

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: April 30, 2019

Findings Date: April 30, 2019

Project Analyst: Celia C. Inman

Team Leader: Fatimah Wilson

Project ID #: G-11655-19

Facility: LeBauer Endoscopy Center

FID #: 923200

County: Guilford

Applicant(s): The Moses H. Cone Memorial Hospital
The Moses H. Cone Memorial Hospital Operating Corporation
Moses Cone Medical Services, Inc.

Project: Relocate no more than one GI endo room from Wesley Long Hospital for a total of no more than five GI endo rooms upon project completion

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.

NA

The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation, and Moses Cone Medical Services, Inc., collectively referred to as "Cone Health" or "the applicant" proposes to relocate one gastrointestinal endoscopy (GI endo) room from Wesley Long Hospital (Wesley Long) to LeBauer Endoscopy Center (LEC).

Wesley Long is licensed as part of Cone Health, License #HO159. LEC is an existing, separately licensed ambulatory surgery facility (ASF), License #AS0052. Both Wesley

Long and LEC are part of the Cone Health “health” system in Guilford County with a total of 11 endoscopy rooms. LEC currently operates four GI endo rooms and is located at 520 N. Elam Avenue in Greensboro, Guilford County and the licensee is Moses Cone Medical Services, Inc. Cone Health, is currently licensed for seven total GI endo rooms, four at Wesley Long and three at the Moses Cone Hospital location. Upon project completion, there will be five GI endo rooms at LEC, three GI endo rooms at Wesley Long, and three GI endo rooms at Moses Cone Hospital for a total of six GI endoscopy rooms on Cone Health’s License #HO159. The total inventory of GI endoscopy rooms operated by Cone Health’s Guilford County health system will not change as a result of this project. In addition, the total inventory of licensed GI endoscopy rooms in Guilford County will not change as a result of this project.

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). There are no policies in the 2019 SMFP which are applicable to this review. Thus, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.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

C

The applicant proposes to relocate one existing licensed GI endoscopy room from Wesley Long to LEC. Upon project completion, LEC will be licensed for five GI endoscopy rooms, and Wesley Long will be licensed for three GI endoscopy rooms. The total inventory of GI endoscopy rooms in Guilford County will not change as a result of this project.

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 in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3901(6) defines the service area “*as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.*” In Section C.4, page 23, the applicant identifies its service area as Guilford County. Facilities may also serve residents of counties not included in their service area.

In Exhibit C.2, page 132, the applicant provides the last full fiscal year (FY), FY2018, (October 1, 2017 through September 30, 2018) patient origin, for the endoscopy services at LEC, as summarized in the following table:

LeBauer Endoscopy Center

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LeBauer Endoscopy Center Historical Patient Origin		
County or State	FY2018 Number of Patients	FY2018 Percent of Patients
Guilford	6,471	77.7%
Rockingham	542	6.5%
Randolph	315	3.8%
Alamance	304	3.6%
Virginia	250	3.0%
Forsyth	186	2.2%
Other Counties/ States	263	3.2%
Total	8,331	100.0%

Source: Table in Exhibit C.2, page 132 of the application. The applicant identifies the “Other counties and states” in a footnote in the Exhibit, sourced to Cone Health Financial Systems.

In Exhibit C.3, page 133, the applicant provides the projected patient origin for the first three full fiscal years following the completion of the project, as summarized in the following table:

LeBauer Endoscopy Center Projected Patient Origin						
County or State	FY2021 (10/1/20-9/30/21)		FY2022 (10/1/21-9/30/22)		FY2023 (10/1/22-9/30/23)	
	# of Patients	% of Patients	# of Patients	% of Patients	# of Patients	% of Patients
Guilford	6,678	77.7%	6,749	77.7%	6,820	77.7%
Rockingham	559	6.5%	565	6.5%	571	6.5%
Randolph	325	3.8%	329	3.8%	332	3.8%
Alamance	314	3.6%	317	3.6%	320	3.6%
Virginia	258	3.0%	261	3.0%	264	3.0%
Forsyth	192	2.2%	194	2.2%	196	2.2%
Other Counties/ States	272	3.2%	275	3.2%	277	3.2%
Total	8,598	100.0%	8,689	100.0%	8,781	100.0%

Totals may not sum due to rounding

Source: Table in Exhibit C.3, page 133 of the application. The applicant identifies the “Other counties and states” in a footnote in the Exhibit, sourced to Cone Health Financial Systems.

The Project Analyst was unable to find a reference to the assumptions and methodology used by the applicant to project its patient origin; however, it is apparent from the historical and projected patient origins that the applicant based the projected patient origin on the historical percentages of total patients by county or state. The applicant’s projected patient origin is reasonable and adequately supported.

Analysis of Need

In Section C.1, page 18, the applicant states that Cone Health is responding to market demands for access to outpatient GI endo services and redistributing its existing GI endo assets to meet that demand. The total inventory of GI endoscopy rooms in Guilford County will not change as a result of the proposed project.

In Section C.4, pages 21-32, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On page 21, the applicant states that the need for the project is based on the following factors:

- Historical utilization of existing GI endoscopy resources at LEC, including utilization in excess of 100% of capacity based on 1,500 procedures per room per year (pages 21 – 23).
- Historical and projected growth of the service area (Guilford County) population and in the age group that is expected to utilize the GI endoscopy services (pages 23 – 25).
- Projected growth of GI endoscopy procedures from 2017 through 2022 and from 2017 through 2027, including analysis of colon cancer risk factors that lead to increased screening colonoscopies and other GI endoscopy procedures (pages 25 – 29).
- Historical utilization of existing GI endoscopy services in Guilford County. The applicant provides the GI endo procedures reported by the Guilford County facilities providing such services during FY2015 – FY2017. The applicant states that the growing volumes coupled with aging of the population and projected growth in utilization indicates a constraint in capacity in the existing facilities. The applicant further states that the relocation of the one existing GI endoscopy room as proposed in this application will provide more outpatient access for patients and thus alleviate the access issues for diagnostic outpatient GI endoscopy procedures (pages 29 – 32).

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

- LEC is operating in excess of 100% of capacity,
- the Guilford County population is growing and aging, and
- relocating the one GI endoscopy room, as proposed, will provide additional outpatient access for area patients.

Projected Utilization

In Section Q, Form C, page 97, the applicant provides historical and projected utilization as summarized in the following table.

LeBauer Endoscopy Center Historical and Projected Utilization FY2016-FY2023								
	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
# GI-Endo Rooms	3	4	4	4	4	5	5	5
Total Procedures	7,218	7,795	8,331	8,419	8,508	8,598	8,689	8,781
Procedures / Room	2,406	1,949	2,083	2,105	2,127	1,720	1,738	1,756
Percent Capacity	160%	130%	139%	140%	142%	115%	116%	117%

In Section Q, pages 98-101, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- The applicant bases future utilization upon historical utilization.
- The applicant states it selected the most conservative growth rate of 1.1% annually, based on the following considerations:
 - LeBauer has operated above 100% capacity between FY2014 – FY2018 at a compound annual growth rate (CAGR) of 2.9%, which the applicant states may be artificially restricted due to capacity constraint.
 - The applicant states that the Advisory Board Company, a national healthcare intelligence firm provides projected growth for specific endoscopy procedures with the overall growth rate for all outpatient endoscopy services in Guilford County, the proposed service area, being 17.5% over the next five years, or a CAGR of 3.3%.
 - Guilford County population is expected to increase by 5.4% between 2018 and 2023 at a five-year CAGR of 1.1%.
 - The Guilford County population age 45 and over is expected to grow at a five-year CAGR of 1.7%.

Projected utilization is reasonable and adequately supported because the percentage growth in the number of GI-Endo procedures is based on the percentage of population growth, a more conservative growth rate than recent historical growth. Furthermore, the applicant adequately demonstrates that it will perform 8,689 total GI endoscopy procedures in five GI endoscopy rooms in the second operating year, FY2022, which is an average of 1,738 procedures per room [8,689 procedures / 5 rooms = 1,738 procedures per room]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

Access

In Section C.8, page 37, the applicant states that it is a private, not-for-profit organization established to serve the community by providing high quality, affordable, and comprehensive health care services to all patients, regardless of their economic status. The applicant further states that it does not discriminate against low income persons, racial and ethnic minorities, women, handicapped persons, the elderly or other classifications of underserved persons, including the medically indigent, the uninsured and the underinsured.

The applicant states that the proposed project will not alter the current level of accessibility to patients of Cone Health. The applicant provides supporting documentation in Exhibits C.11-1 and C.11-2.

In Section L.3, page 81, 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.

LeBauer Endoscopy Center Projected Payor Mix 10/1/2021-09/30/2022	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	2.4%
Charity Care^	NA
Medicare*	41.8%
Medicaid*	2.8%
Insurance*	52.8%
Workers Compensation	0.0%
TRICARE	0.2%
Other	0.0%
Total	100.0%

Source: Section L, page 81

^Charity Care is not considered a separate payor class and is offered to qualifying patients in all payor categories

* Including any managed care plans

In Section Q-Notes and Assumptions, page 114, the applicant states that it uses existing LeBauer Endoscopy Center services during FY2018 to forecast assumptions for FY2019 through FY2023 and that the forecasted model for payors includes management’s best estimate of future changes to collections by payor beginning in fiscal year 2019. The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- The applicant adequately 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 (payer 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

The applicant proposes to relocate one existing GI endoscopy room from Wesley Long to LEC. Wesley Long is licensed under the Cone Health Hospital license #HO159. LEC is a separately licensed ASF. Both Wesley Long and LEC are in Greensboro, in Guilford County and are currently licensed for four GI endo rooms each. Upon project completion, LEC will be licensed for five GI endo rooms and Wesley Long will be licensed for three GI endo rooms.

In Section D, page 42, 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, stating:

“With a total of 3,295 GI endoscopy procedures performed in four (4) licensed GI endoscopy rooms at Wesley Long Hospital, the endoscopy unit operated at 54.9% of capacity in FY2018. Upon project completion, Wesley Long Hospital will be licensed for three (3) GI endoscopy rooms. At its current level of utilization, Wesley Long Hospital would operate at 73.2% capacity with three (3) licensed GI endoscopy rooms. Therefore, Wesley Long Hospital will therefore [sic] retain sufficient capacity to continue serving the current and future patient population for hospital based endoscopy services.”

In Section Q, page 102, the applicant provides the projected utilization for GI endoscopy services at Wesley Long, summarized as follows:

Wesley Long Hospital Historical and Projected GI Endoscopy Utilization FY2016-FY2023								
	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
# GI-Endo Rooms	4	4	4	4	4	3	3	3
# Inpatient GI Endo Procedures	690	778	843	852	861	870	879	888
# Outpatient GI Endo Procedures	2,644	2,574	2,452	2,478	2,504	2,531	2,558	2,585
Total GI Endo Procedures	3,334	3,352	3,295	3,330	3,365	3,401	3,437	3,473
Procedures / Room	834	838	824	833	841	1,134	1,146	1,158
Percent Capacity	55.6%	55.9%	54.9%	55.5%	56.1%	75.6%	76.4%	77.2%

In Section Q, pages 103-106, the applicant provides the assumptions and methodology for projecting utilization at Wesley Long, discussing much the same factors as driving demand and for projecting utilization as in the projections for LEC, and consistently selecting the population growth factor of 1.1% for projecting growth at Wesley Long. The proportion of inpatient to outpatient procedures is kept constant based on the historical FY2018 proportion.

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

- The applicant bases projected utilization upon historical utilization.
- Consistent with its utilization projections for LEC, the applicant uses the population growth rate to project future utilization at Wesley Long.

In Section D.5, page 46, the applicant states:

“The relocation of one (1) licensed GI endoscopy procedure room from Wesley Long Hospital to LeBauer Endoscopy Center will not impact patients seeking hospital based GI endoscopy services in any way, including any changes to charges, cost, or access.”

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that:

- the needs of the population currently using the services to be relocated will be adequately met following project completion, and
- the project will not adversely impact the ability of underserved groups to access these services following project completion.

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

CA

The applicant proposes to relocate one existing licensed GI endoscopy room from Wesley Long to LEC for a total of five GI endoscopy rooms at LEC, upon project completion.

In Section E, pages 47-48, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that this option does not provide additional endoscopy capacity in a freestanding setting to meet the future demand for routine outpatient services. It also does not allow for the addition of future providers to the medical staff of LeBauer Endoscopy Center, as the current procedure rooms are over utilized, as measured by the state’s definition of capacity.
- Increase Hours of Operation– The applicant states that this is not the best alternative. Opening earlier in the day would require patients to prepare earlier the day before, which may not be an option for some patients. Expanding hours at the end of the day would require patients to fast for a longer amount of time, which decreases patient comfort and satisfaction. Additionally, adding to the operating hours would result in additional staffing requirements which means increased operational expenses, plus lowered staff and physician morale.
- The Project as Proposed - The applicant states that utilizing existing space at LeBauer Endoscopy Center to house one additional GI endoscopy procedure room to be relocated from Wesley Long and reconfiguring existing space to accommodate necessary additional support spaces is the most cost-efficient and effective method of meeting the identified need.

On page 48, the applicant states that the project as proposed is the most effective alternative because it is the alternative determined to be the least costly while ensuring access to necessary outpatient GI endoscopy services in the most appropriate setting while appropriately organizing Cone Health’s existing, system-wide GI endoscopy assets within Guilford County to meet patient demand where needed.

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

- It will increase overall patient access to outpatient GI endoscopy services.

- It will redistribute Cone Health's existing GI endoscopy assets to better serve Guilford County residents.
- The application is conforming to all statutory 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, and
- exhibits to the application.

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

- 1. The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. shall materially comply with all representations made in the certificate of need application.**
- 2. The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section F of the application or that would otherwise require a certificate of need.**
- 3. The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. shall relocate no more than one gastrointestinal endoscopy procedure room from Wesley Long Hospital to LeBauer Endoscopy Center for a total of no more than five upon project completion. Cone Health, License #HO159, shall be licensed for a total of no more than six gastrointestinal endoscopy procedure rooms; no more than three at Wesley Long Hospital and no more than three at Moses Cone Hospital following project completion.**
- 4. The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. shall take the necessary steps to delicense one gastrointestinal endoscopy procedure room at Wesley Long Hospital.**
- 5. For the first three years of operation following completion of the project, The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. 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.

- 6. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. 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.**
 - 7. The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation and Moses Cone Medical Services, Inc. shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**
- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to relocate one existing licensed GI endoscopy room from Wesley Long to LEC for a total of five GI endoscopy rooms at LEC, upon project completion.

In Section Q, page 107, the applicant projects the total capital cost of the project as shown in the table below.

LeBauer Endoscopy Center Projected Capital Cost	
Construction / Renovation	\$1,079,780
Architect/Engineering	\$113,375
Medical Equipment	\$398,508
Furniture	\$87,500
Structural Engineering Fees	5,000
Contingency	\$100,000
Total	\$1,784,163

In Section Q, page 108, the applicant provides the assumptions used to project the capital cost.

In Section F, pages 53-54, the applicant projects no start-up costs and no initial operating expenses because the proposed project is not a new service or facility.

Availability of Funds

In Section F, page 51, the applicant states that the capital cost will be funded as shown in the table below.

Type	The Moses H. Cone Memorial Hospital	Total
Loans		
Accumulated reserves or OE*	\$1,784,163	\$1,784,163
Bonds		
Other (Specify)		
Total Financing	\$1,784,163	\$1,784,163

* OE = Owner's Equity

Financial Feasibility

The applicant provides pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.3, page 110, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as summarized below in the table.

LeBauer Endoscopy Center GI-Endo Procedure Rooms			
	1st Full FY FY2021	2nd Full FY FY2022	3rd Full FY FY2023
Total Procedures	8,598	8,689	8,781
Total Gross Revenues (Charges)	\$11,956,980	\$12,566,872	\$13,207,929
Total Contractual Adjustments*	\$5,252,786	\$5,647,950	\$6,067,193
Other Revenue	\$429	\$429	\$429
Total Net Revenue	\$6,704,623	\$6,919,351	\$7,141,165
Average Net Revenue per Procedure	\$780	\$796	\$813
Total Operating Expenses (Costs)	\$4,535,993	\$4,723,533	\$4,919,806
Average Operating Expense per Procedure	\$528	\$544	\$560
Net Income	\$2,168,629	\$2,195,817	\$2,221,358

Totals may not sum due to rounding

*Includes charity care and bad debt

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, and
- exhibits to the application.

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

- The applicant adequately demonstrates that the capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

The applicant proposes to relocate one existing licensed GI endoscopy room from Wesley Long to LEC for a total of five GI endoscopy rooms at LEC, upon project completion.

The 2019 SMFP does not define the service area for GI endo procedure rooms, however, the applicant defines its service area as Guilford County, in compliance with Administrative Rule 10A NCAC 14C .3901(6). Facilities may also serve residents of counties not included in their service area.

In Section G, Table G-1, page 59, the applicant identifies the existing and approved GI endo services in Guilford County and the number of GI endo procedures performed during FY2017, as provided in the 2019 SMFP and summarized in the following table.

**Guilford County GI Endoscopy Utilization
 FY2017**

Facility	Facility Type	# GI Endo Rooms	# GI Procedures	% Of Capacity
Bethany Endoscopy Medical Center	GI ASF	2	2,284	76.1%
Cone Health	Hospital	7	6,154	58.6%
Eagle Endoscopy Center	GI ASF	4	5,895	98.3%
Greensboro Specialty Surgical Center	Multi-Specialty ASF	2	963	32.1%
Guilford Endoscopy Center	GI ASF	2	3,774	125.8%
High Point Endoscopy Center	GI ASF	3	7,691	170.9%
High Point Regional Health System	Hospital	2	2,346	78.2%
LeBauer Endoscopy Center	GI ASF	4	7,795	129.9%

Source: Table 6F, page 91 of the 2019 SMFP

As illustrated in the table above, in 2017, LEC was operating in excess of 129% of the state threshold utilization capacity of 1,500 GI endo procedures per room, whereas, Cone Health, License #HO159, which includes Wesley Long, was operating at only 58.6% of capacity. In addition to LEC, three other ASFs operated at or above capacity.

In Section G, pages 49-50, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI Endo services in its primary service area of Guilford County. The applicant states:

“... the need for the project is based on the historical volumes and projected growth at LeBauer Endoscopy Center. Therefore, no other providers can meet the need identified by the proposed project.”

In Section C.1, page 18, the applicant states that Cone Health is responding to market demands for access to outpatient GI endo services and redistributing its existing GI endo assets to meet that demand. The total inventory of GI endoscopy rooms in Guilford County will not change as a result of the proposed project.

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 relocation of the GI endo procedure room will not duplicate the existing or approved GI endoscopy services in Guilford County.

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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 above stated reasons.

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

C

In Section Q, Form H, pages 116-117, the applicant provides current and projected staffing in full-time equivalent (FTE) positions for the proposed services as illustrated in the following table.

LeBauer Endoscopy Center Current & Projected Staffing FTEs				
Position	Current	Projected		
	FY2018	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
RN	14.38	14.69	14.84	15.00
LPN	1.00	1.02	1.03	1.04
Technicians	6.71	6.86	6.93	7.00
Clerical	4.96	4.96	4.96	4.96
Total	27.06	27.53	27.76	28.01

Totals may not sum due to rounding
 Source: Form H in Section Q of the application

The assumptions and methodology used to project staffing are provided in Section Q, page 114-115. The assumptions state that allocated general and administrative expense includes costs for billing, information technology, security, case management, finance and other system overhead. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F.3, page 110, which is found in Section Q. In Section H, pages 61-63, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 64, the applicant identifies the current medical director, and confirms his commitment to continue to serve in this role. In Section H, pages 64-65, the applicant describes its physician recruitment plans. Exhibit H.4 contains 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, and
- exhibits to the application.

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

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

C

In Section I, page 66, the applicant states that the following ancillary and support services are necessary for the proposed services:

- admitting / registration,
- medical records,
- medical / central sterile supply,
- biomedical engineering,
- nursing,
- anesthesia,
- laboratory,
- pharmacy,
- radiology,
- environmental services,
- administrative services, and
- business office / support services.

On page 66, the applicant adequately explains how ancillary and support services are currently made available and will continue to be provided at LEC. The applicant provides supporting documentation in Exhibit I.1.

In Section I, page 67, the applicant describes its existing and proposed relationships with other local health care and social service providers. Physician support letters are provided in Exhibit H.4.

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

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
- (i) would be available under a contract of at least 5 years duration;
 - (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
 - (iii) would cost no more than if the services were provided by the HMO; and
 - (iv) would be available in a manner which is administratively feasible to the HMO.

NA

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (11) Repealed effective July 1, 1987.
- (12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

C

In Section K, page 71, the applicant states that the project involves renovating 3,819 square feet of existing space. Line drawings are provided in Exhibit K.2.

On pages 72-73, 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 Exhibits F.1 and K.2. The applicant states:

“Because the project involves the renovation of existing space and will utilize existing furniture and equipment where possible, the cost of the project is minimal compared to the alternatives that would require the construction of new space.”

On page 73, 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, stating that relocating the services simply ensures access to the services for patients in the most cost effective setting, a freestanding GI endo ASF, which has a lower cost of care for routine outpatient care when compared to the hospital setting in which the existing GI endo room is currently located.

The applicant identifies any applicable energy saving features that will be incorporated into the proposed renovation plans on page 73 of the application.

Conclusion

The Agency reviewed the:

- application, and
- exhibits to the application.

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

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such

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

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

C

In Section L, page 79, the applicant provides the historical payor mix during 10/01/2017 – 09/30/2018, the last full fiscal year for the proposed services, as shown in the table below.

LeBauer Endoscopy Center Projected Payor Mix FY2018	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	2.5%
Charity Care [^]	NA
Medicare*	41.2%
Medicaid*	2.6%
Insurance*	53.3%
Workers Compensation	0.0%
TRICARE	0.3%
Other	0.0%
Total	100.0%

Totals may not sum due to rounding
 Source: Section L, page 79, Cone HealthLink
[^]Charity Care is not considered a separate payor class and is offered to qualifying patients in all payor categories
 * Including any managed care plans

In Section L, page 79, the applicant provides the following comparison.

	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	54.9%	52.4%
Male	45.1%	47.6%
Unknown	0.0%	0.0%
64 and Younger	61.3%	82.9%
65 and Older	38.7%	17.1%
American Indian	0.3%	0.6%
Asian	1.1%	4.8%
Black or African-American	22.5%	33.9%
Native Hawaiian or Pacific Islander	>0.1%	Included in Asian
White or Caucasian	71.6%	53.8%
Other Race (inc Hispanic)	3.3%	6.9%
Declined / Unavailable	1.2%	0.0%

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 80, the applicant states,

“Cone Health has no obligation under applicable federal regulations to provide uncompensated care, community service, or access to care by minorities or handicapped persons. However, Cone Health is dedicated to providing care for all in its communities regardless of the ability to pay, as

demonstrated in Exhibit C.11-1, which contains copies of Cone Health's Financial Assistance Program and Hardship Settlement policies."

In Section L, page 80, the applicant states that during the last five years one patient civil rights equal access complaint alleging failure to provide an interpreter was filed against Cone Health and the case was subsequently closed without remediation. No civil rights equal access complaints have been filed against LEC.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L, page 81, the applicant projects the following payor mix for the proposed services at LEC during the second full fiscal year of operation following completion of the project, as shown below in the table.

LeBauer Endoscopy Center Projected Payor Mix 10/1/2021-09/30/2022	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	2.4%
Charity Care^	NA
Medicare*	41.8%
Medicaid*	2.8%
Insurance*	52.8%
Workers Compensation	0.0%
TRICARE	0.2%
Other	0.0%
Total	100.0%

Source: Section L, page 81

^Charity Care is not considered a separate payor class and is offered to qualifying patients in all payor categories

* Including any managed care plans

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 2.4% of total services will be provided to self-pay patients, 41.8% to Medicare patients and 2.8% to Medicaid patients.

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 in Section Q. The projected payor mix is reasonable and adequately supported because the applicant assumes the proposed project will not have a significant impact on payor mix, thus the projected payor mix will closely resemble the existing payor mix.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section L.5, pages 82-83, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- application, and
- exhibits to the application.

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

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

C

In Section M, pages 84-86, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides a list of professional training programs currently utilizing the training opportunities at Cone Health. The applicant states that each of the training programs will continue to have access to clinical training opportunities at Cone Health, including LaBauer Endoscopy Center, as appropriate.

The Agency reviewed the:

- application, and
- exhibits to the application.

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to this criterion.

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

C

The applicant proposes to relocate one existing licensed GI endoscopy room from Wesley Long to LEC for a total of five GI endoscopy rooms at LEC, upon project completion.

The 2019 SMFP does not define the service area for GI endo procedure rooms, however, the applicant defines its service area as Guilford County, in compliance with Administrative Rule 10A NCAC 14C .3901(6). Facilities may also serve residents of counties not included in their service area.

In Section G, Table G-1, page 59, the applicant identifies the existing and approved GI endo services in Guilford County and the number of GI endo procedures performed during FY2017, as summarized in the following table.

**Guilford County GI Endoscopy Utilization
 FY2017**

Facility	Facility Type	# GI Endo Rooms	# GI Procedures	% Of Capacity
Bethany Endoscopy Medical Center	GI ASF	2	2,284	76.1%
Cone Health	Hospital	7	6,154	58.6%
Eagle Endoscopy Center	GI ASF	4	5,895	98.3%
Greensboro Specialty Surgical Center	Multi-Specialty ASF	2	963	32.1%
Guilford Endoscopy Center	GI ASF	2	3,774	125.8%
High Point Endoscopy Center	GI ASF	3	7,691	170.9%
High Point Regional Health System	Hospital	2	2,346	78.2%
LeBauer Endoscopy Center	GI ASF	4	7,795	129.9%

Source: Table 6F, page 91 of the 2019 SMFP

As illustrated in the table above, in 2017 LEC was operating in excess of 129% of the state threshold utilization capacity of 1,500 procedures per room, whereas, Cone Health was operating at only 58.6% of capacity. In addition to LEC, three other ASFs operated at or above capacity.

In Section N, page 88-89, 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. The applicant states:

“The proposed project will result in additional capacity in the outpatient setting that will more efficiently serve patients. By utilizing and reconfiguring existing space for the proposed project, Cone Health has chosen the most cost effective option, thereby improving the value to the patient and fostering competition.

...

Cone Health and LeBauer Endoscopy Center have been recognized for quality care as shown in Section O of this application. The proposed project will allow Cone Health to continue delivering quality care to patients seeking GI endoscopy services.

...

By relocating a GI endoscopy procedure room to LeBauer Endoscopy Center, a freestanding GI ASF, Cone Health will increase access to the setting of care most utilized by patients while retaining sufficient capacity in the hospital-based setting for patients who need a higher acuity location for GI endoscopy procedures.

Moreover, Cone Health has a longstanding, demonstrated commitment to the underserved residents in its communities.”

The applicant provides supporting documentation of its commitment to the community in Exhibits C.11-1 and C.11-2.

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 referenced exhibits).
- Quality services will be provided (see Section O of the application and any referenced exhibits).
- Access will be provided to underserved groups (see Section L of the application and any referenced exhibits).

Conclusion

The Agency reviewed the:

- application,
- exhibits to the application, and
- 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.

C

In Section O, page 93, the applicant refers to Exhibit O.3 which contains a list of all healthcare facilities located in North Carolina owned, operated or managed by the applicant or a related entity, including five acute care facilities and three ambulatory surgical facilities that provide GI endoscopy services.

In Section O, page 94, the applicant states that none of the Cone Health related facilities have operated out of compliance with any Medicare Conditions of Participation during the 18 months immediately preceding the submittal of the application. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding submission of the application through the date of this decision, incidents related to quality of care have not occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all eight facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

- (21) Repealed effective July 1, 1987.
- (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.

NA

The applicant proposes to relocate one existing licensed GI endoscopy room from Wesley Long to LEC. Upon project completion, LEC will be licensed for five GI endoscopy rooms, and Wesley Long will be licensed for three GI endoscopy rooms. The total inventory of GI endoscopy rooms operated by the Cone Health "health system" will not change as a result of this project. In addition, the total inventory of licensed GI endoscopy rooms in Guilford County will not change as a result of this project. Therefore, the Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900 are not applicable to this review.