

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

x

Decision Date: October 28, 2016

Findings Date: October 28, 2016

Project Analyst: Tanya S. Rupp

Team Leader: Lisa Pittman

Project ID #: G-11205-16

Facility: LeBauer Endoscopy Center

FID #: 933200

County: Guilford

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

Project: Relocate one GI endoscopy procedure room from Moses Cone Hospital to LeBauer Endoscopy Center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 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 applicants are 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 applicants." LeBauer Endoscopy Center (LEC) is an existing, licensed ambulatory surgery center that is part of the Cone Health system. LEC currently operates three gastrointestinal (GI) endoscopy rooms and is located at 520 N. Elam Avenue in Greensboro, Guilford County. Cone Health proposes to relocate one existing licensed GI endoscopy room from The Moses H. Cone Memorial Hospital to LEC, for a total of four licensed GI endoscopy rooms at LEC upon project completion. The total inventory of GI endoscopy rooms operated by Cone Health 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 2016 State Medical Facilities Plan (2016 SMFP). In addition, no policies in the 2016 SMFP are applicable to this review, including Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities, since the total projected cost of the proposal is less than two million dollars. Therefore, this criterion is not applicable in 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 applicants propose to relocate one existing licensed GI endoscopy room from The Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center. Upon project completion, LEC will be licensed for four GI endoscopy rooms, and The Moses H. Cone Memorial Hospital will be licensed for seven GI endoscopy rooms. The total inventory of GI endoscopy rooms operated by Cone Health 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.

Population to be Served

The 2016 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as *“the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.”* In Section III.5, page 35, the applicant defines its primary service area as Guilford County. Facilities may also serve residents of counties not included in their service area.

In Exhibit 17, the applicants provide FY 2016 and projected patient origin for FY 2018 (the second project year) for the GI endoscopy services at LEC, as illustrated in the following table:

County	FY 2016 % of Total Patients	FY 2018 % of Total Patients
Guilford	76.7%	76.7%
Rockingham	8.2%	8.2%
Randolph	5.2%	5.2%
Alamance	3.8%	3.8%
Forsyth	2.2%	2.2%
Virginia	1.6%	1.6%
Other Counties and States	2.4%	2.4%
Total	100.0%	100.0%

Source: Table in Exhibit 17 of the application. The applicants list the “Other counties and states” in a footnote in the Exhibit.

On page 36, the applicant states future patient origin is based on current patient origin for LEC. The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1, pages 22 – 33, the applicants describe the following factors to support the need to relocate one existing licensed GI endoscopy room from The Moses H. Cone Memorial Hospital to LEC:

- Historical utilization of existing GI endoscopy rooms and resources at LEC, including continued utilization in excess of 100% of capacity based on 1,500 procedures per room per year (pages 22 – 24).
- Historical and projected growth of Guilford County population in different age groups that are expected to utilize the GI endoscopy services (pages 24 – 26).
- Projected growth of GI endoscopy procedures from 2015 through 2025, including analysis of colon cancer risk factors that lead to increased screening colonoscopies and other GI endoscopy procedures (pages 26 – 30).
- Historical utilization of existing GI endoscopy services in the service area. The applicants account for a period of “flat volume” during FY 2013 – FY 2014, which the applicants state could be the result of access issues that patients faced. The applicants state the relocation of the one GI endoscopy room as proposed in this application will provide more outpatient access for patients and thus alleviate the access issues for many patients (pages 30 – 33).

Projected Utilization

In Section IV.1, pages 41 - 46, the applicants provide historical utilization of the three existing GI endoscopy rooms at LEC, and project utilization following the relocation of the one GI endoscopy room from the hospital. The applicants present the projections in a series of four steps, each of which is discussed below:

Step 1: Review Historical Utilization at LEC

In Section IV.1, pages 42 – 43, the applicants provide historical utilization of the three existing GI endoscopy rooms at LEC, as shown in the table below:

LEC Historical Utilization, FY 2012 – FY 2016*

	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016
# Procedures	5,893	6,569	6,784	6,486	6,842
# Rooms	6,870	7,287	7,441	6,989	7,392
# Procedures / Room	3	3	3	3	3
% Utilization	152.7%	161.9%	165.4%	155.3%	164.3%

Source: Page 43 of the application.

*Applicants state FY 2016 data is annualized based on six months of data

On page 43, the applicants state that the three rooms at LEC have operated in excess of 100% of capacity since FY 2012.

Step 2: Review Projected Growth in GI Endoscopy Procedures

On page 44, citing information obtained from The Advisory Board Company, which the applicant states is a national healthcare intelligence firm, the applicants project an increase in GI endoscopy procedures during the first three project years by a compound annual growth rate (CAGR) of 3.5%. This growth is based on the factors discussed in its need analysis, such as population increase projections, increase in the incidence of colorectal cancer, and the aging of the population of Guilford County.

Step 3: Review Projected Population Growth

On pages 44 – 45, the applicants examine population growth projections in the service area based on data from Truven Analytics. The applicants state the total population in Guilford County is projected to grow by 5.5% from 2016 to 2021, or a CAGR of 1.5%. However, the applicants state the population cohort most likely to utilize GI endoscopy screening and other procedures is the over 45 age cohort. That population group, according to the applicant, is projected to grow by 9.7% in Guilford County for the same time period, or a CAGR of 1.9%.

Step 4: Select Most Conservative Population Growth Rate Projection

On pages 45 – 46, the applicants compare the projected CAGR in GI endoscopy procedures from various sources they used in their research, as shown in the following table:

	CAGR
LEC 2012- 2016	1.8%
Advisory Board Projections (2015 – 2020)	3.5%
Truven Health Analytics (2016 – 2021)	1.1%
Truven Health Analytics Age 45+ (2016 – 2021)	1.9%

Source: Page 45 of the application

On page 42, the applicants project utilization at LEC for FY 2018 – FY 2020, as shown in the following table:

	FY 2018	FY 2019	FY 2020
# GI endoscopy rooms	4	4	4
# GI endoscopy procedures	7,553	7,635	7,718

Source: page 42 of the application

On page 46, the applicants state that they chose the most conservative population growth rate, 1.1%, by which to project growth in GI endoscopy procedures at LEC following the relocation of the room from Cone Health.

The historical growth in GI endoscopy procedures at LEC shows that the facility has performed in excess of 100% of capacity as defined in the Administrative Rules for at least the past five

years. The GI endoscopy rooms at Cone Health have been less utilized, and the applicants state that access and cost issues are what prevent higher utilization of those rooms.

Furthermore, the applicants adequately demonstrate that it will perform 7,635 total GI endoscopy procedures in four GI endoscopy rooms in the second operating year, FY 2019, which is an average of 1,908 procedures per room [7,635 procedures / 4 rooms = 1,908 procedures per room]. Thus, the applicants reasonably demonstrate 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 VI.2, page 56, the applicants state Cone Health and thus LEC provide GI endoscopy services to all patients regardless of economic status.

In Section VI.12, page 63, the applicants state that Medicare comprised 39.1% of LEC's historical payor mix and Medicaid comprised 2.3% of its historical payor mix for GI endoscopy services in FY 2015. In Section VI.14, page 64, the applicants project that Medicare will comprise 38.3% and Medicaid 2.4% of its projected payor mix for GI endoscopy services in the second year of operation, FY 2019.

The applicants describe charity and financial payment policies on pages 59 - 61. The applicants project, in Section VI.8, page 60, that LEC will provide \$156,869 (2.8% of net revenue) in charity care to GI endoscopy patients in the second year of operation.

In summary, the applicants adequately identify the population to be served and demonstrate the need the population proposed to be served has for one additional GI endoscopy procedure room at LEC, by relocating an existing GI endoscopy room from Cone Health. The applicants also adequately demonstrate the extent to which all residents of the service area, in particular, the underserved, will have access to the proposed services. Consequently, the application is conforming to this criterion.

- (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 applicants propose to relocate one existing GI endoscopy room from The Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center. Both facilities are in Greensboro, in Guilford County.

Table 6F: Endoscopy Room Inventory on page 99 in the 2016 SMFP consists of data submitted by GI endoscopy services providers on their 2015 License Renewal Applications (LRAs). The Guilford County providers and reported utilization are illustrated in the following table:

PROVIDER	LOCATION	# GI ENDOSCOPY ROOMS	# PROCEDURES	# PROCEDURES / ROOM
Bethany Endoscopy Medical Center	507 Lindsay St., High Point	2	1,924	962
Cone Health	1200 N. Elm St., Greensboro	8	5,534	692
Eagle Endoscopy Center	1002 N. Church St., Greensboro	4	6,429	1,607
Greensboro Specialty Surgical Center	3812 N. Elm St., Greensboro	2	1,109	555
Guilford Endoscopy Center	1593 Yanceyville St. Greensboro	2	2,560	1,280
High Point Endoscopy Center	624 Quaker Lane, High Point	3	9,496	3,165
High Point Regional Health System	601 N. Elm St., High Point	3	1,731	577
LeBauer Endoscopy Center	520 N. Elm St., Greensboro	3	7,441	2,480
Total		27	36,224	1,342

Source: 2016 License Renewal Applications and 2016 SMFP, Table 6F, page 96

According to the data, LEC performed a total of 7,441 total procedures in FY 2014. The *Performance Standards* in 10A NCAC 14C .3903(b) require an applicant to reasonably project to perform an average of “at least 1,500 GI endoscopy procedures only per GI endoscopy room, in each licensed facility that the applicant or a related entity owns in the propose service area, during the second year of operation following completion of the proposed project.” Although the Administrative Rules do not apply to this review, the performance standards are a guide for minimum utilization. In FY 2014, LEC performed an average of 2,480 GI endoscopy procedures per room, which is a utilization of 165% of the minimum utilization set forth in the Administrative Rules [2,480 procedures / 1,500 = 1.65]. In Section III.1, page 23, the applicants state that in FY 2015 LEC performed an average of 2,330 procedures per room, which is a utilization of 155% [6,989 total procedures / 3 rooms = 2,330 average procedures per room. 2,330 / 1,500 = 1.55].

In FY 2014, the eight GI endoscopy rooms located at Cone Health performed a total of 5,534 GI endoscopy procedures, which is 692 procedures per room, or 46% utilization [5,534 / 8 = 692; 692 / 1,500 = 0.461]. Therefore, relocating one of the eight rooms to LEC will not have an adverse effect on the patients currently being served at Cone Health. Furthermore, the seven GI endoscopy rooms that will remain at Cone Health will continue to adequately serve the patients needing GI endoscopy services.

In summary, the applicants adequately demonstrate that the needs of the population presently served at Cone Health will continue to be adequately met following the relocation of one of the existing GI endoscopy procedure rooms to LEC. Therefore, the application is conforming to this criterion.

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

CA

In Section III.8, pages 36 - 38, the applicants describe the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicants state that maintaining the status quo is not an effective alternative because it would not address current demand for additional endoscopy capacity in a freestanding setting. Furthermore, it would not address the current overutilization of existing space at LEC and would not allow for additional medical staff to accommodate patient needs.
- Increase Hours of Operation – The applicant states that this is not an effective alternative because it would not provide additional endoscopy capacity to meet future demands for outpatient GI endoscopy services. The applicants state that opening earlier and extending evening hours would not best serve the needs of existing and future patients or medical staff.
- Add One New GI Endoscopy Room – The applicants state this alternative is not an effective alternative because it would not allow Cone Health to maximize its existing GI endoscopy services in the most efficient manner. Furthermore, the applicants state this option would unnecessarily increase the GI endoscopy room inventory in Guilford County.

After considering those alternatives, the applicants state the alternative represented in the application is the most effective alternative to meet the identified need.

Furthermore, the application is conforming to all other statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

In summary, the applicants adequately demonstrate that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion, 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 VIII 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 The Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center and shall be licensed for a total of no more than seven gastrointestinal endoscopy**

procedure rooms at The Moses H. Cone Memorial Hospital and four gastrointestinal endoscopy procedure rooms at LeBauer Endoscopy Center 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 The Moses H. Cone Memorial Hospital.**
 - 5. 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 applicants propose to relocate one existing GI endoscopy room from the Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center.

Capital and Working Capital Costs

In Section VIII.1, page 75, the applicants state the total capital cost is projected to be as follows:

DESCRIPTION	COST
Site Costs	\$0
Construction/Renovation Costs	\$0
Equipment/Miscellaneous	\$151,737
Architect/Engineering/Consult Fees	\$170,320
TOTAL CAPITAL COST	\$322,057

Source: Table on page 75 of the application.

In Section IX, page 80, the applicants state there will be no start-up expenses or initial operating expenses associated with the project.

Availability of Funds

In Section VIII.3, page 76, the applicant states that the capital costs will be funded with the accumulated reserves of Cone Health. In Exhibit 24, the applicants provide a July 11, 2016 letter from the CFO of LEC, documenting its intention and ability to fund the capital costs for the proposed project. Exhibit 25 contains the FY 2015 audited financial statements for Cone Health which document sufficient unrestricted net assets (\$1,450,272,000) to fund the capital

costs for the proposed project. The applicants adequately demonstrate that sufficient funds will be available for the capital needs of the project.

Financial Feasibility

In the pro forma financial statements for LEC (Form B), the applicants project that revenues will exceed operating expenses in each of the first three operating years of the project, as shown in the table below:

LEC Lithotripsy Services			
	FY 2018	FY 2019	FY 2020
Total Net Patient Revenues	\$5,432,613	\$5,622,967	\$5,830,132
Total Expenses	\$3,800,212	\$3,933,870	\$4,072,503
Net Income (Loss)	\$1,625,585	\$1,691,326	\$1,759,902

The assumptions used by the applicants in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization projections found in Criterion (3) is incorporated herein by reference. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

Conclusion

In summary, the applicants adequately demonstrate that sufficient funds will be available for the capital and working capital needs of the project. Furthermore, the applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

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LEC is an existing, licensed ambulatory surgery center located in Greensboro, Guilford County. LEC is part of the Cone Health system, which also operates The Moses H. Cone Memorial Hospital, The Moses H. Cone Memorial Hospital Operating Corporation, and Moses Cone Medical Services, Inc. Cone Health proposes to relocate one existing GI endoscopy room from The Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center. Cone Health will be licensed for seven GI endoscopy rooms and LEC will be licensed for four GI endoscopy rooms following project completion. Both facilities are in Greensboro, in Guilford County. The total inventory of GI endoscopy rooms operated by Cone Health 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 2016 SMFP does not define a service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A

NCAC 14C .3901(6) does define the service area as “the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.” In Section III.5, page 29, the applicant defines its service area as Guilford County. Facilities may also serve residents of counties not included in their service area.

There are currently eight providers of GI endoscopy services in Guilford County. Each facility is located in either Greensboro or High Point, which are approximately 18 miles apart. Six of the facilities are outpatient surgical facilities, and two are hospitals (Cone Health and High Point Regional Health System). Cone Health is located approximately six minutes driving time and 3.2 miles from LeBauer endoscopy

Table 6F: Endoscopy Room Inventory on page 99 in the 2016 SMFP consists of data submitted by GI endoscopy services providers on their 2015 License Renewal Applications (LRAs). The Guilford County providers and reported utilization are illustrated in the following table:

Guilford County GI Endoscopy Utilization FY 2014

PROVIDER	LOCATION	# GI ENDOSCOPY ROOMS	# PROCEDURES	# PROCEDURES / ROOM
Bethany Endoscopy Medical Center	507 Lindsay St., High Point	2	1,924	962
Cone Health	1200 N. Elm St., Greensboro	8	5,534	692
Eagle Endoscopy Center	1002 N. Church St., Greensboro	4	6,429	1,607
Greensboro Specialty Surgical Center	3812 N. Elm St., Greensboro	2	1,109	555
Guilford Endoscopy Center	1593 Yanceyville St. Greensboro	2	2,560	1,280
High Point Endoscopy Center	624 Quaker Lane, High Point	3	9,496	3,165
High Point Regional Health System	601 N. Elm St., High Point	3	1,731	577
LeBauer Endoscopy Center	520 N. Elm St., Greensboro	3	7,441	2,480
Total		27	36,224	1,342

Source: 2016 License Renewal Applications and 2016 SMFP, Table 6F, page 96

In addition, in Section III.9, page 39, the applicants provide FY 2015 utilization in those same facilities, as shown in the following table:

Guilford County GI Endoscopy Utilization FY 2015

PROVIDER	LOCATION	# GI ENDOSCOPY ROOMS	# PROCEDURES	# PROCEDURES / ROOM
Bethany Endoscopy Medical Center	507 Lindsay St., High Point	2	2,057	1,029
Cone Health	1200 N. Elm St., Greensboro	8	5,822	728
Eagle Endoscopy Center	1002 N. Church St., Greensboro	4	6,020	1,505
Greensboro Specialty Surgical Center	3812 N. Elm St., Greensboro	2	455	228
Guilford Endoscopy Center	1593 Yanceyville St. Greensboro	2	2,322	1,161
High Point Endoscopy Center	624 Quaker Lane, High Point	3	6,191	2,064
High Point Regional Health System	601 N. Elm St., High Point	3	1,327	442
LeBauer Endoscopy Center	520 N. Elm St., Greensboro	3	6,486	2,162
Total		27	30,680	1,136

Source: Page 39 of the application

The tables show that LeBauer Endoscopy Center continues to perform in excess of 140% of the minimum utilization of 1,500 GI endoscopy procedures per room. Furthermore, the existing GI endoscopy rooms at Cone Health continue to be utilized at between 46% - 48%, although utilization increased from FY 2014 to FY 2015. The applicants' proposal to relocate one existing licensed GI endoscopy room from Cone Health to LeBauer Endoscopy Center will allow Cone Health to continue to provide GI endoscopy services to its patients; indeed, relocating a room to an outpatient center will allow Cone Health to respond to increasing market demands for those services in an outpatient setting (see page 15).

The applicants adequately demonstrate that relocating one existing GI endoscopy room from The Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center would not result in an unnecessary duplication of existing or approved health service capabilities or facilities.

Therefore, the application is conforming to this criterion.

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

C

In Section VII.1, page 66, the applicants project to employ a total of 1.66 new FTE registered nurses, 1.76 new FTE aides, orderlies or attendants, and 0.9 FTE "non-health" and "technical" personnel in the second year of the project. In Section VII.3, page 67, the applicants describe the experience and process for recruiting and retaining staff. Exhibit 18 contains a letter from Daniel P. Jacobs, M.D., current medical director of LEC, expressing his commitment to continue to serve in that capacity. Exhibit 18 also contains letters from area physicians and other healthcare providers expressing support for the proposed project. The applicants adequately demonstrate the availability of sufficient health manpower and management personnel to provide the proposed services. Therefore, the application is conforming to this criterion.

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

C

In Section II.2, page 16, the applicants describe the manner in which they will continue to provide all necessary ancillary and support services. Exhibit 18 contains letters of support from physicians and other health care providers. The applicants adequately demonstrate that necessary ancillary and support services are currently available and will continue to be available and that the proposed endoscopy services will be coordinated with the existing healthcare system. Therefore, 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

- (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

- (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

- (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 Sections VI.12 and VI.13, pages 63 - 64, the applicants provide the following payor mix for LEC for FY 2015:

PAYOR	PERCENT OF TOTAL
Commercial / Managed Care	55.7%
Medicare / Medicare Managed Care	39.1%
Medicaid	2.3%
Self Pay / Indigent	2.1%
Other (Tricare, other payors)	0.8%
Total	100.0%

Source: Tables on pages 63 and 64 of the application

The United States Census Bureau provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	% 65+	% Female	% Racial & Ethnic Minority*	% Persons in Poverty**	% < Age 65 with a Disability	% < Age 65 without Health Insurance**
Guilford	14%	53%	48%	17%	7%	18%
Statewide	15%	51%	36%	17%	10%	15%

Source: <http://www.census.gov/quickfacts/table>, 2014 Estimate as of December 22, 2015.

*Excludes "White alone" who are "not Hispanic or Latino"

**"This geographic level of poverty and health estimates are not comparable to other geographic levels of these estimates. Some estimates presented here come from sample data, and thus have sampling errors that may render some apparent differences between geographies statistically indistinguishable...The vintage year (e.g., V2015) refers to the final year of the series (2010 thru 2015). Different vintage years of estimates are not comparable."

However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities, women or handicapped persons utilizing health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. 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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 63, the applicants state, “Cone Health has no obligation under applicable federal regulations to provide uncompensated care, community service, or access to care by minorities and handicapped persons. However, Cone Health is dedicated to providing care for all in its communities.” In Exhibits 15 and 20, the applicants provide copies of Cone Health’s Financial Assistance Program and policy and a report that details charity care policies which were followed in FY 2015. In Section VI.10 (a), page 62, the applicants state that no civil rights access complaints have been filed against it in last five years. 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 VI.14, page 64, the applicants project the following payor mix for GI endoscopy services at LEC during the second operating year (FY 2019):

PAYOR	PERCENT OF TOTAL
Commercial / Managed Care	56.2%
Medicare / Medicare Managed Care	38.3%
Medicaid	2.7%
Self Pay / Indigent	2.4%
Other (Tricare, other payors)	0.4%
Total	100.0%

Source: Table on page 64 of the application

On page 64, the applicants state projected payor mix is based upon its actual year-to-date 2016 (through March 2016) payor mix at LEC. The applicants demonstrate that the medically underserved population will continue to have adequate access to the proposed GI endoscopy services. Therefore, the application is conforming to this criterion.

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

C

In Section VI.9(a), page 61, the applicants describe the range of means by which a person will have access to the GI endoscopy services. The applicants state patients may be referred by physicians or even self-referral for screening services. The applicants

adequately demonstrate that LEC will offer a range of means by which patients will have access to the proposed services. 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 Section V.1, pages 47 - 49, the applicants provide information with regard to Cone Health's affiliations with area health professional training programs. A list of sites with which Cone Health currently has clinical training programs is provided on pages 47 – 48. The information provided is reasonable and credible and supports a finding of conformity with 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

LEC is an existing, licensed ambulatory surgery center located in Greensboro, Guilford County. LEC is owned by Cone Health, which also owns The Moses H. Cone Memorial Hospital. Cone Health proposes to relocate one existing GI endoscopy room from The Moses H. Cone Memorial Hospital to LeBauer Endoscopy Center. Both facilities are in Greensboro, in Guilford County.

The 2016 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.*” Therefore, the service area for this review is Guilford County. An applicant may also serve residents of counties not included in its service area.

LeBauer Endoscopy Center is one of eight providers of GI endoscopy services in its defined service area (Guilford County). The table below lists information about all providers of GI endoscopy services in Guilford County (taken from Table 6F, pages 93-102, of the 2016 SMFP).

Guilford County GI Endoscopy Utilization FY 2014

PROVIDER	LOCATION	# GI ENDOSCOPY ROOMS	# PROCEDURES	# PROCEDURES / ROOM
Bethany Endoscopy Medical Center	507 Lindsay St., High Point	2	1,924	962
Cone Health	1200 N. Elm St., Greensboro	8	5,534	692
Eagle Endoscopy Center	1002 N. Church St., Greensboro	4	6,429	1,607
Greensboro Specialty Surgical Center	3812 N. Elm St., Greensboro	2	1,109	555
Guilford Endoscopy Center	1593 Yanceyville St. Greensboro	2	2,560	1,280
High Point Endoscopy Center	624 Quaker Lane, High Point	3	9,496	3,165
High Point Regional Health System	601 N. Elm St., High Point	3	1,731	577
LeBauer Endoscopy Center	520 N. Elm St., Greensboro	3	7,441	2,480
Total		27	36,224	1,342

Source: 2016 License Renewal Applications and 2016 SMFP, Table 6F, page 96

LeBauer Endoscopy Center has performed and continues to perform in excess of 140% of the minimum utilization of 1,500 GI endoscopy procedures per room. Furthermore, the existing GI endoscopy rooms at Cone Health continue to be utilized at between 46% - 48%, although utilization increased from FY 2014 to FY 2015. The applicants' proposal to relocate one existing licensed GI endoscopy room from Cone Health to LeBauer Endoscopy Center will allow Cone Health to continue to provide GI endoscopy services to its patients and also allow LEC to provide additional GI endoscopy capacity where it is needed. Indeed, relocating an existing GI endoscopy room to an outpatient center will allow Cone Health to respond to increasing market demands for those services in an outpatient setting (see page 15).

In Section V.7, pages 54 - 55, the applicants discuss the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality, and access. The applicant states that prior to its presence in the region, the only option for GI endoscopy procedures was via hospital-based providers, and that it has provided a regional choice for cost-effective, efficient, and state of the art endoscopic procedures.

See also Sections II, III, V, VI, and VII of the application where the applicants discuss the impact of the project on cost effectiveness, quality, and access.

The information provided by the applicants in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to GI endoscopy services. This determination is based on the information in the application and the following analysis:

- The applicants adequately demonstrate the need for the project and that it is a cost-effective alternative. The discussions regarding the analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicants adequately demonstrate they will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.

- The applicants demonstrate that they will provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3) and (13) is incorporated herein by reference.

Therefore, the application is conforming to this criterion.

- (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 Exhibit 4, Cone Health provides a list of health care facilities it currently owns, leases or manages in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of this application through the date of the decision, no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, all of the facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at both 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