

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: September 25, 2019

Findings Date: September 25, 2019

Project Analyst: Gregory F. Yakaboski

Team Leader: Gloria C. Hale

Project ID #: F-11724-19

Facility: Langtree Endoscopy Center

FID #: 170528

County: Iredell

Applicant: Langtree Endoscopy Center, LLC

Project: Change of scope for Project ID #F-11443-17 (Develop an ASF with 1 GI-Endo room) for a total of 2 GI-Endo rooms

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

C

The applicant, Langtree Endoscopy Center, LLC, (Langtree) proposes a change of scope (COS) for the approved, but undeveloped, Langtree Endoscopy Center (LEC) project [Project I.D.#F-11443-17], which authorized the development of 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.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2019 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations applicable to this review.

Policies

In the original LEC project, Project I.D. # F-11443-17, the application was conforming to the following policy:

- **Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities**

Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, on page 31 of the 2019 SMFP, states:

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

In approving a certificate of need proposing an expenditure greater than \$5 million to develop, replace, renovate or add to a health service facility pursuant to G.S. 131E-178, Certificate of Need shall impose a condition requiring the applicant to develop and implement an Energy Efficiency and Sustainability Plan for the project that conforms to or exceeds energy efficiency and water conservation standards incorporated in the latest editions of the North Carolina State Building Codes. The plan must be consistent with the applicant’s representation in the written statement as described in paragraph one of Policy GEN-4.

Any person awarded a certificate of need for a project or an exemption from review pursuant to G.S. 131E-184 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 of the current project to develop one additional GI endoscopy room at the approved LEC is less than \$2.0 million dollars. Therefore, Policy GEN-4 is not applicable.

There are no additional policies applicable to this review.

Conclusion

The Agency reviewed the:

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

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

- The applicant does not propose to develop any beds, services or acquire any equipment for which there is a need determination in the 2019 SMFP.
 - The applicant adequately demonstrates that there are no policies in the 2019 SMFP which are applicable to this review.
- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

Patient Origin

The 2019 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 Project I.D. #F-11443-17, the applicant defined the primary service as Iredell County. In Section C, page 27, the applicant states that the “*service area for LEC has not changed from the previously approved project.*” Facilities may also serve residents of counties not included in their service area.

The following table illustrates projected patient origin.

**Langtree Endoscopy Center: Projected Patient Origin
FY2021 – FY2023**

County	Percent of Total
Iredell	63.4%
Mecklenburg	14.1%
Lincoln	7.2%
Catawba	6.1%
Rowan	2.4%
Cabarrus	1.6%
Gaston	0.4%
Other*	4.7%
Total	100.0%

*Other includes <1% each from other counties and other states. See page 16 for complete list of other counties.
Source: Table in Section C, page 16.

In Section C, pages 16-17, the applicant provides the assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 17-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 17, the applicant states:

- The population of Iredell County, the service area, is steadily increasing.
- During the next five years the service area residents age 50 and older are projected to increase an average 2.2 percent annually.
- Cancer incidence will increase as the average age of the population increases.
- The number of Iredell County residents seeking GI endoscopy services in adjacent Mecklenburg County is increasing.
- Compared to the statewide GI endoscopy patient use rate the GI endoscopy use rate in Iredell County is higher.
- Patients are being continually encouraged by third-party payors to choose lower-cost options for outpatient care.

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

- Address limited capacity to accommodate additional physicians or growth at the facility caused by only one GI endoscopy room.

- Improve access to lower-cost GI endoscopy services at a freestanding, non-hospital-based facility.
- Enable additional physicians to shift appropriate GI endoscopy procedures to a more cost-effective and efficient non-hospital licensed facility from a hospital-based setting.
- The number of Iredell County GI endoscopy patients increased by a compound annual growth rate (CAGR) of 5.0% from 2012 to 2017.
- The number of Iredell County GI endoscopy patients served by facilities in Mecklenburg County increased by a CAGR of 6.1% from 2012 to 2017 “*likely because Mecklenburg county has greater access to freestanding GI endoscopy rooms compared to Iredell County.*” Mecklenburg has over 60 percent more freestanding GI endoscopy rooms per population age 50+ compared to Iredell County.
- Third-party payers continue to direct patients to more cost-effective settings thus Iredell County residents will seek a more cost-effective option for GI endoscopy services.

Projected Utilization

In supplemental information, the applicant provides interim and projected utilization as illustrated in the following table.

	Interim Year FY2020	OY1 FY2021	OY2 FY2022	OY3 FY2023
# of GI Rooms	2	2	2	2
# of GI Procedures	873	2,604	3,146	3,164
Average # of GI Procedures Per GI Room	436.5	1,302	1,573	1,582

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

Step 1: Service Area Population

The service area for the current COS project is the same as the original approved project, Iredell County. Based on the North Carolina Office of State Budget and Management (NCOSBM) the applicant provides the projected overall population for Iredell County for 2019-2023 which shows a CAGR of 1.7%.

Step 2: GI Endoscopy Patient Use Rate

The applicant calculates the GI endoscopy patient use rate per 1,000 patients as illustrated in the table below:

	2017 Population	FY2017 GI Endo Patients	FY2017 GI Endo Patient Use Rate per 1,000
Statewide	10,272,692	544,044*	52.96
Iredell County	176,563	10,231	57.95

*North Carolina GI endoscopy patients only. Excludes patients from SC, TN and VA that were served in NC and identified in patient origin report.
 Source: NCOSBM, FY2017 GI endoscopy patient origin report.

Step 3: Projected GI Endoscopy Patients

Projected overall GI endoscopy patients for Iredell County for the years 2019-2023.

		2019	2020	2021	2022	2023
A	Iredell County Total Population (From Step 1)	182,915	186,093	189,268	192,445	195,623
B	Population / 1000	182.9	186.0	189.2	192.4	195.6
C	Row B x 57.95 (from Step 2)	10,599	10,783	10,967	11,151	11,335

The Iredell County GI endoscopy patient use rate of 57.95 per 1,000 was held constant.

Step 4: Projected GI Endoscopy Procedures Per Patient

1) Calculate a ratio of the number of GI endoscopy cases by population.

	FY2017
GI Endo Procedures Performed in Iredell County	15,266
GI Endo Patients (Cases) Served in Iredell County	11,401
Ratio Procedures per Patient (Case)	1.34

Source: 2019 SMFP, Table 6F: Endoscopy Room Inventory; FY2017 GI Endoscopy patient origin report.

2) Apply the ratio to the projected number of GI endoscopy patients.

		2019	2020	2021	2022	2023
A	Iredell Co. GI Endo Patients (from Step 3, Row C)	10,599	10,783	10,967	11,151	11,335
B	X 1.34					
C	Iredell County GI Endo Procedures*	14,192	14,439	14,685	14,932	15,178

Total may not foot due to rounding.

*Formula Row A x Row B (1.34) = Row C

Step 5: GI Endoscopy Procedures to Shift from LNRMC to LEC for Iredell County and Mecklenburg County patients.

In the original approved application, Project ID #F-11443-17, the applicant projected utilization for FY2020 – FY2022 as shown in the table below:

	FY2020	FY2021	FY2022
# of GI Endoscopy Procedures	1,410	1,741	2,091

Then, since the original approved project is currently projected to be operational on April 1, 2020, the applicant updated its original projected utilization and extended utilization by one additional year, as follows:

	Interim Year 4/2020-9/2020	FY2021	FY2022	FY2023*
# of GI Endoscopy Procedures	705	1,741	2,091	2,091

*Note: The applicant did not project any growth between OY2 and OY3.

To be conservative, the applicants held projected utilization constant from FY2022 to FY2023.

Next, the applicant then projected the number of Iredell County GI Endoscopy Procedures that will shift from LNRMC to LEC by applying the LNRMC FY2018 GI endoscopy patient origin for Iredell County patients (63.4%) to the previously approved utilization projections [Project ID F-11443-17] as illustrated below:

	Interim Year 4/2020-9/2020	FY2021	FY2022	FY2023*
Total # of GI Endoscopy Procedures Projected to Shift from LNRMC to LEC	705	1,741	2,091	2,091
Iredell County GI Endoscopy Procedures Projected to Shift from LNRMC to LEC*	447	1,104	1,321	1,327

*Equal to the total # of GI Endoscopy Procedures x 63.4% Iredell County Patient Origin.

Note: Totals may not foot due to rounding.

Next, the applicant projected the number of Mecklenburg County GI Endoscopy Procedures that will shift from LNRMC to LEC by applying the LNRMC FY2018 GI endoscopy patient origin for Mecklenburg County patients (14.1%) to the previously approved utilization projections [Project ID F-11443-17] as illustrated below:

	Interim Year 4/2020-9/2020	FY2021	FY2022	FY2023*
Total # of GI Endoscopy Procedures Projected to Shift from LNRMC to LEC	705	1,741	2,091	2,091
Mecklenburg County GI Endoscopy Procedures Projected to Shift from LNRMC to LEC*	50	245	294	294

*Equal to the total # of GI Endoscopy Procedures x 14.1% Mecklenburg County Patient Origin.

Note: Totals may not foot due to rounding.

Step 6: Market Share

The applicant estimates the current % of Iredell County Market Share based on the number of Iredell County GI Endoscopy Procedures projected to shift from LNRMC to LEC as illustrated in the table below.

		Interim Year 4/2020-9/2020	FY2021	FY2022	FY2023*
A	Iredell County GI Endo Procedures (Step #4)	14,439	14,685	14,932	15,178
B	Iredell County GI Endoscopy Procedures Projected to Shift from LNRMC to LEC* (Step #5)	447	1,104	1,327	1,327
C	Estimated Iredell County Market Share*	3.1%	7.5%	8.9%	8.7%

*Market Share Formula: Row B / Row A = Row C
 Totals may not foot due to rounding.

The applicant is also projecting utilization based on additional incremental market share from Iredell County over and above the GI Endoscopy Procedures projected to shift from LNRMC to LEC as shown in the following table.

	Interim Year 4/2020-9/2020	FY2021	FY2022	FY2023
Projected Incremental Market Share Iredell County	4.0%	5.0%	6.0%	6.0%

The projected gain of incremental Iredell County market share, over and above projected shifts from LNRMC, is based on the following factors:

- Established referral relationships from local providers;
- The overall population growth and aging of Iredell County;
- Continued efforts from insurers to encourage patients to utilize lower-cost GI endoscopy providers;
- Capacity constraints at existing freestanding GI endoscopy rooms in Iredell County;
- The need for increased local access to freestanding GI endoscopy services;
- The letters of support from local providers (see Exhibit 3 and supplemental information);
- To be conservative, the applicant does not project any additional GI endoscopy procedures based on Mecklenburg County residents.

Step 7: Service Area GI Endoscopy Procedures Based on Existing and Incremental Market Share

**Langtree Endoscopy Center
 Projected GI Endoscopy Procedures: FY2020 – FY2023**

	FY2020*	FY2021	FY2022	FY2023
Iredell County GI Endo Procedures	14,439	14,685	14,932	15,178
Shift from LNRMC to LEC	447	1,104	1,327	1,327
Incremental Market Share	289	734	896	911
Total Iredell County GI Endo Procedures	736	1,839	2,222	2,237
Mecklenburg County GI Endo Procedures				
Shift from LNRMC to LEC	50	245	294	294
Total Iredell and Mecklenburg County's GI Endoscopy Procedures	786	2,084	2,516	2,531

*Reflects one-half year utilization based on updated project timetable
 Source: Supplemental Information

Step 8: In-Migration and Overall Projected GI Endo Procedures

In supplemental information the applicant also projects in-migration from counties other than Iredell County and Mecklenburg County. The applicant states “According to the FY2017 GI endoscopy patient origin report (pages 16-17, see also Exhibit 8), of the GI endoscopy patients served in Iredell County, 23.4% were residents of other counties (2,389/ 10,231).”

**Langtree Endoscopy Center
 Projected GI Endoscopy Procedures: FY2020 – FY2023**

	FY2020*	FY2021	FY2022	FY2023
Iredell County GI Endo Procedures Shift from LNRMC to LEC	447	1,104	1,327	1,327
Incremental Market Share	289	734	896	911
Total Iredell County GI Endo Procedures	736	1,839	2,222	2,237
Mecklenburg County GI Endo Procedures				
Shift from LNRMC to LEC	50	245	294	294
Total Iredell and Mecklenburg County’s GI Endoscopy Procedures	786	2,084	2,516	2,531
In-Migration % of the facilities total volume**	10%	20%	20%	20%
In-Migration	87	521	629	633
Total GI Endo Procedures (Iredell County, Mecklenburg County and In-Migration from other Counties)	873	2,604	3,146	3,164

Source: Supplemental Information

*Reflects one-half year utilization based on updated project timetable

**In supplemental information the applicant states that the 20% in-migration projection is less than the actual in-migration projection for the existing Iredell County GI endoscopy facilities.

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

- The applicant bases its methodology, in part, on projected population data from NCOSBM, the historical GI Endo patient use rate for Iredell County from FY2017 and the historical Iredell County ratio of procedures per patient.
- The applicant conservatively only projects a shift of Iredell and Mecklenburg County patients from LNRMC to LEC. The applicant does not project a shift of LNRMC patients from other counties to LEC.
- For FY2021, this application only projects an increase of 863 GI endoscopy procedures over the originally projected 1,741 GI endoscopy procedures. [2,604 – 1,741 = 863]
- For FY2022, this application only projects an increase of 1,055 GI endoscopy procedures over the originally projected 2,091 GI endoscopy procedures. [3,164 – 2,091 = 1,055]
- The applicant provides support letters from two additional physicians who perform gastrointestinal endoscopy procedures who intend to seek privileges at LEC and perform GI endoscopy procedures at the proposed facility.
- LEC will be a non-hospital licensed facility which will provide a lower-cost option than existing hospital-based GI endoscopy services.
- Third-party payors are encouraging patients to choose lower-cost options for outpatient care.

- Projected market shares of patients from Iredell County, Mecklenburg County and other counties are based on historical market shares.
- Projected growth and aging of the population in Iredell County.

Access

In Section C, page 37, the applicant states, “All area residents, including low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, Medicare beneficiaries, Medicaid recipients, and other underserved groups, will have access to the LEC, as clinically appropriate. LEC will not discriminate based on race, ethnicity, age, gender, or disability.” In Section L, page 75, 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.

LEC Projected Payor Mix: FY 2022	
Payor Category	Percent
Self-Pay	1%
Medicare*	48%
Medicaid*	2%
Commercial Insurance*	47%
Other (other govt)	2%
Total	100%

Source: Table on page 75

*Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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.

C

In the original LEC project, Project I.D. # F-11443-17, the applicant was found conforming with this criterion. In Section D, page 50, the applicant states there have been no changes to the responses provided in that application, and the applicant proposes no changes in the current COS application which would affect that determination.

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.

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

CA

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

In Section E, pages 51-53, the applicant describes the alternatives 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 upon approval of LEC additional physicians have expressed interest in performing procedures at the proposed facility. LEC originally only applied for and was approved for one GI endoscopy room. Maintaining the status quo would not allow area physicians to meet the patient need to provide GI endoscopy procedures in a non-hospital licensed ASF which offers more

affordable healthcare options at a high quality. Therefore, the applicant determined that this was not the least costly or most effective alternative.

- Relocate Another GI Endoscopy Room From LNRMC- The original project approving the development of LEC (Project I.D.#F-11443-17) involved transferring one existing GI Endoscopy Room from LNRMC to the proposed ASF. After development of LEC, LNRMC will have two licensed GI Endoscopy Rooms. LNRMC determined that it was necessary to maintain a complement of two GI endoscopy rooms at LNRMC. Therefore, the applicant determined that this was not the least costly or most effective alternative.
- Develop a Different Complement of GI Endoscopy Rooms at LEC- The proposed two GI endo rooms are supported by projected population growth of Iredell County and the surrounding areas as well as the proposed number of additional physicians seeking privileges at LEC. Therefore, the applicant determined that it was not the least costly or most effective alternative to seek to develop more than two GI endoscopy rooms at the proposed facility.

On pages 51-53, the applicant states that the proposal is the most effective alternative because it allows projected patient need to be met in a non-hospital licensed ASF which provides high-quality healthcare services at a lower cost than a hospital licensed facility.

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

- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

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

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

- 1. Langtree Endoscopy Center, LLC shall materially comply with all representations made in the certificate of need application and any supplemental responses. In the event that representations conflict, Langtree Endoscopy Center, LLC shall materially comply with the last made representation.**

- 2. Langtree Endoscopy Center, LLC shall develop one new additional gastrointestinal endoscopy procedure room at the approved, but undeveloped, Langtree Endoscopy Center (Project I.D. #F-11443-17).**
 - 3. Upon completion of this project and Project I.D. #F-11443-17 (Develop an ASF with one GI-Endo room) Langtree Endoscopy Center shall be licensed for no more than two gastrointestinal endoscopy procedure rooms.**
 - 4. 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 Q of the application and that would otherwise require a certificate of need.**
 - 5. 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.**
 - 6. 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 Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.**
 - 7. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Langtree Endoscopy Center, LLC shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:**
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.**
 - 8. 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

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

In the original LEC project, Project I.D. # F-11443-17, the application was conforming to this criterion with approved capital costs of \$3,182,299 and working capital costs of \$1,050,000, as shown below.

Capital and Working Capital Costs

In Section Q, Form F.1b, the applicant projects the total capital cost of this project (add one GI Endo Room) as shown in the table below.

	Original Costs (Project ID# F-11443-17)	Additional Costs for One GI Endo Room	Total
Site Preparation Costs	\$0	\$0	\$0
Construction Costs	\$2,240,724	\$38,000	\$2,278,724
Miscellaneous Costs	\$941,575	\$469,571	\$1,411,146
Total Capital Costs	\$3,182,299	\$507,571	\$3,689,870

In Section Q, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 56-57, the applicant projects working capital costs for this project (add one GI endo Room), as shown in the table below.

	Original Working Capital Costs (Project ID# F-11443-17)	Additional Working Capital Costs for One GI Endo Room	Total
Start-up Costs	\$200,000	\$100,000	\$300,000
Initial Operating Cots	\$850,000	\$175,000	\$1,025,000
Total Working Capital Costs	\$1,050,000	\$275,000	\$1,325,000

In Sections F and Q, the applicant provides the assumptions used to project the working capital cost.

Availability of Funds

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

Sources of Capital Cost Financing

Type	Langtree Endoscopy Center, LLC	Total
Loans	\$0	\$0
Accumulated reserves or OE *	\$507,571	\$507,571
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$507,571	\$507,571

* OE = Owner's Equity

In Section F, page 57, 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)	Loans	\$0
(b)	Cash or Cash Equivalents, Accumulated Reserves or Owner's Equity	\$275,000
(c)	Lines of credit	\$0
(d)	Bonds	\$0
(e)	Total *	\$275,000

Exhibit 7 contains a letter dated June 13, 2019 from the President of CHS-ASC, LLC, a member of Langtree Endoscopy Center, LLC, committing to fund the capital costs and working capital for the proposed project. Exhibit 7 also contains a letter from the President of Langtree Endoscopy Center, LLC committing to use the funds from CHS-ASC, LLC for the proposed project. In supplemental information, the applicant provides a letter dated August 28, 2019 from the Senior Vice President of Pinnacle Financial Partners confirming that CHS-ASC, LLC has \$1.0 million dollars in its account available for funding the proposed project.

Financial Feasibility

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

	1 st Full Fiscal Year	2 nd Full Fiscal Year	3 rd Full Fiscal Year
Total Procedures	2,604	3,146	3,164
Total Gross Revenues (Charges)	\$8,334,065	\$10,065,618	\$10,124,797
Total Net Revenue	\$3,027,349	\$3,656,336	\$3,677,833
Average Net Revenue per Procedure	\$1,163	\$1,162	\$1,162
Total Operating Expenses (Costs)	\$2,207,811	\$2,385,819	\$2,406,528
Average Operating Expense per Procedure	\$848	\$758	\$761
Net Income	\$819,538	\$1,270,517	\$1,271,304

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- 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

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

Patient Origin

The 2019 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 Project I.D. #F-11443-17, the applicant defined the primary service as Iredell County. In Section C, page 27, and in Section Q, the applicant states that the “*service area for LEC has not changed from the previously approved project.*” Facilities may also serve residents of counties not included in their service area.

Pursuant to the 2019 State Medical Facilities Plan, Table 6F: Endoscopy Room Inventory, page 92, there are currently five (four existing and one approved) facilities with licensed GI Endoscopy Rooms in the applicant’s service area of Iredell County as illustrated in the table below.

	# of GI Procedures	# of GI Endoscopy Rooms	# of GI Procedures per room	Utilization Rate per Room*
Davis Regional Medical Center	404	2	202	13.5%
Iredell Memorial Hospital	3,242	3	1,081	72.1%
Lake Norman Regional Medical Center**	4,892	3	1,631	108.7%
Piedmont HealthCare Endoscopy Center	6,728	3	2,243	149.5%
Langtree Endoscopy Center**	0	0	0	na

*Calculated as: # of GI Procedures per room/ 1,500

**Upon project completion, one of the existing GI endoscopy rooms currently licensed at Lake Norman Regional Medical Center will be relocated from LNRMC to LEC.

The existing Piedmont HealthCare Endoscopy Center and the approved LEC are the only non-hospital licensed GI endoscopy facilities in Iredell County. As illustrated in the table above, the utilization rate per GI endoscopy room is 149.5% at Piedmont HealthCare Endoscopy Center. Upon project completion, one GI endoscopy room from LNRMC will be relocated to LEC. Further, GI endoscopy cases are projected to shift from LNRMC to the non-hospital based LEC upon completion of Project I.D. # F-11443-17.

In Section G, page 63 and supplemental information 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:

“The proposed project will not result in unnecessary duplication of existing facilities in Iredell County. The proposed project is needed to expand local access to freestanding GI endoscopy services. As described in Section C.4, LEC demonstrates the need the population has for the proposed new GI endoscopy room based on demographic data specific to the defined service area, historical GI endoscopy utilization, and qualitative benefits.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed non-hospital licensed GI endoscopy room is needed in addition to the existing or approved GI Endoscopy rooms in Iredell County.

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

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

In the original LEC project, Project I.D. # F-11443-17, the application was conforming to this criterion.

In Section H.4, page 66, the applicant states, “*LEC projects no change to the information it provided in the previously approved CON application (F-11443-17) regarding 1) staff recruitment, training and continuing education, and 2) physician recruitment and the prospective Medical Director. The only change regarding health manpower is the incremental staffing and physicians associated with addition of a second GI endoscopy room at LEC.*”

In the previously approved project, Project I.D.# F-11443-17, in Section VII.1, page 74, the applicant provides projected staffing for the proposed services as illustrated in the following table.

**LEC Projected Staffing
CY2021**

Position	Staff FTEs
Administrator	1.00
Clinical Director	1.00
Registered Nurse (RN)	4.00
Endoscopy Technician	2.00
Receptionist/Scheduler	1.50
Business Office Supervisor	1.00
Total	10.50

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

**LEC Projected Staffing
FY2 (10/1/2021 – 9/30/2022)**

Position	Staff FTEs
Administrator	1.00
Director of Nursing	1.00
Registered Nurse (RN)	5.00
Endoscopy Technician	3.00
Registration/Billing Clerk	1.75
Business Office Supervisor	1.00
Total	12.75

The applicant only projects an increase of 2.25 FTE's from the original approved project.

The assumptions and methodology used to project staffing are provided in Section Q, Form H, and Exhibit 3. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in supplemental information.

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 Project I.D. # F-11443-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination. In Section H, page 68, the applicant states,

“LEC projects no change to the information it provided in the previously approved CON application regarding 1) ancillary and support services, and 2) coordination with the existing health system. LEC anticipates having two additional physicians perform cases at the facility... Otherwise, the addition of a second GI endoscopy room at LEC

does not fundamentally change the ancillary and support services of the planned GI endoscopy center, including anesthesia and pathology 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.

- (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.

NA

The applicant does not propose to make more than minor renovations to existing space. Therefore, Criterion (12) is not applicable to this review.

- (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 Project I.D. # F-11443-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination.

The Agency reviewed the:

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

In Project I.D. # F-11443-17, this Criterion was deemed not applicable because the applicant did not own or operate any existing GI endoscopy procedure rooms and

proposed to develop a new facility. The applicant proposes no changes in the current COS application that would affect that determination.

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.

- (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

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

In Section L, page 75, 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.

LEC Projected Payor Mix: FY 2022	
Payor Category	Percent
Self-Pay	1%
Medicare*	48%
Medicaid*	2%
Commercial Insurance*	47%
Other (other govt)	2%
Total	100%

Source: Table on page 75

*Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 48.0% of total services will be provided to Medicare patients and 2.0% to Medicaid patients.

In Section L.6, page 76, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported for the following reasons:

- Given that the physicians projected to utilize LEC currently perform the majority of the GI endoscopy procedures at LNRMC, the projected payor mix is based on the current outpatient GI endoscopy payor mix at LNRMC.
- The projected payor mix is not substantively different from the payor mix provided in the prior approved application, Project I.D.# F-11443-17.

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 Project I.D. # F-11443-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination.

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.

- (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 Project I.D. # F-11443-17, the application was conforming to this criterion and the applicant proposes no changes in the current COS application that would affect that determination.

In Section M, page 77, the applicant describes the extent to which health professional training programs in the area have will have access to the facility for training purposes. The applicant states, “*LEC will be available for students training in clinical health services, as needed.*”

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

The applicant proposes a COS for the approved, but undeveloped, LEC project [Project I.D.#F-11443-17], which authorized the development of a new ASF by acquiring one existing GI endoscopy procedure room from LNRMC and relocating it to the proposed new facility in Mooresville.

In the current COS application, the applicant proposes to develop one additional GI endoscopy room at the approved LEC.

The 2019 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 Project

I.D. #F-11443-17, the applicant defined the primary service as Iredell County. In Section C, page 27, and in Section Q, the applicant states that the “*service area for LEC has not changed from the previously approved project.*” Thus, the service area for this facility consists of Iredell County. Facilities may also serve residents of counties not included in their service area.

Pursuant to the 2019 State Medical Facilities Plan, Table 6F: Endoscopy Room Inventory, page 92, there are currently five (four existing and one approved) facilities with licensed GI Endoscopy Rooms in the applicant’s service area of Iredell County as illustrated in the table below.

	# of GI Procedures	# of GI Endoscopy Rooms	# of GI Procedures per room	Utilization Rate per Room*
Davis Regional Medical Center	404	2	202	13.5%
Iredell Memorial Hospital	3,242	3	1,081	72.1%
Lake Norman Regional Medical Center**	4,892	3	1,631	108.7%
Piedmont HealthCare Endoscopy Center	6,728	3	2,243	149.5%
Langtree Endoscopy Center**	0	0	0	na

*Calculated as: # of GI Procedures per room/ 1,500

**Upon project completion, one of the existing GI endoscopy rooms currently licensed at Lake Norman Regional Medical Center will be relocated from LNRMC to Langtree Endoscopy Center.

In Section N, pages 78-79, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On page 79, the applicant states “*LEC projects no change to the information it provided in the previously approved application (F-11443-17) regarding the cost effectiveness and quality of, and medically underserved access to GI endoscopy services at LEC. As a new freestanding GI endoscopy center, LEC will have a positive effect on competition in the service area. The proposed project will promote cost-effective, high quality GI endoscopy services that will be broadly accessible by residents, as described in the previously approved application. ... The change of scope application to add room capacity will enable LEC to better meet the needs of the local patient population, and to ensure more timely provision of and convenient access to outpatient GI endoscopy services for area residents.*”

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

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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.

- (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 Project I.D. # F-11443-17, this criterion was found to be “NA” and the applicant proposes no changes in the current COS application that would affect that determination. In Section O, page 81, the applicant states “*LEC has not had its Medicare or Medicaid provider agreement terminated. And there are no related entities.*”

The Agency reviewed the:

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

C

In Project I.D. # F-11443-17, the application was conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900.

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

.3903 PERFORMANCE STANDARDS

- (a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*
- NA- The applicant does not propose to develop operating rooms. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI-Endo procedures only per GI-Endo room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*
- C- In supplemental information, the applicant states that they project to perform an average of 1,582 GI-Endo procedures per GI-Endo room in the proposed facility during the second year of operation following completion of the project. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference. Neither the applicant nor any related entities own any other licensed facilities in the proposed service area.
- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall demonstrate that at least the following types of GI-Endo procedures will be provided in the proposed facility or GI-Endo room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section C, page 40, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures will be provided at the LEC.
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria:*
- (1) *if the applicant or a related entity performs GI-Endo procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI-Endo cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or*
 - (2) *demonstrate that GI-Endo procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or*

shared operating rooms in the last 12 months and will not be performed in those rooms in the future.

- NA- In Section C, page 41, the applicant states that neither they nor any related entities own any inpatient operating rooms, outpatient operating rooms or shared operating rooms in the proposed service area. 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-Endo procedures or develop an additional GI-Endo room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*
- C- In Section Q, pages 84-92, the applicant provides the assumptions and methodology used to project GI-Endo procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.