

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: Julie M. Faenza

Team Leader: Gloria C. Hale

Project ID #: J-11708-19

Facility: Duke GI at North Durham

FID #: 190214

County: Durham

Applicant: Private Diagnostic Clinic, PLLC

Project: Develop a new ambulatory surgical facility with no more than four gastrointestinal 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 (hereinafter referred to as PDC or “the applicant”) proposes to develop a new ambulatory surgical facility (ASF), Duke GI at North Durham (Duke GI-ND), with four gastrointestinal endoscopy (GI endoscopy) 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 2019 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities (page 31 of the 2019 SMFP) is applicable to this review. **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. In Section B, pages 13-14, the applicant provides a written statement describing its plan to assure improved energy efficiency and water conservation. On page 13, the applicant states:

“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 the 2019 SMFP Policy GEN-4.”

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

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the application is consistent with Policy GEN-4.

- (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.

In Section A, page 10, the applicant states it is the physician practice of Duke Health, but that it is not owned or operated by Duke Health or Duke University Health System, and further states it is not a related entity to Duke Health or Duke University Health System. The applicant states the medical office building where it proposes to develop its facility will be developed by Duke University Health System. On May 6, 2019, Duke University Health System provided written notice to the Agency of its plan to develop the medical office building discussed in this application, and the Agency confirmed the development was exempt from review in its response on May 16, 2019.

Patient Origin

The 2019 SMFP does not define the service area for GI endoscopy rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), define 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, page 19, the applicant defines the primary service area as Durham County. Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

Projected Patient Origin – Duke GI-ND – OYs 1-3 (CYs 2022-2024)						
	OY 1 – CY 2022		OY 2 – CY 2023		OY 3 – CY 2024	
	# Procedures	% of Total	# Procedures	% of Total	# Procedures	% of Total
Durham	2,631	74.8%	3,872	63.4%	4,283	62.9%
Orange	536	15.2%	709	11.6%	824	12.1%
Person	35	1.0%	152	2.5%	169	2.5%
Granville	32	0.9%	140	2.3%	156	2.3%
Alamance	25	0.7%	109	1.8%	121	1.8%
Other*	260	7.4%	1,127	18.4%	1,256	18.4%
Total	3,520	100.0%	6,109	100.0%	6,810	100.0%

Source: Section C, page 18

*On page 18, the applicant states the “Other” category includes counties in North Carolina and other states with less than one percent of projected patients.

In Section C, page 19, 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, pages 29-35, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. The applicant states:

- Third-party payor trends encourage patients to receive GI endoscopy services at freestanding non-hospital-based facilities, which results in cost savings for patients.
- The medical office building which will house the proposed ASF is the former location of Macy’s at the Northgate Mall. The medical office building will also house several other types of healthcare services, which will allow patients to receive multiple types of healthcare services in a single location.
- The overall population of Durham County, according to the North Carolina Office of State Budget and Management (NC OSBM), will increase at a Compound Annual Growth Rate (CAGR) of 1.4 percent between 2019 and 2024, which is higher than the projected statewide CAGR of 1.1 percent for the same period.
- The Durham County population of people age 50 and older, the recommended age range for GI endoscopy screening services, is projected to grow at a CAGR of 2.7 percent.
- PDC also operates Duke GI at Brier Creek, with its four GI endoscopy rooms, in Wake County. Despite its Wake County location, it serves many Durham County residents. Duke GI at Brier Creek has a three, four, and five-year CAGR of 11.8 percent, 11.9 percent, and 14.5 percent, respectively. The historical utilization at Duke GI at Brier Creek was essentially flat between FFY 2017 and FFY 2018. The applicant states capacity constraints in both the GI endoscopy rooms as well as the physician clinic which sees patients served by the GI endoscopy rooms contributed to the lack of growth.

- There are currently three GI endoscopy service providers in Durham County: Duke University Hospital, Duke Regional Hospital, and Triangle Endoscopy Center. Only one, Triangle Endoscopy Center, is a freestanding non-hospital-based provider. There is a total of 19 GI endoscopy rooms in Durham County. In FFY 2018, 28,041 GI endoscopy procedures were performed in the three facilities. Based on the performance standard promulgated in 10A NCAC 14C .3903(b), the 19 GI endoscopy rooms are operating at 98.4 percent of capacity.

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

- The applicant provides data from official sources (NC OSBM and the Agency).
- The applicant relies on historical utilization at facilities which are similar in size to the proposed facility and which serve patients from the proposed service area.

Projected Utilization

In Section Q, Form C, the applicant provides projected utilization for the first three full fiscal years following project completion, as shown in the table below.

Duke GI-ND Projected Utilization – FYs 1-3 (CYs 2022-2024)			
	FY 1 CY 2022	FY 2 CY 2023	FY 3 CY 2024
# of GI Endo Rooms	4	4	4
# of GI Endo Procedures	3,520	6,109	6,810
Average # of Procedures per Room	880	1,527	1,703

In Section Q, pages 110-123, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- Actual population and projected population data for 2019 through 2024 for Durham and Orange counties is obtained from NC OSBM.
- Durham and Orange County GI endoscopy patient use rates were calculated for FFY 2017 by dividing the number of GI endoscopy patients in Durham and Orange counties by the 2017 population of each county. The number of GI endoscopy patients in each county for FFY 2017 was obtained from patient origin reports in License Renewal Applications (LRAs). Both Durham and Orange counties have lower GI endoscopy patient use rates than the statewide average.
- The applicant applied the patient use rate for Durham County and Orange County to the respective county's projected population from 2019 through 2024 to project the total number of GI endoscopy patients from each county.
- Based on the FFY 2017 data, the applicant calculated the GI endoscopy procedure per patient ratio for each county, dividing the number of GI endoscopy procedures performed

in each county by the number of GI endoscopy patients served in each county. The applicant states more than half the patients served in Durham County were not Durham County residents, and that fact likely created a higher ratio of GI endoscopy procedures per patient than would ordinarily exist in Durham County. The applicant states that, to be conservative, it instead looked at its FFY 2017 data for GI endoscopy procedures per patient ratio from Duke GI at Brier Creek, which is lower than the calculated ratio of GI endoscopy procedures per patient for Durham County, and used that ratio (1.24 procedures per patient) instead of the actual calculated ratio based on patient origin (1.41 procedures per patient). The applicant used the ratio it calculated for Orange County (1.04 procedures per patient) without any changes.

- The applicant applied the ratio of GI endoscopy procedures per patient it calculated for Durham County and Orange County to the projected GI endoscopy patients from each county for CYs 2019-2024 to obtain the projected number of annual GI endoscopy procedures for each county.
- The applicant projects it will gain market share in Durham and Orange counties in addition to patients shifting from other Duke or PDC facilities. The applicant states it will gain market share due to existing referral relationships, the existence of additional freestanding GI endoscopy services, capacity constraints and use rates of existing Durham County GI endoscopy rooms, population growth, physician recruitment, and support from local providers.
- The applicant projects patients will shift their care from Duke GI at Brier Creek to the proposed facility due to additional capacity created by Duke GI-ND, patients wanting to visit physician clinics which will be located in the same place as Duke GI-ND, efforts to decompress capacity at Duke GI of Brier Creek, more timely access to services, and a reduced travel burden for patients. To calculate projected growth at Duke GI of Brier Creek during the interim and first three operating years of the proposed project, the applicant projects the number of procedures at Duke GI at Brier Creek will grow at an annual rate of 3.5 percent from annualized FFY 2019 through FFY 2025. The applicant states this growth rate is conservative when considering its three, four, and five-year CAGR (11.8 percent, 11.9 percent, and 14.5 percent, respectively) and when considering its year-to-date FFY 2019 utilization is 4.3 percent higher than the same period during FFY 2018. The applicant converts its FFY projections into CY projections via the following formula, which uses FFY and CY 2023 as an example: $CY\ 2023 = (FFY\ 2023 \times 0.75) + (FFY\ 2024 \times 0.25)$. The applicant then determined the number of procedures from Durham and Orange counties based on its FFY 2018 historical utilization at Duke GI of Brier Creek. The applicant projects the shift of procedures from each county will ramp up during each of the first three operating years.
- The applicant projects in-migration from other surrounding counties, based on existing patterns of in-migration. The applicant states approximately 42 percent of patients at Duke GI of Brier Creek originate from counties other than Wake or Durham, and states more than half of GI endoscopy patients served in Durham County during FFY 2017 were from

other counties. The applicant projects in-migration will ramp up during the first two operating years and then remain steady.

- The first three full fiscal years of the project are CYs 2022, 2023, and 2024.

A summary of the applicant’s assumptions and methodology for projecting utilization is shown in the table below.

Duke GI-ND – Projected Utilization – Summary of Assumptions/Methodology							
	2019	2020	2021	2022	2023	2024	2025
Durham County Projected Population	315,510	320,173	324,838	329,499	334,161	338,826	
Durham County FFY 2017 Patient Use Rate	41.66	41.66	41.66	41.66	41.66	41.66	
Durham County Projected Patients	13,146	13,340	13,534	13,728	13,923	14,117	
Durham County Procedure/Patient Ratio	1.24	1.24	1.24	1.24	1.24	1.24	
Durham County Projected Procedures	16,353	16,595	16,837	17,078	17,320	17,562	
Durham County Projected Increased Market Share				10%	15%	15%	
Durham County Patients from Increased Market Share				1,708	2,598	2,634	
Orange County Projected Population	145,383	146,889	148,394	149,896	151,396	152,898	
Orange County FFY 2017 Patient Use Rate	41.77	41.77	41.77	41.77	41.77	41.77	
Orange County Projected Patients	6,073	6,136	6,199	6,262	6,324	6,387	
Orange County Procedure/Patient Ratio	1.04	1.04	1.04	1.04	1.04	1.04	
Orange County Projected Procedures	6,336	6,402	6,467	6,533	6,598	6,664	
Orange County Projected Increased Market Share				4%	5%	5%	
Orange County Patients from Increased Market Share				261	330	333	
Duke GI at Brier Creek Projected Procedures (in FFYs)	7,565*	7,830	8,104	8,388	8,681	8,985	9,299
Duke GI at Brier Creek Projected Procedures (conv. to CYs)				8,461	8,757	9,064	
Durham & Orange County Procedures (based on FFY 2018, 2019 LRA)				3,996	4,135	4,280	
% to Shift				30%	40%	50%	
# Procedures to Shift				1,199	1,655	2,140	
Total Procedures Before In-migration				3,168	4,582	5,107	
In-migration % of Procedures				10%	25%	25%	
In-migration # of Procedures**				352	1,527	1,702	
Total Procedures				3,520	6,109	6,810	

*Annualized.

**The applicant appears to have calculated this number by dividing the total number of procedures prior to in-migration by the assumed percentage those procedures would constitute, and then subtracted the total number of procedures prior to in-migration to get the number of in-migrated procedures. Example for CY 2022: 3,168 / 90% = 3,520; 3,520 – 3,168 = 352.

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

- The applicant uses its own historical data from similar facilities to project utilization.
- The applicant uses reliable and publicly available data sources when not relying on its own historical data.

Access

In Section C, page 40, 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 facility, as clinically appropriate. PDC does not discriminate on the basis of race, ethnicity, age, gender, or disability.”

In Section L, page 93, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Duke GI-ND Payor Mix – OY 2 (CY 2023)	
Payor Source	Percent of Services
Self-Pay/Charity Care	1.5%
Medicare*	27.6%
Medicaid*	1.6%
Insurance*	68.3%
Other	1.0%
Total	100.0%

*Including any managed care plans

The projected payor mix is reasonable and adequately supported.

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

In Section E, pages 52-55, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo: The applicant states that, due to increasing demand for GI endoscopy services and utilization of GI endoscopy rooms in Durham County at 98.4 percent of capacity, maintaining the status quo is not an effective alternative.
- Develop Additional GI Endoscopy Rooms at Duke GI at Brier Creek: The applicant states this alternative would expand access to patients in Wake County, but not necessarily in Durham County. The applicant states that, due to high utilization of existing GI endoscopy rooms in Durham County, this was not an effective alternative.
- Develop Duke GI-ND in a Different Location: The applicant states the location for Duke GI-ND was chosen because of the plan to locate multiple types of medical services in a single location. The applicant states locating Duke GI-ND at a different location would not allow patients to experience the benefits of multiple services at a single location; therefore, this was not an effective alternative.
- Develop a Different Number of GI Endoscopy Rooms: The applicant states it determined the appropriate number of GI endoscopy rooms based on demand, medical specialties that will be located at the same site as Duke GI-ND, and population growth; therefore, developing a different number of GI endoscopy rooms was not an effective alternative.

On pages 52-55, the applicant states its proposal is the most effective alternative because it provides increased access to freestanding GI endoscopy services in Durham County, it allows patients to see multiple physicians and have access to multiple services in the same location,

and it alleviates some of the high utilization of existing GI endoscopy rooms in Durham County.

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 applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

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. 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.**
- 2. Private Diagnostic Clinic, PLLC shall develop a new ambulatory surgical facility with no more than four gastrointestinal endoscopy rooms.**
- 3. Upon completion of the project, Duke GI at North Durham shall be licensed for no more than four gastrointestinal endoscopy rooms.**
- 4. 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 Sections F and Q of the application and that would otherwise require a certificate of need.**
- 5. Duke GI at North Durham 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.**
- 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 Sections F and Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the**

proposed increase is in material compliance with the representations in the certificate of need application.

- 7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, 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.

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	\$1,750,000
Architect/Engineering Fees	\$180,000
Medical Equipment	\$1,425,797
Non-Medical Equipment	\$132,525
Consultant Fees/Contingency	\$65,000
Total	\$3,553,322

In Section F, page 56, the applicant provides the assumptions used to project the capital cost.

The applicant states it will incur construction and renovation costs to upfit the space via the lease agreement. The applicant states that, since the lease is an operational cost, the financial pro formas reflect the costs of the lease. On page 56, the applicant states:

“PDC will lease all the equipment via an equipment lease with First Citizens Bank. Although PDC will lease both the facility and all the medical and non-medical equipment, the project capital cost table...reflects all these project costs...”

The applicant provides supporting documentation in Exhibits 7, 9, and 11.

In Section F, pages 58-59, the applicant projects start-up costs of \$225,000 and initial operating expenses of \$125,000 for a total working capital of \$350,000. In Section Q, Financial Assumptions, Assumption (10), the applicant provides the assumptions used to project the working capital needs of the project.

Availability of Funds

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

Sources of Capital Cost Financing	
Type	PDC
Accumulated Reserves or OE*	\$65,000
Equipment Lease	\$1,558,322
Facility Lease	\$1,930,000
Total Financing	\$3,553,322

*OE = Owner's Equity

In Section F, page 60, the applicant states the working capital costs will be funded via cash or cash equivalents.

See Exhibits 7, 9, and 11 for documentation of potential lease agreements for space in the medical office building and medical equipment, PDC's commitment to fund the project, and First Citizen Bank's documentation of available funding for the proposed project's capital and working capital costs.

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.3, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown in the table below.

Duke GI-ND – Revenues/Operating Expenses – OYs 1-3 (CYs 2022-2024)			
	OY 1 – CY 2022	OY 2 – CY 2023	OY 3 – CY 2024
Total Procedures	3,520	6,109	6,810
Total Gross Revenues (Charges)	\$10,296,800	\$17,872,502	\$19,922,034
Total Net Revenue	\$4,396,182	\$7,630,600	\$8,505,641
Average Net Revenue per Procedure	\$1,249	\$1,249	\$1,249
Total Operating Expenses (Costs)	\$2,874,715	\$4,037,928	\$4,553,979
Average Operating Expense per Procedure	\$817	\$661	\$669
Net Income	\$1,521,466	\$3,592,672	\$3,951,662

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 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 endoscopy rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), define 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, page 19, the

applicant defines the primary service area as Durham County. Facilities may also serve residents of counties not included in their service area.

There are a total of three facilities with 19 GI endoscopy rooms in Durham County – two hospitals and one freestanding ASF. Utilization at each facility during FFYs 2017 and 2018 are shown in the table below.

Durham County GI Endoscopy Services – FFY 2017 and FFY 2018			
Existing Facilities	# of Endoscopy Rooms	FFY 2017 # of Procedures	FFY 2018 # of Procedures
Duke University Hospital	11	20,356	15,674
Duke Regional Hospital	4	5,783	6,905
Triangle Endoscopy Center	4	4,281	5,462
Total	19	30,420	28,041

Sources: Table 6F: Endoscopy Room Inventory, page 90 of the 2019 SMFP; Application, Section G, page 65 (from 2019 LRAs)

In Section G, page 66, the applicant explains why it believes the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Durham County. The applicant states it demonstrates the need for the proposed facility based on historical utilization in Durham County, demographic data specific to Durham County, and other qualitative reasons. On page 66, the applicant states:

“PDC determined that patients will greatly benefit from development of a new freestanding facility in Durham County. ...freestanding outpatient facilities provide a high quality, more affordable healthcare service option for patients. They offer valuable procedural services at a fraction of the cost that hospitals incur for the same services. In addition, patients typically pay less coinsurance for procedures performed in freestanding facilities than for comparable procedures in a hospital setting. By having the procedure performed in the dedicated-outpatient setting, the patient saves a notable difference compared to their out-of-pocket coinsurance for the same procedure in the hospital.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area for the following reasons:

- The proposal would create another freestanding ASF and provide patients with another lower cost option for GI endoscopy services.
- The applicant adequately demonstrates that the proposed GI endoscopy services are needed in addition to the existing or approved GI endoscopy services.

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.

Duke GI-ND Projected (FYs 1-3) Staffing in FTEs			
Positions	FY 1 (CY 2022)	FY 2 (CY 2023)	FY 3 (CY 2024)
Medical Records			
Manager	1.0	1.0	1.0
Clerical (PSA/Reimbursement)	1.0	2.0	2.5
Surgery			
Registered Nurses	9.0	13.0	15.0
Technicians	5.5	7.0	8.0
Certified Medical Assistants	1.0	1.0	1.5
Administration			
Administrator	1.0	1.0	1.0
Assistant Administrator	0.0	1.0	1.0
Clerical	1.0	1.0	1.0
Total	19.5	27.0	31.0

The assumptions and methodology used to project staffing are provided in Section H, page 68, and Section Q. 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 69-70, the applicant describes the methods used to recruit or fill new positions and its proposed training and continuing education programs. In Section H, page 71, the applicant identifies the proposed medical director. In Exhibit 2, the applicant provides a letter from the proposed 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 73-74, the applicant states the following ancillary and support services are necessary for the proposed services:

- Anesthesia
- Administration
- Patient Scheduling
- Human Resources/Payroll
- Accounting/Billing
- Information Technology
- Quality & Performance Improvement
- Staff Education
- Infection Control
- Reception
- Medical Records
- Pharmacy Services
- Pathology Services
- Linen Service/Housekeeping
- Medical Supplies
- Dietary

On pages 73-74, the applicant adequately explains how each ancillary and support service will be made available and provides supporting documentation in Exhibits 8 and 13.

In Section I, page 74, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 13.

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 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 78, the applicant states the project involves upfitting 8,200 square feet of space in a medical office building. Line drawings are provided in Exhibit 10.

On page 79, 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.

On page 79, 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.

On page 80, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

On pages 81-87, the applicant identifies the proposed site and provides information about the current owner, zoning and special use permits for the site, and the availability of water, sewer and waste disposal, and power at the site.

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;

NA

Neither the applicant nor any related entities own, operate, or manage an existing GI endoscopy ASF located in the service area. Therefore, Criterion (13a) is not applicable to this review.

- (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;

NA

Neither the applicant nor any related entities own, operate, or manage an existing GI endoscopy ASF located in the service area. Therefore, Criterion (13b) is not applicable to this review.

- (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 93, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as shown in the table below.

Duke GI-ND Payor Mix – OY 2 (CY 2023)	
Payor Source	Percent of Services
Self-Pay/Charity Care	1.5%
Medicare*	27.6%
Medicaid*	1.6%
Insurance*	68.3%
Other	1.0%
Total	100.0%

*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 percent of total services will be provided to self-pay/charity care patients, 27.6 percent to Medicare patients, and 1.6 percent to Medicaid patients.

On page 93, 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. The projected payor mix is reasonable and adequately supported for the following reasons:

- The projected payor mix is based on the applicant's experience with similar facilities in nearby service areas.
- The projected payor mix is based in part on historical payor mix for other providers that currently provide the same services in Durham County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, page 95, the applicant adequately describes the range of means by which patients will have access to the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section M, page 96, 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 6.

Conclusion

The Agency reviewed the:

- Application
- 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 endoscopy rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), define 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, page 19, the applicant defines the primary service area as Durham County. Facilities may also serve residents of counties not included in their service area.

There are a total of three facilities with 19 GI endoscopy rooms in Durham County. Utilization at each facility during FFYs 2017 and 2018 are shown in the table below.

Durham County GI Endoscopy Services – FFY 2017 and FFY 2018			
Existing Facilities	# of Endoscopy Rooms	FFY 2017 # of Procedures	FFY 2018 # of Procedures
Duke University Hospital	11	20,356	15,674
Duke Regional Hospital	4	5,783	6,905
Triangle Endoscopy Center	4	4,281	5,462
Total	19	30,420	28,041

Sources: Table 6F: Endoscopy Room Inventory, page 90 of the 2019 SMFP; Application, Section G, page 65 (from 2019 LRAs)

In Section N, pages 97-102, 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 97, the applicant states:

“...Duke GI at North Durham 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.... 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.”

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
- 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 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 106, the applicant identifies the existing GI endoscopy ASFs in North Carolina owned, operated, or managed by the applicant or a related entity. The applicant identifies one facility of this type, Duke GI at Brier Creek, located in North Carolina.

In Section O, page 106, the applicant states that, during the 18 months immediately preceding the submittal of the application, there were no incidents related to quality of care at Duke GI at Brier Creek. 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, there were no incidents related to quality of care at Duke GI at Brier Creek. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at Duke GI at Brier Creek, 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

**CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY
PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES**

10A NCAC 14C .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 endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*
- C- In Section Q, the applicant projects to perform 6,109 GI endoscopy procedures in four GI endoscopy rooms, or an average of 1,527 GI endoscopy procedures per room, at Duke GI-ND during the second year of operation following completion of the project. Neither the applicant nor any related entities own any other licensed facilities providing GI endoscopy services in the proposed service area.
- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section C, page 43, the applicant states it will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at its proposed facility.
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*

- (1) *if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or*
 - (2) *demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*
- NA- Neither the applicant nor any related entities own any inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the proposed service area, either currently or within the last 12 months. Therefore, this Rule is not applicable to this review.
- (e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*
- C- In Section Q, pages 110-123, the applicant provides the assumptions and methodology used to project utilization of GI endoscopy services at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.