

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: March 26, 2018

Findings Date: March 26, 2018

Team Leader: Gloria C. Hale

Co-Signer: Fatimah Wilson

Project ID #: F-11443-17

Facility: Langtree Endoscopy Center

FID #: 170528

County: Iredell

Applicant: Langtree Endoscopy Center, LLC

Project: Develop a new ambulatory surgical facility by acquiring one existing GI endoscopy procedure room from Lake Norman Regional Medical Center and relocating it within Iredell County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Langtree Endoscopy Center, LLC, (Langtree) proposes to develop a new ambulatory surgical facility (ASF) by acquiring one existing GI endoscopy procedure room from Lake Norman Regional Medical Center (LNRMC) and relocating it to 309 Alcove Road in Mooresville, Iredell County.

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 2017 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There is one policy in the 2017 SMFP which is applicable to this review: *Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities.*

Policy GEN-4 states:

“Any person proposing a capital expenditure greater than \$2 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178 shall include in its certificate of need application a written statement describing the project’s plan to assure improved energy efficiency and water conservation.

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, the Certificate of Need Section 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 are required to submit a plan of energy efficiency and water conservation that conforms to the rules, codes and standards implemented by the Construction Section of the Division of Health Service Regulation. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4. The plan shall not adversely affect patient or resident health, safety or infection control.”

The proposed capital expenditure for this project is greater than \$2 million and less than \$5 million. In Section III.4, page 47, and Section XI.8, pages 99-100, the applicant provides a written statement describing its plan to ensure energy efficiency and water conservation, stating that its HVAC, electrical, and lighting systems will meet State codes and industry standards. In addition, the applicant will use water fixtures designed to conserve water.

Conclusion

The Agency reviewed the:

- Application

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

Based on that review, the Agency concludes that the application is conforming to this criterion because the applicant adequately demonstrates that the proposal is consistent with *Policy GEN-4* because it provides a statement describing how it will meet State codes and industry standards to address energy efficiency and water conservation.

This determination is based on a review of the:

- Information in the application, including any exhibits.
- Information which was publicly available during the review and used by the Agency.

(2) Repealed effective July 1, 1987.

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

C

Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to 309 Alcove Road in Mooresville, Iredell County.

Patient Origin

The 2017 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) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. In Section III.1, page 32, the applicant defines the primary service area as Iredell County. Facilities may also serve residents of counties not included in their service area.

In Section III.6, page 49, the applicant provides a table illustrating the projected patient origin for GI endoscopy services at Langtree, for the first two operating years, fiscal year (FY) 2020 and FY2021, as follows:

**Langtree
Projected Patient Origin
FY2020 – FY2021**

County	Percent of Total
Iredell	55.6%
Mecklenburg	21.1%
Catawba	6.7%
Rowan	4.5%
Lincoln	4.3%
Cabarrus	2.7%
Gaston	1.9%
Other*	3.2%
Total	100.0%

*Other includes <1% from other counties and other states. See page 49 for complete list of other counties.

In Section III.6, page 49, the applicant provides the assumptions and methodology used to project patient origin. The applicant states it is based on historical patient origin at LNRMC since a portion of outpatients who receive GI endoscopy services at LNRMC will be shifted to Langtree. Therefore, the projected patient origin is expected to be consistent with historical patient origin. Both LNRMC and Langtree are located in Mooresville, approximately two miles apart. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section III, pages 20-38, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 28-36, the applicant states:

- Higher incidence of cases of colon/rectum cancer in Iredell County than statewide for all ages, 40.7 per 100,000 persons compared to 36.6 per 100,000 persons, respectively, and for those aged 65 and older than statewide, 177.8 per 100,000 persons compared to 159.3 per 100,000 persons, respectively [page 33]
- Higher incidence of colon cancer deaths in Iredell County than statewide, 40.7 deaths per 100,000 persons compared to 36.6 deaths per 100,000, respectively, from 2011-2015 [page 28]
- Increased pressure from employers and payors for patients to use lower cost, freestanding outpatient health care facilities than hospitals [pages 30-32]
- Higher growth in overall population and in persons aged 50 and above in Iredell County compared to statewide [pages 32-33]
- Increasing number of Iredell County residents traveling to Mecklenburg County for GI endoscopy services, likely due to greater access to freestanding GI endoscopy procedure rooms [page 35]

- Higher utilization of freestanding GI endoscopy procedure rooms than hospital-based GI endoscopy procedure rooms in Iredell County [page 36]

The information in the pages referenced above is reasonable and adequately supported for the following reasons:

- Colon/rectum cancer incidence and deaths are increasing in Iredell County at a higher rate than statewide,
- The overall population and the 50+ population of Iredell County is increasing at a higher rate than statewide, and
- Access to lower-cost GI endoscopy services provided at freestanding GI endoscopy medical facilities is limited in Iredell County.

Projected Utilization

In Section III.1, pages 38-42, the applicant provides its methodology for projecting utilization of GI endoscopy services at Langtree, summarized as follows:

Step 1. Two physicians who currently serve patients in the GI endoscopy procedure rooms at LNRMC, Dr. T. Ryan Heider and Dr. John Clements, will utilize the GI endoscopy procedure room to be relocated to Langtree. Letters of support, including their intent to perform GI endoscopy procedures at Langtree are included in Exhibit 17. The applicant states, on page 38, that Drs. Heider and Clements perform over 60% of the GI endoscopy procedures performed at LNRMC.

The applicant provides the number of historical outpatient GI endoscopy procedures performed by Drs. Heider and Clements at LNRMC in a table on page 38, summarized as follows:

**Historical GI Endoscopy Procedures
 FYs 2014 – 2017**

Physician	FY2014	FY2015	FY2016	FY2017	CAGR*
Clements	1,086	1,494	1,658	2,220	26.9%
Heider	177	259	323	366	27.4%
Total	1,263	1,753	1,981	2,586	27.0%

*Compound Annual Growth Rate

Step 2. The applicant utilizes the projected growth rate for Iredell County’s population ages 50 and older of 2.9% to project the number of GI endoscopy procedures forward through FY2021 for Drs. Clements and Heider, as follows:

**Projected GI Endoscopy Procedures
FYs 2018 through FY2022**

Physician	FY2018	FY2019	FY2020	FY2021	FY2022
Clements	2,285	2,352	2,421	2,491	2,564
Heider	377	388	399	411	423
Total	2,662	2,739	2,820	2,902	2,987

The applicant’s application of a 2.9% growth rate is reasonable given the following factors:

- The 2.9% growth rate is much lower than the historical CAGRs for either Dr. Clements or Dr. Heider’s GI endoscopy procedures, FY2014-FY2017, of 26.9% and 27.4%, respectively [see page 38].
- The 2.9% growth rate is lower than the historical CAGR for total Iredell County GI endoscopy patients served in licensed facilities, 2012-2016, of 3.8% [see page 34].
- The 2.9% growth rate is lower than the historical CAGR for total GI endoscopy procedures performed in Iredell County, FY2013 – FY2016, of 4.9% [see page 36].
- Historical out-migration of Iredell County GI endoscopy patients to Mecklenburg County of 8.5%, from 2012-2016, is expected to decrease once the proposed, freestanding GI endoscopy facility is operational, resulting in additional growth in utilization at the proposed facility.

Step 3. The applicant states that Drs. Clements and Heider expect a gradual shift in the number of patients who will have GI endoscopy procedures performed at Langtree for the first three operating years of the project, as follows:

**Shift in GI Endoscopy Procedures from LNRMC to
Langtree**

	FY2020	FY2021	FY2022
Percent Shift	50%	60%	70%

The applicant states, on page 40, that the expected shift is reasonable given the lower cost structure of a freestanding GI endoscopy facility.

Step 4. The applicant applies the projected, annual percentages of shift in Step 3 to the projected utilization in Step 2 to determine the number of GI endoscopy procedures Langtree is projected to perform in the first three operating years of the project, FY2020-FY2022, as follows:

**Langtree GI Endoscopy Procedures
with Shift**

	FY 2020	FY 2021	FY 2022
Number of GI Endoscopy Procedures	1,410	1,741	2,091

In addition, the applicant provides the projected number of GI endoscopy cases it expects to have at Langtree by applying the historical ratio of GI endoscopy cases to GI endoscopy procedures, from FY2015-FY2016, of 1.27, which results in the following:

**Langtree
Projected GI Endoscopy Procedures and Cases
FY2020 through FY2022**

	FY 2020	FY 2021	FY 2022
Number of GI Endoscopy Procedures	1,410	1,741	2,091
Number of GI Endoscopy Cases	1,114	1,376	1,652

The applicant adequately demonstrates that Langtree will perform 1,741 GI endoscopy procedures in one GI endoscopy procedure room during the second operating year following project completion, FY 2021.

Projected utilization is reasonable and adequately supported because the applicant's assumptions and methodology used to project utilization are reasonable and adequately supported.

Access

In Section VI.2, page 63, the applicant states,

“Patients will have a right to healthcare at LEC [Langtree] without regard to age, gender, sexual orientation, gender identity or expression, race, ethnicity, cultural, language, physical or mental disability, or religious background.”

In addition, on page 63, the applicant states that the GI endoscopy services provided at Langtree will be available to any person with a need for GI endoscopy services, including those whose care is paid for by Medicare, Medicaid, or other governmental payor programs.

In Section VI.14, page 72, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

Langtree FY 2021	
Payor Category	Percent
Self-Pay/Indigent/Charity	1%
Medicare	45%
Medicaid	3%
Commercial	19%
Blue Cross Blue Shield	30%
Other	2%
Total	100%

The applicant states, in Section VI.13, page 71, that there is no historical payor mix for Langtree since it will be a new, freestanding ASF. On pages 71 and 72, the applicant states that it bases its projected payor mix on the historical utilization of GI endoscopy services at LNRMC since the physicians projected to utilize Langtree perform over 60% of the GI endoscopy procedures at LNRMC and, moreover, based on the physicians' referral patterns, it does not expect any significant changes in payor mix.

The projected payor mix is reasonable and adequately supported.

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 identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low

income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

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Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to 309 Alcove Road in Mooresville, Iredell County. The new, proposed ASF is approximately two miles from LNRMC.

In Sections III and VI, pages 45 – 72, 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.

The applicant states:

- the relocation of one GI endoscopy procedure room to a freestanding GI endoscopy facility, Langtree, will result in a gradual shift of patients from LNRMC’s GI endoscopy services to Langtree due to the lower cost structure compared to that of hospital-based GI endoscopy services in Iredell County. [page 54]
- all patients, including low income and medically underserved groups, will have access to services at Langtree. [page 63]
- the payor mix for Langtree’s GI endoscopy services will be consistent with the payor mix for GI endoscopy services at LNRMC. [pages 71-72]
- LNRMC will have two GI endoscopy procedure rooms at the completion of the proposed project, and will, therefore, continue to provide access to GI endoscopy services. [page 55]

In Section III.3, pages 45-46, the applicant provides projected utilization as illustrated in the following table.

**LNRMC
Projected GI Endoscopy Procedures**

	FY2020	FY2021	FY2022
Number of GI endoscopy procedure rooms	2	2	2
Total	2,814	2,606	2,384

In Section III.3, pages 45-46, the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

The applicant projects GI endoscopy procedure volume at LNRMC, FY2017 through FY2022, by applying the same growth rate that it uses to project GI endoscopy procedure volume for Langtree of 2.9%. Next, the applicant subtracts its projected GI endoscopy

procedure volume at Langtree, resulting in the following projected volume for LNRMC's GI endoscopy procedure rooms for the first three operating years of the proposed project.

The applicant states, on page 46, that based on the target utilization of 1,500 GI endoscopy procedures per GI endoscopy procedure room (2 x 1,500 = 3,000), LNRMC's two remaining GI endoscopy procedure rooms will be able to accommodate LNRMC's projected GI endoscopy procedures.

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

- There will be a gradual shift of GI endoscopy patients from LNRMC to Langtree due to the lower cost structure of the proposed, freestanding facility, but overall GI endoscopy services will not be reduced.
- LNRMC will continue to serve GI endoscopy patients in its two GI endoscopy procedure rooms upon completion of the project.

In Section VI, page 63, the applicant states that patients will have access to Langtree's GI endoscopy services without regard to age, gender, sexual orientation, gender identity or expression, race, ethnicity, Medicaid or Medicare recipients, and other underserved groups.

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 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.
- The project will not adversely impact the ability of underserved groups to access these services following project completion.

Therefore, the application is conforming to this criterion.

- (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.

Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to 309 Alcove Road in Mooresville, Iredell County.

In Section III.8, pages 50-53, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – the applicant states that this option would not allow for a lower cost option for GI endoscopy services which would, in turn, lower the financial burden for these services for residents of Iredell County and the surrounding area. In addition, it would not address the outmigration of residents to Mecklenburg County for GI endoscopy services, a county that has nearly twice as many freestanding GI endoscopy procedure rooms per person age 50+ compared to Iredell County. Therefore, this is not the most effective alternative.
- Utilize Existing, Hospital-based GI endoscopy procedure rooms - the applicant states that this alternative would be a higher cost option for GI endoscopy patients. Freestanding facilities provide lower costs where patients typically pay less out-of-pocket coinsurance for services. Therefore, this is not the least costly or most effective alternative to meet the need.
- Develop the ASF in another Geographic Area – the applicant states that the only other freestanding GI endoscopy services facility is located in Statesville and that by choosing to locate the proposed facility in Mooresville near LNRMC, it will improve geographic access to freestanding GI endoscopy services which are a lower cost option. Therefore, this is not the most effective alternative.
- Pursue a Joint Venture – the applicant states that this is a viable option, however there is currently only one member of Langtree, CHS-ASC, LLC. The applicant states that some of the prospective user physicians may seek equity ownership in Langtree upon completion of the project. However, at this time pursuing a joint venture is not the most effective alternative.

On page 53, the applicant states that its proposal is the most effective alternative because relocating an existing licensed GI endoscopy procedure room from LNRMC to Langtree is *“an effective alternative to utilize existing licensed resources in a setting that is cost-effective for local patients.”*

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

- it is expected to address outmigration
- it offers a lower-cost alternative

Conclusion

The Agency reviewed the:

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

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

- 1. Langtree Endoscopy Center, LLC shall materially comply with all representations made in the certificate of need application.**
- 2. Langtree Endoscopy Center, LLC shall develop a new ambulatory surgical facility by acquiring one existing gastrointestinal endoscopy procedure room from Lake Norman Regional Medical Center and relocating it within Iredell County.**
- 3. Upon completion of the project, Langtree Endoscopy Center shall be licensed for no more than one gastrointestinal endoscopy procedure room.**
- 4. Langtree Endoscopy Center, LLC shall take the necessary steps to delicense one gastrointestinal endoscopy procedure room at Lake Norman Regional Medical Center, for a total of no more than two gastrointestinal endoscopy procedure rooms upon project completion.**
- 5. Langtree Endoscopy Center, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**
- 6. Langtree Endoscopy Center, LLC shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
- 7. For the first three years of operation following completion of the project, Langtree Endoscopy Center, LLC shall not increase charges more than 5% of the charges projected in Section XIII 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.**

8. **The procedure room shall not be used for procedures that should be performed only in an operating room based on current standards of practice.**
 9. **Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in a gastrointestinal endoscopy room and shall not be reported on the facility's license renewal application as procedures performed in a gastrointestinal endoscopy room.**
 10. **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, & 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.**
 11. **Langtree Endoscopy Center, LLC 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

Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to 309 Alcove Road in Mooresville, Iredell County.

Capital and Working Capital Costs

In Section VIII.1, page 81, the applicant states that CH Properties, LLC will construct the medical office building within which the GI endoscopy center will be located. Langtree will lease the space. Therefore, Langtree's capital costs consist of only those costs to be incurred for the upfit of the space and costs associated with developing the GI endoscopy center. In Section VIII.1, page 82, the applicant projects the total capital cost for the project as shown in the table below.

Langtree Capital Costs

Subtotal Construction Contract*	\$2,240,724
Fixed Equipment**	\$ 550,254
Moveable Equipment**	\$ 117,878
Architect and Engineering Fees	\$ 134,443
Reimbursables	\$ 50,000
Interest during Construction	\$ 30,000
Other (freight)	\$ 56,000
Contingency	\$ 3,000
Total Capital Cost	\$3,182,299

*Includes tenant improvement costs for upfit of space.

**Includes sales taxes.

In Section VIII, page 83 and Exhibit 16, the applicant provides the assumptions used to project the capital cost.

In Section IX.1, page 88, the applicant projects that start-up costs will be \$200,000 and initial operating expenses will be \$850,000 for a total working capital of \$1,050,000. On page 88, the applicant provides the assumptions and methodology used to project the working capital needs of the project.

Availability of Funds

In Section VIII.3, page 84, the applicant states that the capital cost will be funded as shown in the table below.

Sources of Capital Cost Financing

Type	Langtree	Total
Conventional Loans	\$ 1,950,000	\$ 1,950,000
Accumulated reserves or OE *		
Bonds		
Other (investment by CHS-ASC)	\$ 1,500,000	\$ 1,500,000
Total Financing	\$ 3,450,000	\$ 3,450,000

* OE = Owner's Equity

In Section IX.2, page 88, 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
(a)	Commercial Loan	\$ 1,050,000
(b)	Cash or Cash Equivalents, Accumulated Reserves Owner's Equity	
(c)	Lines of credit	
(d)	Bonds	
(e)	Total *	\$ 1,050,000

Financial Feasibility

In Section XIII, the applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form B/C of the pro forma financial statements, the applicant projects that operating expenses will exceed revenues in the first full fiscal year and that revenues will exceed operating expenses in the second and third full fiscal years, as shown in the table below:

Langtree			
GI Endoscopy Services	Project Year 1 FY2020	Project Year 2 FY2021	Project Year 3 FY2022
Total Procedures	1,410	1,741	2,091
Total Gross Revenues (Charges)	\$ 4,511,407	\$ 5,794,925	\$ 7,236,843
Total Net Revenue	\$ 1,793,284	\$ 2,303,483	\$ 2,876,645
Average Net Revenue per Procedure	\$ 3,200	\$ 3,329	\$ 3,461
Total Operating Expenses (Costs)	\$ 1,888,314	\$ 2,003,232	\$ 2,090,763
Average Operating Expense per Procedure	\$ 1,339	\$ 1,151	\$ 1,000
Net Income	\$ (95,030)	\$ 300,251	\$ 785,882

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

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

C

Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from Lake Norman Regional Medical Center and relocating it to 309 Alcove Road in Mooresville, Iredell County.

The 2017 SMFP does not define the service area for GI endoscopy procedure rooms, however the applicant defines its service area as Iredell County. Facilities may also serve residents of counties not included in their service area.

There are four locations where patients can access GI endoscopy services in Iredell County, which is the applicant's primary service area, as stated in Section III.5, page 47. In Section III.1, page 35, the applicant provides a table listing all of the GI endoscopy services locations in the service area, the number of licensed GI endoscopy procedure rooms, and the number of GI endoscopy procedures performed at each location during FY2016. Additional information is provided by the Team Leader.

**Iredell County GI Endoscopy Facilities
 FY2016**

HOSPITAL BASED	# OF GI ROOMS	TOTAL # OF GI PROCEDURES PERFORMED	# OF GI PROCEDURES PER GI ROOM*
Davis Regional Medical Center	2	321	161
Iredell Memorial Hospital	3	2,943	981
Lake Norman Regional Medical Center	3	3,764	1,255
Subtotal	8	7,028	
# of Procedures/ 1,500		4.69	
# of Procedures/ # of Rooms		879	
% of Regulatory Performance Std.		58.6%	
FREESTANDING, NON-HOSPITAL BASED			
Piedmont HealthCare Endoscopy Center	3	5,849	1,950
Subtotal	3	5,849	
# of Procedures / 1,500		3.90	
# of Procedures / # of Rooms		1,950	
% of Regulatory Performance Std.		1.3%	
TOTALS			
# of GI endoscopy procedure rooms/ Procedures	11	12,877	
# of Procedures / 1,500		85.8	
# of Procedures / # of Rooms		1,171	
% of Regulatory Performance Std.		78.1%	

*Rounded to the nearest whole number.

As illustrated in the table above, only one of the 11 GI endoscopy facilities in Iredell County, a freestanding GI endoscopy facility, has exceeded 1,500 procedures per GI endoscopy procedure room in FY2016. All of Iredell County’s endoscopy procedure rooms combined are operating at 78.1% of the performance standard of 1,500 procedures per GI endoscopy procedure room.

In Section III, pages 42-43, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Iredell County. The applicant states,

“There is currently just one licensed freestanding GI endoscopy center in Iredell County...located in Statesville. No freestanding GI endoscopy services are located in Mooresville.

...there are nearly three times as many hospital-based GI endoscopy rooms compared to freestanding GI endoscopy rooms in Iredell County.”

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

- The proposal would not result in an increase in the number of GI endoscopy procedure rooms.
- The applicant adequately demonstrates that the proposed GI endoscopy procedure room is needed in addition to the existing or approved GI endoscopy procedure rooms.

Conclusion

The Agency reviewed the:

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

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

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

C

In Section VII.1, page 74, the applicant provides projected staffing for the proposed services as illustrated in the following table.

**Langtree Projected Staffing
CY2021**

Position	Staff FTEs
Administrator	1.0
Clinical Director	1.0
Registered Nurse (RN)	4.0
Endoscopy Technician	2.0
Receptionist/Scheduler	1.5
Business Office Supervisor	1.0
Total	10.5

The assumptions and methodology used to project staffing are provided in Section VII, pages 76-77. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form B/C of the pro forma financial statements, which is found in Section XIII. In Section VII, page 75, the applicant describes the methods to be

used to recruit or fill new positions and its proposed training and continuing education programs. In Section VII.9, page 79, the applicant states that Dr. T. Ryan Heider will serve as Medical Director of GI endoscopy services at Langtree. Exhibit 4 contains a letter from Dr. Heider in which he agrees to serve as Medical Director.

In Section VII.7, page 78, the applicant describes its physician recruitment plans. In Exhibit 7, the applicant provides supporting documentation.

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

Conclusion

The Agency reviewed the:

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

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

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

C

In Section II.1 and Section II.2, pages 8-10, the applicant discusses all of the necessary ancillary and support services that will be available at Langtree and provides supporting documentation in Exhibit 10.

In Sections V.2 - V.6, pages 57-60, the applicant discusses its efforts to develop relationships with the existing health care system and provides supporting documentation in Exhibits 12 and 17.

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

Conclusion

The Agency reviewed the:

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

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

- (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

Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to 309 Alcove Road in Mooresville, Iredell County. The applicant states, in Section III.3, page 46, that Langtree will be located in a medical office building. In Section XI.1, page 93, the applicant states that the medical office building will be new construction and that Langtree will lease a portion of the building. In Section XI.5, page 97, the applicant states that 9,035 square feet will be utilized by Langtree for the proposed services. Exhibit 14 contains a line drawing of the proposed ASF.

In Section VIII, pages 81, 83, and 87, and Section XI, pages 99-100, the applicant adequately explains how the cost, design, and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit 14.

In Section X, page 90, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services.

In Section III.4, page 47, and Section XI.8, pages 99-100, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

In Section XI, pages 93-97, and Exhibit 14, the applicant identifies the proposed site and provides information about the current owner and zoning for the site.

Conclusion

The Agency reviewed the:

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

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and,

ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

In Section VI.13, page 71, the applicant provides the historical payor mix for LNRMC's GI endoscopy services, FY2016, since one GI endoscopy procedure room is proposed to be relocated from LNRMC, as shown in the table below.

LNRMC Historical Payor Mix FY 2016	
Payor Category	Percent
Self-Pay/Indigent/Charity	1%
Medicare	45%
Medicaid	3%
Commercial	19%
Blue Cross Blue Shield	30%
Other	2%
Total	100%

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 handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

NA

The applicant does not own or operate any existing GI endoscopy procedure rooms. Therefore, Criterion 13(b) is not applicable to this review.

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

C

In Section VI.14, page 72, the applicant projects the following payor mix for the proposed services during the second full fiscal year of operation following completion of the project, as shown in the table below:

Langtree Projected Payor Mix FY 2021	
Payor Category	Percent
Self-Pay/Indigent/Charity	1%
Medicare	45%
Medicaid	3%
Commercial	19%
Blue Cross Blue Shield	30%
Other	2%
Total	100%

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 1% of total services will be provided to self-pay, indigent, charity care patients, 45% to Medicare patients and 3% to Medicaid patients.

On page 72, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because it is based on the current outpatient payor mix for GI endoscopy services at LNRMC.

The Agency reviewed the:

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

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

- (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 VI.9, page 69, 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
- Information which was publicly available during the review and used by the Agency.

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

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

C

In Section V.1, page 57, 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 9.

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 demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

- (15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

- (18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will

have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

Langtree proposes to develop a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to 309 Alcove Road in Mooresville, Iredell County.

The 2017 SMFP does not define the service area for GI endoscopy procedure rooms, however the applicant defines its service area as Iredell County. Facilities may also serve residents of counties not included in their service area.

There are four locations where patients can access GI endoscopy services in Iredell County, which is the applicant's primary service area, as stated in Section III.5, page 47. In Section III.1, page 35, the applicant provides a table listing all of the GI endoscopy services locations in the service area, the number of licensed GI endoscopy procedure rooms, and the number of GI endoscopy procedures performed at each location during FY2016. The table includes additional information provided by the Team Leader.

**Iredell County GI Endoscopy Facilities
 FY2016**

HOSPITAL BASED	# OF GI ROOMS	TOTAL # OF GI PROCEDURES PERFORMED	# OF GI PROCEDURES PER GI ROOM*
Davis Regional Medical Center	2	321	161
Iredell Memorial Hospital	3	2,943	981
Lake Norman Regional Medical Center	3	3,764	1,255
Subtotal	8	7,028	
# of Procedures/ 1,500		4.69	
# of Procedures/ # of Rooms		879	
% of Regulatory Performance Std.		58.6%	
FREESTANDING, NON-HOSPITAL BASED			
Piedmont HealthCare Endoscopy Center	3	5,849	1,950
Subtotal	3	5,849	
# of Procedures / 1,500		3.90	
# of Procedures / # of Rooms		1,950	
% of Regulatory Performance Std.		1.3%	
TOTALS			
# of GI endoscopy procedure rooms/ Procedures	11	12,877	
# of Procedures / 1,500		85.8	
# of Procedures / # of Rooms		1,171	
% of Regulatory Performance Std.		78.1%	

*Rounded to the nearest whole number.

As illustrated in the table above, only one of the 11 GI endoscopy facilities in Iredell County, a freestanding GI endoscopy facility, has exceeded 1,500 procedures per GI endoscopy procedure room in FY2016. All of Iredell County's endoscopy rooms combined are operating at 78.1% of the performance standard of 1,500 procedures per GI endoscopy procedure room.

In Section V.7, pages 60-62, the applicant discusses how the proposed project will enhance competition in the service area by having a positive impact on the cost-effectiveness, quality and access to the proposed services. On page 60, the applicant states,

“The proposed project is in response to the growing demand in the local service area for GI endoscopy services, and for a desire to offer patients the comfort and convenience of receiving outpatient endoscopy services in the most cost-effective manner.”

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

- The cost-effectiveness of the proposal (see Sections VIII and XIII of the application and any exhibits)
- Quality services will be provided (see Section II of the application and any exhibits)
- Access will be provided to underserved groups (see Section VI of the application and any exhibits)

Conclusion

The Agency reviewed the:

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

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

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

NA

In supplemental information, the applicant states that neither it nor any related entities own or manage any other licensed health care facilities in North Carolina.

Therefore, Criterion (20) is not applicable to this review.

- (21) Repealed effective July 1, 1987.
- (b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

The proposal is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900. The specific criteria are discussed below.

.3903 PERFORMANCE STANDARDS

- (a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*
- NA- The applicant does not propose to develop operating rooms. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*
- C- In Section IV.1, page 56, the applicant states it will perform 1,741 GI endoscopy procedures in FY2021, the second operating year of the proposed project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.
- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section II, page 17, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at Langtree, consistent with outpatient GI endoscopy procedures currently performed by Drs. Clements and Heider in LNRMC's GI endoscopy procedure rooms.
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*
 - (1) *if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average*

number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or

(2) *demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*

-NA- Neither the applicant nor any related entities own any operating rooms in Iredell County. Therefore, this Rule is not applicable to this review.

(e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*

-C- In Section III.1, pages 38-42, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.