

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: August 4, 2022

Findings Date: August 4, 2022

Project Analyst: Ena Lightbourne

Co-Signer: Gloria C. Hale

Project ID #: G-12220-22

Facility: Digestive Health Specialists, P.A.

FID #: 070435

County: Forsyth

Applicant(s): Digestive Health Specialists, P.A.

Project: Relocate existing facility and add no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms

REVIEW CRITERIA

G.S. 131E-183(a): The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

- (1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

NA

Digestive Health Specialists, P.A. (“applicant” or “DHS”) proposes to develop a GI endoscopy ambulatory surgical facility (ASF) by relocating an existing ASF with two GI endoscopy rooms, to a newly constructed medical office building on Kimel Park Drive in Winston-Salem, approximately one mile away, and adding no more than one GI endoscopy room for a total of no more than three 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 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There are no policies in the 2022 SMFP which are applicable to this project.

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 Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Forsyth County. In Section C, page 31, the applicant projects that 58.7% of its patients will originate from Forsyth County. Thus, the primary service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	Digestive Health Specialists, P.A. GI Endoscopy Historical Patient Origin	
	Last Full FY 01/01/2021-12/31/2021	
	Patients	% of Total
Forsyth	3,625	58.7%
Davidson	824	13.3%
Stokes	308	5.0%
Guilford	306	5.0%
Wilkes	156	2.5%
Other*	960	15.5%
Total	6,178	100.0%

Source: Section C, page 30

*Other includes 34 North Carolina counties and other State counties.

Digestive Health Specialists, P.A. (Proposed) GI Endoscopy Projected Patient Origin						
County	1 st Full FY		2 nd Full FY		3 rd Full FY	
	CY2024		CY2025		CY2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Forsyth	4,305	58.7%	4,481	58.7%	4,665	58.7%
Davidson	978	13.3%	1,019	13.3%	1,060	13.3%
Stokes	366	5.0%	381	5.0%	397	5.0%
Guilford	363	4.9%	378	4.9%	393	4.9%
Wilkes	185	2.5%	193	2.5%	201	2.5%
Other*	1,140	15.5%	1,187	15.5%	1,235	15.5%
Total	7,337	100.0%	7,638	100.0%	7,951	100.0%

Source: Section C, page 31

*Other includes 34 North Carolina counties and other State counties.

In Section C, page 31, the applicant refers to Section Q for the assumptions and methodology used to project its patient origin. However, in Section Q, the applicant provides the assumptions and methodology to project the number of procedures. Based on the percentage of total patients by county, as stated in the table above, the Analyst assumes that projected patient origin is based on the historical percentage of total patients by county.

Analysis of Need

In Section C, pages 32-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services, as summarized below.

Population Growth in the Service Area (pages 33-34)

The applicant cites data from the North Carolina Office of State Budget and Management (NCOSBM) to demonstrate projected population growth in the service area. According to the data, population in Forsyth County is projected to grow 9.0% over the next 10 years (CY2022 – CY2032). The secondary service area (Davidson, Guilford, Stokes, Wilkes counties) is projected to grow 7.5% during the same period. The 65+ population is projected to experience the highest growth in the entire service area. In Section C, page 34, the applicant states that the 65+ population accounts for 34.1% of GI endoscopy patients treated at DHS facilities.
DHS GI Endoscopy Service Growth (page 35)

The applicant states that DHS has experienced a 4-year Compound Annual Growth Rate (CAGR) of 8.2% between CY2018 and annualized CY2022.

Digestive Health Specialists, P.A. Annual GI Endoscopy procedures CY2018 – Annualized CY2022					
	CY2018	CY2019	CY2020	CY2021	Annualized CY2022
Procedures	5,581	6,493	6,069	6,979	7,651
Annual Change		16.3%	-6.5%	15.0%	9.6%
4-Year CAGR					8.2%

Source: Section C, page 35; Digestive Health Specialists

GI Endoscopy Industry Growth (pages 35-38)

The applicant provides excerpts from articles related to the GI endoscopy industry highlighting future growth and expansion based on factors such as:

- Advancement in technology will lead interventional radiology into other, more complex areas of treatment.
- The aging U.S. population and the increasing incidence of GI disease will continue to drive the demand for endoscopy procedures.
- GI endoscopy procedure volumes will continue to move from hospitals to lower-cost ASFs that practice gastroenterology, which includes single specialty endoscopy centers.

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

- Projected population growth in service area, particularly among the 65+ population.
- The historical growth in GI endoscopy procedures performed at DHS facilities.
- The growing trend in the GI endoscopy industry.

Projected Utilization

In Section Q, Form C.3, the applicant provides historical and projected utilization, as illustrated in the following tables.

Digestive Health Specialists, P.A. GI Endoscopy Historical and Interim Utilization			
	Prior Full Fiscal Year	Interim Full Fiscal Year 1	Interim Full Fiscal Year 2 (Partial)
	CY2021	CY2022	01/01/2023- 6/30/2023
# of Rooms	2	2	2
# Inpatient GI Endoscopy Procedures	0	0	0
# Outpatient GI Endoscopy Procedures	6,979	7,651	3,983
Total GI Endoscopy Procedures	6,979	7,651	3,983
Average # of Procedures per Room	3,490	3,826	2,655 [1,992]

Note: The Project Analyst's calculations are in brackets.

Digestive Health Specialists, P.A. (Proposed) GI Endoscopy Projected Utilization				
	Partial Fiscal Year	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
	07/01/2023- 12/31/2023	CY2024	CY2025	CY2026
# of Rooms	3	3	3	3
# Inpatient GI Endoscopy Procedures	0	0	0	0
# Outpatient GI Endoscopy Procedures	3,983	8,291	8,631	8,985
Total GI Endoscopy Procedures	3,983	8,291	8,631	8,985
Average # of Procedures per Room	2,655[1,328]	2,764	2,877	2,995

Note: The Project Analyst's calculations are in brackets.

In Section Q, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify the number of procedures performed at the existing facility from CY2018 through CY2021.

	CY2018	CY2019	CY2020	CY2021
Procedures	5,581	6,493	6,069	6,979

Step 2: Annualize CY2022 based on procedures performed for the first three months of year (Analyst calculations in brackets)

1,912 procedures / 3 months) x 12 months = 7,651 [7648] procedures

Step 3: Calculate the 4-Year CAGR for CY2018 through CY2022

$$\text{CAGR} = (\text{CY2022} / \text{CY2018}) \times (1 / \# \text{ of years}) - 1 \times 100$$

$$\text{CAGR} = (7,651 / 5,581) \times (1 / 4) - 1 \times 100$$

$$\text{CAGR} = 8.21\%$$

Step 4: Calculate 50% of the 4-Year CAGR calculated in Step 3

$$8.21\% \times 50.0\% = 4.1\%$$

Step 5: Project utilization for CY2023 through CY2026 using the 4-Year CAGR of 4.1%.

Digestive Health Specialists, P.A. Historical Utilization					
	CY2018	CY2019	CY2020	CY2021	Annualized CY2022
Procedures	5,581	6,493	6,069	6,979	7,651
4-Year CAGR					8.21%
50% of the 4-Year CAGR					4.10%

Digestive Health Specialists, P.A. (Proposed) Projected Utilization				
	CY2023	CY2024	CY2025	CY2026
Procedures	7,965	8,292	8,632	8,986
50% of the 4-Year CAGR				4.10%

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

- Projected utilization is based on the most recent GI endoscopy procedure data annualized.
- The applicant’s projected growth rate in GI endoscopy procedures is conservative and supported by the historical four-year average growth rate.
- The applicant demonstrates that the projected utilization exceeds the required 1,500 procedures per GI endoscopy room.

Access to Medically Underserved Groups

In Section C, page 44, the applicant states:

“Most of the patients proposed to be served by DHS can be classified into one or more categories of medically underserved groups...”

The applicant provides the estimated percentage for each medically underserved group proposed to be served during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	8.0%
Racial and ethnic minorities	27.6%
Women	56.2%
Persons with Disabilities*	n/a
Persons 65 and older	34.1%
Medicare beneficiaries	32.3%
Medicaid recipients	3.1%

Source: Section C, page 44

*On page 44, the applicant states that this information is not tracked.

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 all the reasons described above.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

C

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

In Section D, page 50, the applicant explains why it believes the needs of the population presently utilizing the services to be relocated will be adequately met following completion of the project. On page 50, the applicant states:

“The DHS GI endoscopy ASF will be relocated from Frontis Plaza Boulevard to Kimel Park Drive. The two locations are less than one mile from each location.”

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

- The two locations are approximately 0.6 miles and 2 minutes driving time from each other, according to Google Maps. Thus, the GI endoscopy services will still be accessible to the same population at the new location.
- The applicant is not proposing to reduce any services at the current location.

Access to Medically Underserved Groups

In Section D, page 51, the applicant states:

“The relocation of the facility will have no effect on DHS’s ability to provide services to the identified groups because the DHS GI endoscopy ASF will be relocated from the Frontis Plaza Boulevard to Kimel Park Drive. The two locations are less than one mile from each location.”

The applicant adequately demonstrates that the needs of medically underserved groups that will continue to use GI endoscopy services will be adequately met following completion of the project because services will still be accessible to the same population at the new location.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the needs of the population currently using the services to be reduced, eliminated or relocated will be adequately met following project completion for all the reasons described above.
- The applicant adequately demonstrates that the project will not adversely impact the ability of underserved groups to access these services following project completion for all the reasons described above.

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

CA

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

In Section E, pages 56-57, 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 Status Quo-The applicant states that maintaining the status quo was a poor alternative due to the expiration of the lease at the existing location and the inability to expand the facility.

Build a Freestanding ASF Building-The applicant states that this alternative was dismissed as a costly option due to the cost to acquire land and construct a new facility.

On page 57, the applicant states that its proposal is the most effective alternative because upfitting space within a medical office building would provide a less expensive option to insurers as opposed to a hospital setting. Additionally, the applicant's proposal would provide more efficient staffing and space utilization and provide a specialized operating environment focused on cost-containment.

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

- The applicant's proposal will provide a more cost-effective and efficient setting for GI endoscopy services.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Digestive Health Specialists, P.A. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a GI endoscopy Ambulatory Surgical Facility (ASF) by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.**

- 3. Upon completion of the project, Digestive Health Specialists, P.A. located on Kimel Park Drive in Winston-Salem, shall be licensed for no more than three GI endoscopy rooms.**
- 4. Progress Reports:**
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on March 1, 2023.**
- 5. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.**
- 6. For the first three years of operation following completion of the project, the certificate holder shall not increase charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
- 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, 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.**
- 8. 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 proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three 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.

Digestive Health Specialists, P.A. Capital Costs	
Construction/Renovation Contract(s)	\$836,334
Architecture/Engineering Fees	\$66,907
Medical Equipment	\$223,582
Furniture	\$24,000
Consultant Fees	\$40,000
Other (Contingency)	\$120,000
Total	\$1,310,823

In Section Q, Form F.2, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions that are based on the vendor's estimated costs for construction and equipment. The applicant provides supporting documentation in Exhibit F.1.

In Section F, page 60, the applicant projects that start-up costs will be \$42,165. On page 61, the applicant states that there will be no initial operating costs based on revenues projected to exceed operating costs in the first operating year. On page 61, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions because it is based on the projected cost for the first month of the first fiscal year of the project, which includes costs for supplies, utilities, salaries for new hires and taxes and benefits.

Availability of Funds

In Section F, page 58, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	Digestive Health Specialists, P.A.	Total
Loans	\$600,823	\$600,823
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (\$100 per square foot up-fit allowance within the lease)	\$710,000	\$710,000
Total Financing	\$1,310,823	\$1,310,823

* OE = Owner's Equity

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

Sources of Financing for Working Capital	Amount
Loans	\$42,165
Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$0
Lines of credit	\$0
Bonds	\$0
Total *	\$42,165

Exhibit F.2 contains a letter dated April 25, 2022, from the Chief Executive Officer of First Citizens Bank, stating their consideration in funding the project through a loan, upon CON approval. The letter includes the proposed terms of the loan and an amortization schedule. The applicant adequately demonstrates the availability of sufficient funds for the capital and working capital needs of the 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 Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Digestive Health Specialists, P.A.	1 st FFY CY 2024	2 nd FFY CY 2025	3 rd FFY CY 2026
Total Procedures	8,291	8,631	8,985
Total Gross Revenues (Charges)	\$17,170,587	\$18,768,461	\$20,515,160
Total Net Revenue	\$4,126,092	\$4,510,061	\$4,929,793
Average Net Revenue per Treatment	\$498	\$523	\$549
Total Operating Expenses (Costs)	\$2,328,485	\$2,402,127	\$2,479,019
Average Operating Expense per Treatment	\$281	\$278	\$276
Net Income	\$1,797,607	\$2,107,934	\$2,450,774

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

- The applicant projects gross revenue based on the historical number of procedures by payor source multiplied by the projected average gross charge with an average 5% increase.
- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Forsyth County. In Section C, page 31, the applicant projects that 58.7% of its

patients will originate from Forsyth County. Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP shows there are 28 existing GI endoscopy rooms in seven facilities in Forsyth County, as shown below.

Forsyth County GI Endoscopy Services – FY2020 Data			
Existing Facilities	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Digestive Health Endoscopy Center of Kernersville	2	2,810	3,084
Digestive Health Specialists, P.A.	2	5,291	5,964
Gastroenterology Associates of the Piedmont	4	4,419	5,930
Gastroenterology Associates of the Piedmont	4	9,105	12,442
NC Baptist Hospital	10	9,055	19,905
Novant Health Forsyth Medical Center	4	2,633	2,953
Wake Forest Baptist Health OP Endoscopy	2	1,452	1,697
Total	28	34,765	51,975

Source: Table 6F: Endoscopy Room Inventory (pages 88-89 of the 2022 SMFP)

In Section G, page 70, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Forsyth County. The applicant states:

“DHS proposes to relocate and expand its existing GI endoscopy ASF less than 1-mile from its current location. The new GI endoscopy ASF location will not result in an unnecessary duplication of existing or approved facilities because the DHS GI endoscopy rooms average at least 1,500 GI procedures in Year 2, as required by the performance standards. The utilization projections are based on reasonable and conservative assumptions.”

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 additional GI endoscopy room is needed in addition to the existing or approved GI endoscopy rooms.

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 all the reasons described above.

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

C

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

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

Position	Current FTE Staff	Projected FTE Staff
	Last Full Fiscal Year (CY 2021)	2nd Full Fiscal Year (CY 2025)
Charge Nurse	1.00	1.00
Registered Nurse	3.00	5.00
LPN	3.00	3.00
Endoscopy Technicians	2.00	4.00
Medical Records	0.25	0.25
Billing Specialist	2.00	2.00
Patient Access Specialist (Front Desk)	1.00	1.00
TOTAL	12.25	16.25

The assumptions and methodology used to project staffing are provided in Section Q. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 72-73, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

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

- The applicant will offer competitive salaries/benefits and recruit staff through traditional methods, including a partnership with local colleges to hire new graduates.
- All DHS employees are required to attend orientation specific to their positions and ongoing education sessions provided by the Charge Nurse.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

Ancillary and Support Services

In Section I, page 75, the applicant identifies the necessary ancillary and support services for the proposed services. On page 76, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit I.1. The applicant adequately demonstrates that the necessary ancillary and support services will be made available. The applicant is relocating an existing facility. Ancillary and support services will be provided by the facility staff.

Coordination

In Section I, page 77, 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 based on the applicant's established relationships with local health care and social service providers in the service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

In Section K, page 80, the applicant states that the project involves constructing 7,100 square feet of new space. Line drawings are provided in Exhibit K.1.

On pages 82-83, 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. Supporting documentation is provided in Exhibit K.4. The site appears to be suitable for the proposed GI endoscopy ASF based on the applicant's representations and supporting documentation.

In Section E, page 57, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant demonstrates cost containment by developing the GI endoscopy ASF in a medical office building as opposed to a hospital setting.
- the applicant's proposal would provide more efficient staffing and space utilization and provide a specialized operating environment focused on cost-containment.

On page 81, 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 based on the following:

- The applicant presents upfit costs as the most cost-effective alternative.
- The applicant is proposing a design project that will follow all applicable federal, state, and local building codes, and requirements for energy efficiency and consumption.

On page 81, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section L, page 85, the applicant provides the historical payor mix during CY 2021 for the proposed services, as shown in the table below.

Digestive Health Specialists, P.A. Historical Payor Mix 01/01/2021-12/31/2021	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	0.4%
Charity Care	
Medicare*	32.3%
Medicaid*	3.1%
Insurance*	59.7%
Workers Compensation	
TRICARE	
Other	4.5%
Total	100.0%

*Including any managed care plans.

In Section L, page 86, the applicant provides the following comparison.

Digestive Health Specialists, P.A.	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	56.2%	52.7%
Male	43.8%	47.3%
Unknown		0.0%
64 and Younger	65.9%	85.6%
65 and Older	34.1%	16.4%
American Indian	0.2%	0.9%
Asian	0.9%	2.6%
Black or African-American	18.8%	27.5%
Native Hawaiian or Pacific Islander		0.1%
White or Caucasian	72.4%	56.3%
Other Race	3.3%	13.3%
Declined / Unavailable	4.4%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

The Agency reviewed the:

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

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

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

C

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

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

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

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

Digestive Health Specialists, P.A. (proposed) Projected Payor Mix 3rd Full FY, CY 2024 [CY 2026] ^	
Payor Category	GI Endo patients as Percent of Total
Self-Pay	0.4%
Charity Care	
Medicare*	32.3%
Medicaid*	3.1%
Insurance*	59.7%
Workers Compensation	
TRICARE	
Other	4.5%
Total	100.0%

*Including any managed care plans.

^On page 88, the applicant identifies the 3rd full FY as CY 2024, however, the Analyst assumes this was a typographical error because the applicant identifies the 3rd FY as CY 2026 in Section Q.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.4% of total services will be provided to self-pay patients, 32.3% to Medicare patients and 3.1% to Medicaid patients.

On page 88, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the applicant's assumption that payor mix is not expected to change from the last full fiscal year.

The Agency reviewed the:

- Application
- Exhibits to the application

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

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

C

In Section L, 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

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

In Section M, page 91, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit M.1. The applicant adequately demonstrates that health professional training programs in the area have will have access to the facility for training purposes based on the following:

- The applicant's commitment to accommodate students from health professional training programs in the area.
- In Exhibit M.1, the applicant provides letters addressed to two universities and two community colleges in the area, stating the facility's availability as a training 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 for all the reasons described above.

- (15) Repealed effective July 1, 1987.
- (16) Repealed effective July 1, 1987.
- (17) Repealed effective July 1, 1987.
- (18) Repealed effective July 1, 1987.
- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

The applicant proposes to develop a GI endoscopy ASF by relocating an existing ASF with two GI endoscopy rooms and adding no more than one GI endoscopy room for a total of no more than three GI endoscopy rooms.

N.C. Gen. Stat. §131E-176(24a) states, "*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*" The 2022 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6), defines the service area as "...*the county where the proposed GI endoscopy room will be developed.*" The facility will be developed in Forsyth County. In Section C, page 31, the applicant projects that 58.7% of its patients will originate from Forsyth County. Thus, the service area for this facility consists of Forsyth County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP shows there are 28 existing GI endoscopy rooms in seven facilities in Forsyth County, as shown below.

Forsyth County GI Endoscopy Services – FY2020 Data			
Existing Facilities	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Digestive Health Endoscopy Center of Kernersville	2	2,810	3,084
Digestive Health Specialists, P.A.	2	5,291	5,964
Gastroenterology Associates of the Piedmont	4	4,419	5,930
Gastroenterology Associates of the Piedmont	4	9,105	12,442
NC Baptist Hospital	10	9,055	19,905
Novant Health Forsyth Medical Center	4	2,633	2,953
Wake Forest Baptist Health OP Endoscopy	2	1,452	1,697
Total	28	34,765	51,975

Source: Table 6F: Endoscopy Room Inventory (pages 89-90 of the 2022 SMFP)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 93, the applicant states:

“With the rising demand for both inpatient and outpatient surgical services that is driven by a growing community, an aging population, and expanding physician base, DHS expects that competition with existing providers will remain robust.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 94, the applicant states:

“DHS provides a more economical choice for outpatient GI endoscopy services to the patients in the service area. A GI endoscopy ASF allows DHS to focus on developing an efficiently operated ASF through the facility’s design, policies and procedures, staffing, and space utilization.”

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

Regarding the impact of the proposal on quality, in Section N, page 94, the applicant states:

“DHS continues to operate a quality improvement plan...the program will provide a methodology to monitor, analyze, and improve performance. It is critical that both GI endoscopy ASF personnel and attending medical staff understand the program.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 95, the applicant states:

“DHS does not discriminate against any class of patient based on age, sex, religion, race, handicap, ethnicity, or ability to pay. DHS actively participates in both the Medicaid and Medicare programs...In the third year of the project, DHS is projected to provide more than \$26,670 in charity care and to write-off \$738,546 in unpaid patient accounts.”

See also Section L and C of the application and any exhibits.

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

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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 based on all the reasons described above.

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

C

In Section Q, Form O, the applicant identifies the ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of five of this type of facility located in North Carolina.

In Section O, page 100, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to immediate jeopardy had not occurred in any of these facilities. According to the files in the Acute Care 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 had not occurred in any of these facilities. After reviewing and considering information provided by the applicant and by the Acute Care and Home Care Licensure and Certification Section and considering the quality of care provided at all five 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.

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

C

The application is conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities. The specific criteria are discussed below.

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

.3903 PERFORMANCE STANDARDS

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

(1) *identify the proposed service area;*

-C- The facility will be developed in Forsyth County. In Section C.3, page 31, the applicant projects that 58.7% of its patients will originate from Forsyth County. Thus, the service area for this facility consists of Forsyth County.

(2) *identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;*

- C- According to the 2022 License Renewal Applications, provided in Exhibit A.6 of the application, there are eight endoscopy existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area.
- (3) *provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;*
- C- In Section C, page 47, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project for all of its GI endoscopy rooms.

	2021	2022	2023	2024	2025	2026
DHS-Winston-Salem	7,004					
DHS-King	2,252					
DHS-Advance	2,215					
DHS-Thomasville	2,681					
DHS-Kernersville	3,450					
GI Endoscopy Procedures	17,602	17,963	18,331	18,707	19,090	19,482
Proposed GI Endoscopy Rooms	8	8	8	9	9	9
Projected GI Endoscopy Procedures per Room	2,200	2,245	2,291	2,079	2,121	2,165

- (4) *project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and*
- C- In Section C, page 47, the applicant projects to perform an average of 2,165 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project.
- (5) *provide the assumptions and methodology used to project the utilization required by this Rule.*
- C- In Section C, page 47 and Section Q, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at its existing and proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.