, “Other includes less than one percent of patients from each of the remaining counties in North Carolina and other states.”

In Exhibit C.3, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

**Analysis of Need**

In Section C.4, pages 24-36, the applicant explains why it believes the population projected to utilize the proposed GI endoscopy rooms needs the proposed services. The applicant states that the need for the project is based on the following factors:

- Historical and projected growth of the service area (Wake County) population (pages 16-17).
- The need for GI endoscopy services to identify patients at risk for colorectal cancer (pages 17-24).
- The fact that Wake County serves as a health care center in North Carolina (page 24).
- Increased traffic congestion in Wake County has had negative impacts on the accessibility to health care services in Raleigh, making it necessary to expand access to that population by providing services in more convenient locations (pages 24-28).
- Freestanding GI endoscopy centers provide patients with more convenient and cost-effective alternatives to hospital-based services (pages 28-30).
- The history of high utilization of the four GI endoscopy rooms at the existing Duke GI at Brier Creek facility (pages 30-31).

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

- The applicant provides data to support its projections of population growth and aging in the proposed service area.
- The applicant provides data regarding the historical utilization of GI endoscopy services by the proposed service area population.

- The applicant provides supporting information regarding traffic congestion and accessibility difficulties by the proposed service area population.

*Projected Utilization*

In Section Q, Form C, the applicant provides projected utilization for the proposed ASF as summarized in the following table.

Duke Gastroenterology of Raleigh	Interim (Partial) Year CY2022*	FY1 CY2023	FY2 CY2024	FY3 CY2025
# of GI Endoscopy Rooms	4	4	4	4
# of GI Endoscopy Procedures	1,788	4,849	6,166	6,689
Annual Percent Change	---	171%	27%	8%
Average # of GI Procedures Per GI Room	447	1,212	1,542	1,672

\*Applicant assumes the project will become operational on July 1, 2022.

As shown in the table above, the applicant projects that it will perform 4,849 total GI endoscopy procedures in four GI endoscopy rooms in the first full operating year, and 6,166 GI endoscopy procedures in the second full operating year, which is an average of 1,542 procedures per room [6,166 procedures / 4 rooms = 1,542 procedures per room], which exceeds the utilization threshold of 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

In Section Q, pages 103-110, the applicant provides the assumptions and methodology used to project the need for GI endoscopy services, which is summarized below.

Step 1 – The applicant defines the service area as Wake County and provides the population projections for the service area from 2020 to 2025 from the North Carolina Office of State Budget and Management (NCOSBM).

Step 2 – The applicant calculates the GI endoscopy patient use rates for North Carolina and Wake County for 2018 based on NCOSBM population data and endoscopy utilization data from the Healthcare Planning and Certificate of Need Section.

Step 3 – The applicant projects GI endoscopy patients for Wake County for 2020 to 2025 based on the Wake County GI patient use rate for 2018

Step 4 – The applicant projects GI endoscopy procedures for Wake County patients for 2020 to 2025 based on the average historical Wake County ratio of GI procedures to GI patients from 2016 to 2018, which the applicant calculates as 1.27.

Step 5 – The applicant projects the GI endoscopy patients who reside outside the proposed service area (non-Wake County patients) based on patient origin data reported in license renewal applications for FY2019 for existing Wake County GI endoscopy providers.

Step 6 – The applicant projects GI endoscopy procedures for non-Wake County patients for 2020 to 2025 based on the average historical statewide ratio of GI procedures to GI patients for 2018, which the applicant calculates as 1.25.

Step 7 – The applicant projects the combined GI endoscopy procedures to be performed in Wake County for both Wake County and non-Wake County patients for 2020 to 2025.

Step 8 – The applicant projects GI endoscopy procedure rooms needed for both Wake County and non-Wake County patients for 2020 to 2025 based on an average of 1,500 GI endoscopy procedures per GI endoscopy procedure room per year.

Step 9 – The applicant projects the GI endoscopy procedure market share for the proposed facility based on the historical GI endoscopy procedure market share for the applicant’s existing Wake County GI endoscopy ambulatory surgical facility, Duke GI at Brier Creek.

Step 10 – The applicant projects the utilization at the proposed ASF based on the projected GI endoscopy procedure market share (Step 9) and the combined GI endoscopy procedures to be performed in Wake County for both Wake County and non-Wake County patients for 2020 to 2025 (Step 7).

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

- Projected number of GI endoscopy patients and procedures are based on historical utilization data for GI endoscopy patients for North Carolina and Wake County.
- The applicant’s market share projections are based on its historical experience operating a GI endoscopy ASF in Wake County.
- Projected utilization is based on the projected Wake County population growth rate.

*Duke GI at Brier Creek Projected Utilization*

The applicant operates an existing ASF with four GI endoscopy rooms, Duke GI at Brier Creek. In Section Q, Form C, the applicant provides projected utilization for Duke GI at Brier Creek, as summarized in the following table.

<b>Duke GI at Brier Creek</b>	<b>CY2019</b>	<b>CY2020</b>	<b>CY2021</b>	<b>CY2022</b>	<b>PY 1 CY2023</b>	<b>PY 2 CY2024</b>	<b>PY 3 CY2025</b>
# of GI Endoscopy Rooms	4	4	4	4	4	4	4
# of GI Endoscopy Procedures	7,327	6,775	8,175	6,801	6,530	6,232	6,348
GI Procedures Per GI Room	1,832	1,694	2,044	1,700	1,633	1,558	1,587

The utilization projections are supported by the historical utilization of the Duke GI at Brier Creek facility. As shown in the table above, the applicant projects that it will perform 6,232 GI endoscopy procedures in the second full operating year of the proposed project, which is an average of 1,558 procedures per room [6,232 procedures / 4 rooms = 1,558 procedures per room], which exceeds the utilization threshold of 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

*Duke GI at Green Level Projected Utilization*

In Project I.D. # J-11709-19, the applicant was approved to develop a new ASF with four GI endoscopy rooms, Duke GI at Green Level. In Section Q, Form C, the applicant provides projected utilization for Duke GI at Green Level, as summarized in the following table. The utilization projections are based on the previously approved project (Project I.D. # J-11709-19).

<b>Duke GI at Green Level</b>	<b>Interim (Partial) Year CY2022*</b>	<b>FY1 CY2023</b>	<b>FY2 CY2024</b>	<b>FY3 CY2025</b>
# of GI Endoscopy Rooms	4	4	4	4
# of GI Endoscopy Procedures	2,275	4,573	6,165	6,969
Average # of GI Procedures Per GI Room	569	1,143	1,541	1,742

\*Applicant assumes the project will become operational on April 1, 2022.

As shown in the table above, the applicant projects that it will perform 6,165 GI endoscopy procedures in the second full operating year of the proposed project, which is an average of 1,541 procedures per room [6,165 procedures / 4 rooms = 1,541 procedures per room], which exceeds the utilization threshold of 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

**Access**

In Section C.8, page 36, the applicant states, “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 GI endoscopy ASC, as clinically appropriate.” In Section L, page 86, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Payor Category</b>	<b>GI Endoscopy Services as Percent of Total</b>
Self-Pay/Charity Care	1.10%
Medicare*	29.00%
Medicaid*	0.03%
Insurance*	69.20%
Other (other government)	0.70%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 86 of the application.

\*Including any managed care.

The projected payor mix is reasonable and adequately supported.

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately identified 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 (payer 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 does not propose to reduce, eliminate or relocate GI endoscopy rooms or services; therefore, Criterion (3a) is not applicable to this review.

- (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, PDC, proposes to develop a new ambulatory surgical facility, Duke Gastroenterology of Raleigh, with four gastrointestinal (GI) endoscopy rooms.

In Section E.2, pages 48-53, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the status quo – The applicant states this was not an effective alternative due to the fact that it would not provide the additional capacity to meet the need for GI endoscopy services in the proposed service area.
- Increase the hours of operation at Duke GI at Brier Creek – The applicant states this was not an effective alternative because extending hours of operation results in patient inconvenience due to earlier and later procedure preparation requirement, physician scheduling conflicts, and additional staffing expense such as shift differential expenses (overtime pay).
- Expanding the existing or approved facility – The applicant states this was not an effective alternative because it would not expand geographic access to GI endoscopy services in Wake County, nor would it take advantage of the proposed facility's proximity to Duke Raleigh Hospital, where many other primary care and specialty care services are currently located.
- Relocate existing GI endoscopy rooms from the Duke GI at Brier Creek facility – The applicant states this was not an effective alternative because relocating existing GI

endoscopy rooms would negatively impact access to that facility, which is currently highly utilized.

- Develop a new facility in another location – The applicant states this was not an effective alternative because no other location in Wake County was deemed superior to the propose location in terms of accessibility based on historical patient origin patterns for GI endoscopy service by residents of Wake County and surrounding areas.

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

- The application is conforming to all statutory and regulatory review criteria.
- The alternative will meet the need for additional capacity to perform GI endoscopy procedures for patients from Wake County and surrounding areas.
- The alternative is more cost-effective and convenient for patients, physicians and staff.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is approved subject to the following conditions:

- 1. Private Diagnostic Clinic, PLLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new ambulatory surgical facility with no more than four gastrointestinal (GI) endoscopy rooms.**
- 3. Progress Reports:**
  - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
  - b. The certificate holder shall complete all sections of the Progress Report form.**
  - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
  - d. Progress reports shall be due on the first day of every fourth month. The first progress report shall be due on March 1, 2021. The second progress report shall be due on July 1, 2021 and so forth.**

4. **The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
  5. **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, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
    - a. **Payor mix for the services authorized in this certificate of need.**
    - b. **Utilization of the services authorized in this certificate of need.**
    - c. **Revenues and operating costs for the services authorized in this certificate of need.**
    - d. **Average gross revenue per unit of service.**
    - e. **Average net revenue per unit of service.**
    - f. **Average operating cost per unit of service.**
  7. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant, PDC, proposes to develop a new ambulatory surgical facility, Duke Gastroenterology of Raleigh, with four gastrointestinal (GI) endoscopy rooms.

**Capital and Working Capital Costs**

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

Construction/Renovation Costs	\$1,600,000
Architect/Engineering Fees	\$150,000
Medical Equipment	\$1,493,433
Non-medical equipment	\$169,483
Miscellaneous (Fees, contingency)	95,000
<b>Total</b>	<b>\$3,507,916</b>

In Section F.1, pages 54-55, the applicant provides the assumptions used to project the capital cost.

In Section F.3, pages 57-58, the applicant projects \$225,000 in start-up costs and \$100,000 in initial operating expenses, for total working capital required of \$325,000.

**Availability of Funds**

In Section F.2, page 55, the applicant states the capital cost will be funded as shown in the table below.

<b>Sources of Capital Cost Financing</b>		
<b>Type</b>	<b>Private Diagnostic Clinic, LLC</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$95,000	\$95,000
Bonds	\$0	\$0
Equipment lease	\$1,662,916	\$1,662,916
Facility lease	\$1,750,000	\$1,750,000
<b>Total Financing</b>	<b>\$3,507,916</b>	<b>\$3,507,916</b>

\* OE = Owner's Equity

In Section F.3, page 57, the applicant states the working capital cost will be funded as shown in the table below.

<b>Sources of Working Capital Cost Financing</b>		
<b>Type</b>	<b>Private Diagnostic Clinic, LLC</b>	<b>Total</b>
Loans	\$0	\$0
Accumulated reserves or OE *	\$325,000	\$325,000
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
<b>Total Financing</b>	<b>\$325,000</b>	<b>\$325,000</b>

\* OE = Owner's Equity

Exhibit F.2 contain copies of a letter and lease agreement from First Citizens Bank and a copy of a letter from the Chief Financial Officer for PDC documenting the applicant has sufficient assets to fund the capital and working capital costs of the proposed project. The applicant adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the proposed project.

**Financial Feasibility**

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

	<b>1<sup>st</sup> Full Fiscal Year CY2023</b>	<b>2<sup>nd</sup> Full Fiscal Year CY2024</b>	<b>3<sup>rd</sup> Full Fiscal Year CY2025</b>
Total Procedures	4,849	6,166	6,689
Total Gross Revenues (Charges)	\$14,189,324	\$18,041,370	\$19,571,296
Total Net Revenue	\$6,106,288	\$7,763,992	\$8,422,387
Average Net Revenue per Procedure	\$1,259	\$1,259	\$1,259
Total Operating Expenses (Costs)	\$3,458,869	\$4,240,785	\$4,636,287
Average Operating Expense per Procedure	\$713	\$688	\$693
Net Income	\$2,647,419	\$3,523,207	\$3,786,100

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
- 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 ambulatory surgical facility, Duke Gastroenterology of Raleigh, with four gastrointestinal (GI) endoscopy rooms.

The 2020 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 Q, page 103, the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

The 2020 State Medical Facilities Plan, Table 6E: Endoscopy Room Inventory, pages 92-93, includes a table showing the existing providers of GI endoscopy services in Wake County, which is summarized below.

Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Center for Digestive Diseases & Cary Endoscopy Center	ASC	3	2,320	2,320
Duke GI at Brier Creek	ASC	4	5,832	7,255
Duke GI at Green Level*	ASC	4	0	0
Duke Raleigh Hospital	Hospital	3	3,423	4,564
GastroIntestinal Healthcare	ASC	2	1,587	1,721
Kurt Vernon, MD PA	ASC	1	2,687	2,834
Raleigh Endoscopy Center	ASC	4	9,154	13,461
Raleigh Endoscopy Center-Cary	ASC	4	8,798	11,892
Raleigh Endoscopy Center-North	ASC	3	804	5,383
Rex Hospital	Hospital	4	4,404	6,565
Triangle Gastroenterology	ASC	2	3,968	4,090
Wake Forest Endoscopy Center	ASC	2	2,959	3,751
Wake Endoscopy Center	ASC	4	9,538	10,782
Wake Endoscopy Center-Cary*	ASC	3	0	0
WakeMed	Hospital	6	6,086	7,255
WakeMed Cary Hospital	Hospital	4	2,235	2,755

Source: 2020 State Medical Facilities Plan, Table 6E.

\*New facility currently under development.

In Section G.2, page 63, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Wake County. The applicant states:

*“The proposal will not result in unnecessary duplication of existing or approved facilities in Wake County. Local patients will greatly benefit from development of a new freestanding facility in Wake County. 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 [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 facility is needed in addition to the existing or approved GI endoscopy facilities.

**Conclusion**

The Agency reviewed the:

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

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

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

C

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

Position	Projected FTE Staff		
	1st Full Fiscal Year (CY2023)	2nd Full Fiscal Year (CY2024)	3rd Full Fiscal Year (CY2025)
Registered Nurses	11.0	13.0	13.0
Surgical Technicians	6.0	7.0	8.0
Certified Medical Assistants	1.0	1.0	1.5
Patient Support Assistant	1.0	2.0	2.0
Medical Records	1.0	1.0	1.0
Administrator	1.0	1.0	1.0
Business Office Clerical	1.0	1.0	1.0
<b>TOTAL</b>	<b>22.0</b>	<b>27.0</b>	<b>29.5</b>

The assumptions and methodology used to project staffing are provided in Section H. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, which is found in Section Q. In Section H.2 and H.3, pages 67-69, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section I.3 page 72, the applicant identifies the proposed medical director. In Exhibit I.3, the applicant provides a letter from the medical director indicating an interest in serving as medical director for the proposed services.

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

**Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

## C

In Section I, pages 70-71, the applicant identifies the ancillary and support services necessary for the proposed services, including:

- Anesthesia
- Pathology
- Pharmaceutical
- Administration
- Materials management
- Human resources/payroll
- Accounting/billing
- Reception/patient scheduling
- Medical records
- Linen/housekeeping

The applicant adequately explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.

In Section I.2, page 71, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I.2.

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

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 applicants do 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.1, page 76, the applicant states the proposed GI endoscopy facility will occupy 7,425 square feet of leased space in the medical office building located on the campus of Duke Raleigh Hospital. Line drawings are provided in Exhibit K.2.

In Section K.3, page 77, 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 K.3.

In Section K.3, pages 77-78, 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.

In Section K.3, page 78, the applicant identifies any applicable energy saving features that will be incorporated into the proposed project.

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 Gastroenterology of Raleigh 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 at Brier Creek during FY2019.

	<b>Percentage of Total Outpatients Served by PDC during the Last Full FY</b>	<b>Percentage of the Population of the Service Area</b>
Female	58.3%	51.3%
Male	41.7%	48.7%
Unknown	0.0%	0.0%
64 and Younger	71.1%	88.4%
65 and Older	28.9%	11.6%
American Indian	0.3%	0.8%
Asian	2.5%	7.5%
Black or African-American	22.8%	21.0%
Native Hawaiian or Pacific Islander	0.1%	0.1%
White or Caucasian	62.5%	59.8%
Other Race	11.8%	10.8%
Declined / Unavailable	0.0%	0.0%

The Agency reviewed the:

- Application
- 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.2, page 84, the applicant states that the facility is under no obligation under any applicable federal regulations.

In Section L.2, page 85, the applicant states that during the last five years, no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 86, the applicant projects the following payor mix during the third full fiscal year of operation following completion of the project, as illustrated in the following table.

<b>Payor Category</b>	<b>GI Endoscopy Services as Percent of Total</b>
Self-pay/Charity Care	1.10%
Medicare*	29.00%
Medicaid*	0.03%
Insurance*	69.20%
Other (other government)	0.70%
<b>Total</b>	<b>100.00%</b>

Source: Table on page 86 of the application.

\*Including any managed care.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 1.1 percent of total services will be provided to self-pay/charity care patients, 29 percent to Medicare patients and 0.03 percent to Medicaid patients. The projected payor mix is reasonable and adequately supported because it is based on the applicant's historical experience at Duke GI at Brier Creek.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L.5, page 89, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 90, the applicant describes the extent to which health professional training programs in the area have will have access to the facility for training purposes and provides supporting documentation in Exhibit M.2.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicants adequately demonstrate 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 ambulatory surgical facility, Duke Gastroenterology of Raleigh, with four gastrointestinal (GI) endoscopy rooms.

The 2020 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 Q, page 103, the applicant identifies the service area as Wake County. Facilities may also serve residents of counties not included in their service area.

The 2020 State Medical Facilities Plan, Table 6E: Endoscopy Room Inventory, pages 92-93, includes a table showing the existing providers of GI endoscopy services in Wake County, which is summarized below.

Existing Facilities	Facility Type	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Center for Digestive Diseases & Cary Endoscopy Center	ASC	3	2,320	2,320
Duke GI at Brier Creek	ASC	4	5,832	7,255
Duke GI at Green Level*	ASC	4	0	0
Duke Raleigh Hospital	Hospital	3	3,423	4,564
GastroIntestinal Healthcare	ASC	2	1,587	1,721
Kurt Vernon, MD PA	ASC	1	2,687	2,834
Raleigh Endoscopy Center	ASC	4	9,154	13,461
Raleigh Endoscopy Center-Cary	ASC	4	8,798	11,892
Raleigh Endoscopy Center-North	ASC	3	804	5,383
Rex Hospital	Hospital	4	4,404	6,565
Triangle Gastroenterology	ASC	2	3,968	4,090
Wake Forest Endoscopy Center	ASC	2	2,959	3,751
Wake Endoscopy Center	ASC	4	9,538	10,782
Wake Endoscopy Center-Cary*	ASC	3	0	0
WakeMed	Hospital	6	6,086	7,255
WakeMed Cary Hospital	Hospital	4	2,235	2,755

Source: 2020 State Medical Facilities Plan, Table 6E.

\*New facility currently under development.

In Section N, pages 91-96, 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 page 91, the applicant states,

*“PDC will increase competition. With this proposed project, PDC will offer GI endoscopy services at a convenient location in central Wake County in order to improve patient access to high quality, cost-effective GI endoscopy care. ... And competition works both ways: as a provider offering services, PDC must outperform others to attract and retain patients. The project will enable PDC to better meet the needs of PDC’s existing patient population in Wake County, 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.”*

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 exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

### **Conclusion**

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 Form A, the applicant identifies three facilities owned by the applicant: Duke GI at Brier Creek, Duke GI at Green Level and Duke GI at North Durham.

In Section O.3, pages 99-100, the applicant states that none of the facilities have operated out of compliance with any Medicare Conditions of Participation during the 18 months immediately preceding the submittal of the application. 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 in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at the three facilities, 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

**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 applicant does not propose to develop operating rooms. Therefore, this Rule is not applicable to this review.

(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 owns one licensed GI endoscopy ASF, Duke GI at Brier Creek. Also, the applicant has been approved to develop a second GI endoscopy ASF, Duke GI at Green Level, but that facility is not currently operational. In Section Q, Form C, the applicant projects to perform an average of 1,542 GI endoscopy procedures per GI endoscopy room in the proposed Raleigh facility during the second year of operation following completion of the project. Also, in Section Q, Form C, the applicant projects to perform an average of 1,558 GI endoscopy procedures per GI endoscopy room in the existing Duke GI at Brier Creek facility during the second year of operation following completion of the project, and the applicant projects to perform an average of 1,541 GI endoscopy procedures per GI endoscopy room in the approved Duke GI at Green Level facility during the second year of operation following completion of the project.

(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.9, pages 39-40, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at the proposed Raleigh facility.

- (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 44, the applicant states that neither it nor any related entities own any inpatient operating rooms, outpatient operating rooms or shared operating rooms.
- (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, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the proposed and existing facilities. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.