

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: January 30, 2025

Findings Date: February 5, 2025

Project Analyst: Crystal Kearney

Co-Signer: Micheala Mitchell

Project ID #: F-12565-24

Facility: Piedmont HealthCare Endoscopy Center

FID #: 240861

County: Iredell

Applicant(s): Piedmont HealthCare, P.A

Davie Valley, LLC

Project: Develop a new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont HealthCare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion

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.

C

Piedmont HealthCare, P.A. and Davie Valley, LLC (hereinafter referred to as “the applicant”), propose to relocate no more than three (3) gastrointestinal (GI) endoscopy rooms from the existing Piedmont HealthCare Endoscopy Center, in Statesville in Iredell County and add one (1) additional GI endoscopy room for a total of no more than four GI endoscopy rooms upon project completion.

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 2024 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2024 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities*.

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on pages 30 of the 2024 SMFP, states:

“Any person proposing a capital expenditure greater than \$4 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 of the project is over \$4 million. In Section B, pages 25-26, the applicant describes its plan to ensure energy efficiency and water conservation. The applicant adequately demonstrates that the application includes a written statement describing the project’s plan to ensure improved energy efficiency and water conservation. Therefore, the application is consistent with Policy GEN-4.

Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2024 SMFP.
 - The applicant adequately demonstrates that the proposal is consistent with Policy GEN-4 because the applicant adequately demonstrates that the application includes a written statement describing the project’s plan to assure improved energy efficiency and water conservation.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, ... 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 new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

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 2024 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 proposed facility will be developed in Iredell County. Thus, the service area for the proposed facility is Iredell County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to relocate the three (3) GI endoscopy rooms from the existing Endoscopy center in Statesville and add one (1) new room to develop a new center consisting of four (4) total licensed GI endoscopy rooms at the corner of Valley Street and Davie Avenue in Statesville, Iredell County.

The following table illustrates historical and projected patient origin.:

GI Endoscopy	Piedmont HealthCare Endoscopy Center				
	County	Historical Last Full FY CY 2023		Projected Third Full FY CY 2029	
		Patients	% of Total	Patients	% of Total
Alexander	593	11.60%	1045	11.60%	
Ashe	1	0.02%	2	0.02%	
Brunswick	1	0.02%	2	0.02%	
Burke	4	0.08%	7	0.08%	
Cabarrus	19	0.37%	33	0.37%	
Caldwell	14	0.27%	24	0.27%	
Carteret	1	0.02%	2	0.07%	
Catawba	207	4.05%	365	4.05%	
Cleveland	1	0.02%	2	0.02%	
Columbus	1	0.02%	2	0.02%	
Davidson	2	0.04%	4	0.04%	
Davie	67	1.31%	118	1.31%	
Durham	1	0.02%	2	0.02%	
Edgecombe	1	0.02%	2	0.02%	
Forsyth	8	0.16%	14	0.16%	
Gaston	3	0.06%	5	0.06%	
Guilford	3	0.06%	5	0.06%	
Hertford	1	0.02%	2	0.02%	
Iredell	3757	73.48%	6620	73.48%	
Jackson	1	0.02%	2	0.02%	
Lincoln	22	0.43%	39	0.43%	
Madison	1	0.02%	2	0.02%	
Mecklenburg	80	1.56%	141	1.56%	
Mitchell	1	0.02%	2	0.02%	
Montgomery	2	0.04%	4	0.04%	
Randolph	1	0.02%	2	0.02%	
Robeson	1	0.02%	2	0.02%	
Rowan	156	3.05%	275	3.05%	
Sampson	1	0.02%	2	0.02%	
Stokes	2	0.04%	4	0.04%	
Surry	2	0.04%	4	0.04%	
Transylvania	1	0.02%	2	0.02%	
Union	2	0.04%	4	0.04%	
Watauga	5	0.10%	9	0.10%	
Wilkes	70	1.37%	123	1.37%	
Yadkin	47	0.92%	83	0.92%	
South Carolina	7	0.14%	13	0.14%	
Other States	25	0.49%	44	0.49%	
Total	5112	100.00%	9009	100.00%	

Source: Table on pages 29 and 30 of the application

In Section C, page 30, the applicant provides the assumptions and methodology used to project its patient origin is based on historical utilization by county, summarized as follows:

- The applicant states that the patient origin is not expected to change from historical experience with the relocation of the center within Statesville.
- The applicant states that the proposed facility will be just under three (3) miles from the existing facility.
- The applicant states that the relocation of the GI endoscopy rooms to the new location is not expected to impact the relative number of patients served from Iredell County and surrounding areas.

Analysis of Need

In Section C, pages 32-34, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services summarized as follows:

- The applicant states that the addition of one procedure room, eight pre- and post- procedure bays, and overall larger facility will allow the facility to accommodate increasing demand for procedures. The current facility is located within a multi-specialty medical office building with no room to grow. Thus, a relocation is required for expansion to meet growing demand.
- The applicant states that the need for this project is driven by a combination of critical factors that underscore the necessity for enhanced facilities and services to meet the evolving healthcare needs of our community.
- The applicant states that the current endoscopy facility is insufficiently sized to accommodate the growing demand for endoscopic procedures. With increasing patient volumes and the need for efficient service delivery, the existing space limits the ability to provide timely and comprehensive care. An expanded facility will enable us to better serve our community, reduce waiting times, and improve patient flow.
- The applicant states the current facility is dated and in need of upgrades. Further, it was built prior to NCDHSR's adoption of FGI guidelines. A new FGI compliant facility would enhance patient comfort and safety but also allow for the implementation of the latest endoscopic technologies, which are crucial for providing high-quality care and improving clinical outcomes.
- The applicant states that there is a growing trend among patients preferring to receive endoscopic procedures in ambulatory surgery centers (ASCs) rather than traditional hospital settings. ASCs offer numerous benefits, including shorter wait times, lower costs, and a more patient-centered experience. By expanding our endoscopy center, we can align with this preference, providing a convenient and comfortable environment that meets the needs of our community.
- The applicant states that the population of Statesville is experiencing steady growth, leading to an increased demand for healthcare services, particularly in preventive care like

colonoscopy screenings. Additionally, the United States Preventive Services Task Force (USPSTF) has recently lowered the recommended screening age for colonoscopies from 50 to 45. This change is expected to significantly increase the number of individuals eligible for screening, further amplifying the need for additional endoscopy resources in our region.

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

- The applicant uses historical data of its existing GI endoscopy services in the proposed service area to support the need for the additional GI endoscopy services in the same service area.
- The applicant provides reliable data to support its projections of current facility size and age, ASC preference, and population growth.

Projected Utilization

In Section Q, Form C.3a and C.3b, the applicant provides historical, interim, and projected utilization, as illustrated in the following table:

Historical, Interim, and Projected GI Endo Room Utilization Piedmont HealthCare, P.A.	Last Full FY 2023	Interim Full FY 2024	Interim Full FY 2025	Interim Full FY 2026	First Full FY 2027	Second Full FY 2028	Third Full FY 2029
GI Endoscopy Rooms							
# of Rooms	3	3	3	3	4	4	4
# of Inpatient GI Endoscopy Procedures	0	0	0	0	0	0	0
# of Outpatient GI Endoscopy Procedures	7,300	8,023	8,817	9,690	10,649	11,703	12,862
Total GI Endoscopy Procedures	7,300	8,023	8,817	9,690	10,649	11,703	12,862
Average # of Procedures per Room	2,433	2,674	2,939	3,230	2,662	2,926	3,215

In Section Q, Form C 3b, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

- The applicant analyzed the historical utilization of its 3 existing GI endoscopy rooms in Iredell County for 2021-2023.
- The applicant states that the compound annual growth rate (CAGR) was determined to be 9.9%.

Compound Annual Growth Rate		2021	2022	2023	CAGR
	Procedures	6,042	6,424	7,300	9.9186

- The applicant states that Iredell County, North Carolina's estimated 2024 population is 203,546 with a growth rate of 1.92% in the past year according to the most recent United States census data. Iredell County, North Carolina is the 14th largest county in North Carolina. The 2010 population was 159,788 and has seen a growth of 27.39% since that time.
- The applicant states that there is a growing trend among patients preferring to receive endoscopic procedures in ambulatory surgery centers (ASCs) rather than traditional hospital settings. ASCs offer numerous benefits, including shorter wait times, lower costs, and a more patient-centered experience.
- The applicant states that by expanding the endoscopy center, it would provide access to a convenient and comfortable environment that meets the needs of the community.

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

- Projected utilization is based on Piedmont HealthCare's historical GI endoscopy procedure data for all three existing Iredell County GI endoscopy procedure rooms.
- The applicant projected growth rates used to project utilization of GI endoscopy procedures by the growing population in Iredell County and surrounding areas.
- The applicant demonstrates that the projected utilization exceeds the performance standards of 1,500 procedures per GI endoscopy room.

Access to Medically Underserved Groups

In Section C, pages 38-39, the applicant states that Piedmont HealthCare Endoscopy Center,

"... provide services without regard to race, color, religion, sex, age, or national origin. The center provides the highest quality care, meeting the expectations of our patients and their families, and serves as a resource area for physicians of the community for treatment, diagnosis, and management of patients with gastrointestinal disorders".

The applicant provides the estimated percentage for each medically underserved group, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low income persons	Unable to Obtain Data
Racial and ethnic minorities	16.72%
Women	56.15%
Persons with Disabilities	Unable to Obtain Data
Persons 65 And older	37.06%
Medicare beneficiaries	36.30%
Medicaid recipients	3.85%

Source: Table on page 39 of the application

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 new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

In Section D, page 44, 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 44, the applicant states:

“The relocation of the existing facility to the new facility will include an overall larger center with an additional procedure room, more pre- and post-procedure bays and sufficiently sized facilities for staff to function. Additionally, parking will become more

accessible for patients and the new facility will be built specifically to current FGI guidelines. The needs of the patients at the existing facility will be met through these measures that prioritize accessibility and ease of use.

Relocation of the existing facility is not expected to negatively impact the ability for any patient groups to obtain services, including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, and Medicaid recipients.”

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

- The new facility will be larger and more accessible to patients.
- The current location of the endoscopy center located at 208 Old Mocksville Road in Statesville and the proposed location on Valley Street in Statesville are approximately 3 miles apart according to Google Maps. Thus, the GI endoscopy services will remain accessible to the same population at the new location.

Access to Medically Underserved Groups

In Section D, page 44, the applicant states:

“Relocation of the existing facility is not expected to negatively impact the ability for any patient groups to obtain services, including low-income persons, racial and ethnic minorities, women, persons with disabilities, persons 65 and older, Medicare beneficiaries, and Medicaid recipients.”

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 continue to be accessible to the same population at the new location.

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 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.

C

The applicant proposes to develop a new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

In Section E, page 48, 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- Remaining in the existing facility would continue to limit staff functionality and patient access by limiting the number of procedures that can be scheduled in the future, which may delay care.
- Shifting procedures to the hospital setting- For those patients meeting the existing facility's admission criteria, hosting their procedures in the hospital setting places an unnecessary burden on already overloaded local hospital systems and increases cost to patient.
- Expanding facility hours to accommodate additional procedures- The existing facility already operates at high capacity over reasonable working day hours. Expanding the facility's hours to later in the afternoon would negatively impact the patient experience and comfort due to the need to refrain from eating or drinking prior to procedures.
- Building an additional, one-procedure room facility- Constructing an additional one-procedure room facility is an unwise allocation of resources, time-intensive and more costly than relocating and constructing a larger endoscopy center. Additionally, this option would result in increased staffing requirements and cost.

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 proposal will provide the necessary access to GI Endoscopy services in Iredell County while meeting the needs of a growing population.
- 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
- 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. Therefore, the application is approved subject to the following conditions:

- 1. Piedmont HealthCare, P.A. and Davie Valley, LLC C (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a new endoscopy center, Piedmont HealthCare Endoscopy Center in Statesville, by relocating three GI endoscopy rooms and adding one GI endoscopy room.**
- 3. Upon completion of the project, Piedmont HealthCare Endoscopy Center shall be licensed for no more than four GI endoscopy rooms.**
- 4. The certificate holder shall 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.**
- 5. The certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 6. 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 June 1, 2025.**

7. The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, page 88, the applicant projects the total capital cost of the project, as shown in the table below.

Form F.1a Capital Cost	Piedmont HealthCare, P.A.	Davie Valley, LLC	Total
Purchase Price of Land	0	\$600,000	\$600,000
Closing Costs	0	\$20,000	\$20,000
Site Preparation	0	\$508,767	\$508,767
Construction/Renovation Contract (s)	0	\$2,886,683	\$2,886,683
Architect/Engineering Fees	0	\$191,300	\$191,300
Medical Equipment	\$259,410	0	\$259,410
Non Medical Equipment	\$3,160	0	\$3,160
Furniture	\$25,000	0	\$25,000
Consultant Fees	\$54,900	0	\$54,900
Financing Costs	0	\$132,510	\$132,510
Interest during Construction	0	\$313,205	\$313,205
Total	\$342,470	\$4,652,465	\$4,994,935

In Section F.1, page 49, Section Q, Form F.1a, page 88, and Exhibit F. 1, F.2, F.3, and F.24, 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 because it is based on the estimated cost to develop a GI endoscopy center and the applicant’s historical experience with similar projects.

In Section F, pages 50-51, the applicant projects that start-up costs will be \$10,000 and there will be no initial operating expenses for a total working capital of \$10,000. On page 51, 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 based on the following:

- The applicant states that the moving fees are included in the start-up costs.
- The applicant states that this is an existing facility, all operating costs are included in Interim Operating Costs and no initial operating costs apply,

Availability of Funds

In Section F, pages 49-50 the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing			
Type	Piedmont HealthCare, P.A.	Davie Valley, LLC	Total
Loans	\$342,470	\$3,954,595	\$4,297,065
Accumulated reserves or OE *	\$	\$697,870	\$697,870
Bonds	\$	\$	\$
Other (Specify)	\$	\$	\$
Total Financing	\$342,470	\$4,652,465	\$4,994,935

* OE = Owner’s Equity

Exhibit F.1 contains a letter dated October 7, 2024, from the Vice President of First Citizens Bank, documenting access to a \$2,500,000 line of credit for the purpose of purchasing equipment and a \$1,000,000 operating line of credit for Piedmont HealthCare, PA. Exhibit F.2 contains a letter dated October 11, 2024, from the Vice President/Business Banker of First Citizens Bank, documenting good faith effort to assist with financing a maximum of 85% of the project cost for Davie Valley, LLC. Exhibit F.3 contains a letter dated October 4, 2024, from the Chief Financial Officer of Piedmont HealthCare, P.A., documenting availability of cash to finance the \$10,000 for working capital for moving costs associated with moving to a new, larger facility. Exhibit 8 and 9 contain the audited financial statements of HealthCare that shows that as of December 31, 2023, Piedmont HealthCare had a total revenue of \$3.3 million.

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 Section Q, Form F.2b, page 90, 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.

	1st Full Fiscal Year 2027	2nd Full Fiscal Year 2028	3rd Full Fiscal Year 2029
Total Procedures	10,649	11,703	12,862
Total Gross Revenues (Charges)	\$7,433,481	\$8,169,396	\$8,978,166
Total Net Revenue	\$4,895,103	\$5,379,719	\$5,912,311
Average Net Revenue per Procedure	\$460	\$460	\$460
Total Operating Expenses (Costs)	\$734,265	\$806,958	\$886,847
Average Operating Expense per Procedure	\$69	\$69	\$69
Net Income	\$4,160,838	\$4,572,761	\$5,025,464

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:

- Projected charges and revenues are reasonable and adequately supported.
- Projected operating expenses are reasonable and adequately supported.
- 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 the 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.

The applicant proposes to develop a new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

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 2024 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.*” Piedmont HealthCare Endoscopy Center is currently located in Iredell County and, with this application, is proposing to relocate to another location also within Iredell County. Thus, the service area for the facility is Iredell County. Facilities may also serve residents of counties not included in their service area.

The 2024 SMFP, Table 6D Endoscopy Room Inventory, page 87, shows there are five existing facilities with GI endoscopy rooms in Iredell County, as shown below.

Iredell County Endoscopy Facilities and Rooms

Existing Facilities	# of Endoscopy Rooms	Adjustments for CONs	Endoscopy Cases	Endoscopy Procedures
Davis Regional Medical Center	2	0	388	467
Iredell Memorial Hospital	3	0	2,882	3,457
Lake Norman Regional Medical Center	2	0	1,950	2,133
Langtree Endoscopy Center	1	1	3,064	3,627
Piedmont HealthCare Endoscopy Center	3	0	4,452	6,337

In Section G, page 57, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved services in Iredell County. The applicant states:

“This will not result in unnecessary duplication of the existing or approved health service facilities as the applicant is already completing the proposed service component in the proposed service area. The applicant completes well-over 1,500 procedures per room per year. The proposed facility will simply allow the applicant to support its existing patient population more comfortably.”

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

- The proposal would not result in unnecessary duplication based on the high utilization of existing endoscopy rooms.
- The applicant adequately demonstrates that the proposed 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 (*if applicable*)

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 new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

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 Staff	Projected Staff		
	12/31/23	1 st Full Fiscal Year (FY2027)	2 nd Full Fiscal Year (FY2028)	3 rd Full Fiscal Year (FY2029)
Registered Nurses	5	7	7	7
Endoscopy Technicians	9	10	10	10
Medical Assistants	1	1	1	1
Office Manager	1	1	1	1
TOTAL	16	19	19	19

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, page 58, 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:

- As an established provider in the service area, the applicant will advertise with online job posting services along with word of mouth and personal referrals are used to fill vacant and new positions.
- New staff are subject to an orientation program with checklists in place and utilized for all new hires.
- Competency validations are completed for all clinical staff upon hire.

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 new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

Ancillary and Support Services

In Section I.1, page 61, the applicant identifies the necessary ancillary and support services for the proposed services. On page 61, and in Exhibit I.1, 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 based on the fact that Piedmont HealthCare Endoscopy Center is an existing GI endo ASF facility and currently provides all necessary ancillary and support services for its GI endo services.

Coordination

In Section I, page 61, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit I-26 to 28 for letters of support. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the following:

- Piedmont HealthCare Endoscopy Center is a GI endo ASF facility with existing relationships with other local health care and social service providers and provide any supporting documentation
- The applicant provides letters of support in Exhibit I.26 to I.28.

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.

- (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 new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

In Section K, page 64, the applicant states that the project involves constructing 8,000 square feet of existing space. Line drawings are provided in Exhibit K-1.

On page 65, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on that the proposed project cost is the most reasonable based on constructing new space

On page 64, 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:

- In Exhibit K.1-31, consist of new construction plan, landowner verification, offer to purchase and sale of land and proposed lease agreement between the applicants (Piedmont HealthCare. and Davie Valley, LLC).
- In Exhibit K, the applicant provided letters of support for the proposed development of a new, larger endoscopy center in Statesville.

On page 65-66, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans and provides supporting documentation in Exhibit 32-36.

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 67, the applicant provides the historical payor mix for Piedmont HealthCare Endoscopy Center during the last full fiscal year (01/01/2023 to 12/31/2023) for the proposed services, as shown in the table below.

Piedmont HealthCare Endoscopy Center	
Payor Source	Percentage of Total Patients Served
Self-Pay	0.65%
Charity Care	Included in Self-Pay%
Medicare*	36.30%
Medicaid*	3.85%
Insurance*	58.44%
Workers Compensation	0%
TRICARE	0.76%
Other (describe)	0%
Total	100.0%

Source: Table on page 67 of the application

*Including any managed care plans

In Section L, page 68, the applicant provides the following comparison.

Last Full FY before Submission of the Application 01/01/2023 to 12/31/2023		
Piedmont HealthCare Endoscopy Center	% of Total Patients Served	% of the Population of the Service Area
Female	56.15%	50.5%
Male	43.85%	49.5%
Unknown	0%	0%
64 and Younger	62.94%	82.9%
65 and Older	37.06%	17.1%
American Indian	0.39%	0.6%
Asian	1.27%	2.8%
Black or African American	10.66%	12.8%
Native Hawaiian or Pacific Islander	0.14%	0.1%
White or Caucasian	83.28%	81.4%
Other Race	0.00%	0.0%
Declined/Unavailable	4.26%	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

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 69, the applicant states

“Piedmont HealthCare Endoscopy Center has no obligation to provide a specific uncompensated care amount, community service, or access to care by minorities or persons with disabilities.”

In Section L, page 69, the applicant states that during the 18 months immediately preceding the application deadline, no patient civil rights equal access complaints have been filed against the licensed entity.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on the review, the Agency concludes that the application is conforming to the 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, pages 69- 70, 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.

Payor Source	% of Total Patients Served
Self-Pay	0.65%
Charity Care	Included in Self-Pay %
Medicare*	36.30%
Medicaid*	3.85%
Insurance*	58.44%
Workers Compensation	0%
TRICARE	0.76%
Other	0%
Total	100.0%

Source: Table on page 70 of the application

*Including any managed care plans

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 0.65% of total inpatient GI endo services will be provided to self-pay patients, 36.30% to Medicare patients and 3.85% to Medicaid patients.

On page 70, the applicant provides the assumptions and methodology used to project payor mix during the three full fiscal years of operation following completion of the project. The projected payor mix is reasonable and adequately supported.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on the 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, pages 70-71, 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 the review, the Agency concludes that the application is conforming to this criterion based on the reasons stated above.

- (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 new GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

In Section M, page 72, the applicant states that,

“The applicant does not currently have an agreement with an educational institution for endoscopy center and students cannot participate in patient care, however, per the applicant’s Observation Policy, students can observe procedures with patient consent.”

Based on that review, the Agency concludes that 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 GI endoscopy facility by relocating no more than 3 GI endoscopy rooms from Piedmont Healthcare Endoscopy Center and developing no more than one additional GI endoscopy room for a total of no more than 4 GI endoscopy rooms upon project completion.

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 2024 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.*” Piedmont HealthCare Endoscopy Center is currently located in Iredell County and, with this application, is proposing to relocate to another location also within Iredell County. Thus, the service area for the facility is Iredell County. Facilities may also serve residents of counties not included in their service area.

Iredell County Endoscopy Facilities and Rooms

Existing Facilities	# of Endoscopy Rooms	Adjustments for CONs	Endoscopy Cases	Endoscopy Procedures
Davis Regional Medical Center	2	0	388	467
Iredell Memorial Hospital	3	0	2,882	3,457
Lake Norman Regional Medical Center	2	0	1,950	2,133
Langtree Endoscopy Center	1	1	3,064	3,627
Piedmont HealthCare Endoscopy Center	3	0	4,452	6,337

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 73, the applicant states:

“We do not expect an impact on competition with this proposal as we are currently providing the proposed services in the service area. All growth projections are based on current facility growth, and not from acquisition of competitors’ patients.”

Regarding the impact of the proposal on cost effectiveness, in Section N, page 73, the applicant states:

“The proposal will allow for more efficient patient flow and throughput resulting in greater cost efficiency with the addition of pre and post procedure bays. We anticipate no changes in cost per procedure and the same fee schedule will be used that PHC is currently using. Low cost is a critical factor to help ensure the highest level of patient compliance with recommended colorectal

cancer screening via GI endoscopy procedures. Patients are more likely to comply with screening guidelines and undergo a GI endoscopy procedure if their out-of-pocket cost is low.”

See also Sections B, F, and Q of the application and any exhibits

Regarding the impact of the proposal on quality, in Section N, page 73, the applicant states:

“The quality of services provided at our center will remain high. The current facility is accredited through AAAHC and will maintain this accreditation at the new facility. Please see exhibit N-1 for AAAHC certificate and N-2 for previous AAAHC accreditation notification. Further, the current facility maintains a robust Quality Improvement Program, which will remain in effect at the new facility. See exhibit N-4 for QI Plan.”

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 73, the applicant states:

“...provide medical care to all patients regardless of ability to pay, insurance coverage type, race, ethnicity, or gender including the medically underserved. We participate with most private health insurance plans and government health programs including Medicare and Medicaid. The proposed new facility will have no negative impact on the ability of the medically underserved to obtain services provided by our organization. See exhibit L-5 for Charity Care and Self-Pay Clients Policy.”

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, page 98, the applicant identifies the ASF located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of one other related facility located in North Carolina.

In Section O, page 75, the applicant states that, during the 18 months immediately preceding the submittal of the application, the facility listed on form O have had no incidents related to quality of care occurred in the facility. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, no incidents related to quality of care occurred in the facilities. After reviewing and considering information provided by the applicant and by the Acute an Home Care Licensure and Certification Section and considering the quality of care provided at the 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, promulgated in 10A NCAC 14C .3903. 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- In Section C, page 26, the applicant states the service area for this project is Iredell 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- On Form O, the applicant identifies one GI endoscopy facilities owned or operated by the applicant or a related entity located in Iredell County.
- (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- On Form C.3b in Section Q, Form C.3b, the applicant provides projected utilization for the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms at Piedmont HealthCare Endoscopy Center.
- (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- On Form C.3b in Section Q, Form C.3b, the applicant projects to perform an average of at least an average of at least 3,200 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following project completion.
- (5) provide the assumptions and methodology used to project the utilization required by this Rule.*
 - C- In Section Q, following Form C.3b, the applicant provides the assumptions and methodology used to project utilization required by this Rule. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.