

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: June 23, 2016

Findings Date: June 23, 2016

Project Analyst: Julie Halatek

Team Leader: Fatimah Wilson

Project ID #: A-11151-16

Facility: Western Carolina Endoscopy Center

FID #: 090837

County: Macon

Applicant: Western Carolina Endoscopy Center, LLC

Project: Develop a second licensed GI endoscopy procedure room in existing space

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Western Carolina Endoscopy Center (WCEC) is an existing, licensed ambulatory surgery center with one gastrointestinal (GI) endoscopy procedure room located in Franklin, in Macon County. The applicant proposes to develop a second licensed GI endoscopy procedure room in existing space. The total cost for the proposed project is \$196,539.

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 (SMFP). In addition, no policies in the 2016 SMFP are applicable to this review. 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- (2) Repealed effective July 1, 1987.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

WCEC is an existing, licensed ambulatory surgery center located in Franklin, Macon County, which operates one GI endoscopy procedure room. WCEC proposes to develop a second GI endoscopy procedure room in existing space.

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. Therefore, the service area for this review is Cherokee, Clay, Graham, Haywood, Jackson, Macon, and Swain counties. The applicant may also serve residents of counties not included in its service area.

In Sections III.6 and III.7, pages 15-16, the applicant provides the current and projected patient origin for GI endoscopy services provided at WCEC, as illustrated in the following table:

WCEC Current & Projected Patient Origin by County		
County	Historical Patient Origin (CY2015)	Projected Patient Origin (CY2016/17)
Macon	36%	36%
Jackson	27%	27%
Swain	12%	12%
Cherokee	7%	7%
Graham	5%	5%
Haywood	2%	2%
Other	11%	11%
Total	100%	100%

The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section III.1, page 13, the applicant states that the following factors support the need to develop an additional GI endoscopy procedure room at WCEC:

- Since originally licensed in 2007 there has been a consistent increase in utilization.

Utilization increased 32 percent between FY 2013 and FY 2014 and increased an additional 14 percent between FY 2014 and FY 2015.

- The utilization threshold for a single GI endoscopy procedure room has been exceeded.
- Because the utilization threshold for a single GI endoscopy procedure room has been exceeded, there have been delays in patient scheduling even with periods of extended hours of operation.

Consistent Increase in Utilization

On page 13, the applicant provides the following information regarding utilization of the single GI endoscopy procedure room, as shown in the table below.

WCEC Procedures – 2010-2015 (2016 Projected)							
Procedure	FY 2010	FY 2011	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016*
Colonoscopy	1,029	968	1,253	1,180	1,485	1,713	1,952
EGD	509	485	604	603	886	990	1,129
Sigmoidoscopy	11	13	22	36	34	31	35
Total Procedures	1,549	1,466	1,879	1,821	2,407	2,734	3,116

*Projected

Utilization Threshold Exceeded

In the Criteria and Standards for GI Endoscopy Procedure Rooms in Licensed Health Service Facilities, 10A NCAC 14C .3903(b), the performance standard is 1,500 GI endoscopy only procedures per room per year. In FY 2015, the applicant exceeded the performance threshold by almost double (2,734 procedures / 1,500 procedures per room = 1.82; 1.82 / 1 = 1.82 or 182 percent).

The applicant adequately demonstrates the need to develop a second GI endoscopy procedure room.

Projected Utilization

In Section IV, page 19, the applicant provides projected utilization as shown in the following table.

WCEC Procedures – Projected Utilization Operating Years 1-3						
	FY 2014	FY 2015	FY 2016	FY 2017 (OY1)	FY 2018 (OY2)	FY 2019 (OY3)
# of Rooms	1	1	1	2	2	2
# of Procedures	2,407	2,734	3,116	3,552	4,049	4,616

As shown in the table above, the applicant projects to be performing 4,049 GI endoscopy procedures in two GI endoscopy rooms during the second year following project completion,

or 2,024 procedures per room. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

On page 19, the applicant states that it made its utilization projections by assuming a 14 percent increase each year, the same as the utilization percentage increase from FY 2014 to FY 2015, and applying the 14 percent increase in utilization to subsequent years through FY 2019.

Because utilization in certain previous years had not increased as much as the rate the applicant used for its projections, the Project Analyst calculated the Compound Annual Growth Rate (CAGR) for WCEC to find out if the utilization projections by the applicant were reasonable and adequately supported. The results are shown in the table below.

WCEC Five Year CAGR – FY 2010 – FY 2015		
Year	# of Procedures	Percent change
FY 2010	1,549	--
FY 2011	1,466	-5.4%
FY 2012	1,879	28.2%
FY 2013	1,821	-3.1%
FY 2014	2,407	32.2%
FY 2015	2,734	13.6%
Five Year CAGR		13.1%

With a Five Year CAGR of 13.1 percent, it is reasonable for the applicant to assume a 14 percent increase in utilization each year.

The applicant adequately demonstrates that it is reasonable to assume it will perform 4,616 GI endoscopy procedures in two GI endoscopy procedure rooms in the second operating year, CY2018, which is an average of 2,308 procedures per room [4,616 procedures / 2 rooms = 2,308 procedures per room]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room per year as required by 10A NCAC 14C .3903(b).

Projected utilization of GI endoscopy procedures is based on reasonable and adequately supported assumptions regarding continued growth.

Access

In Section VI.2, page 23, in response to a question about accessibility of services, the applicant states that it has a relationship with the Good Samaritan Clinic in Jackson County to assist low income persons; it serves many patients from the Cherokee Health Service (Native American); the majority of its patients are women; the facility is handicapped accessible with accommodations available; and that it provides financial counseling for patients as well as charity care. In Section VI.12, page 26, the applicant reports that 24 percent of the patients who received services at WCEC had some or all of their services paid

for by Medicare or Medicaid in CY 2015. The historical payor mix for patients as a percent of total cases is shown in the table below.

WCEC Historical Payor Mix – CY 2015	
Payor	% of Procedures
Self-Pay/Indigent	1%
Commercial	70%
Medicare/Medicare Managed Care	21%
Medicaid	3%
Other – Gov't	5%
Total	100%

In Section VI.14, page 27, the applicant projects that 24 percent of the patients who will receive treatments at WCEC in the second operating year (FY 2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility.

WCEC Projected Payor Mix – FY 2018	
Payor	% of Procedures
Self-Pay/Indigent	1%
Commercial	70%
Medicare/Medicare Managed Care	21%
Medicaid	3%
Other – Gov't	5%
Total	100%

In supplemental information received June 21, 2016, the applicant states that some of the patients reported under the Commercial payor mix are Medicare patients who are on Medicare-replacement plans (such as Medicare Part C plans).

The applicant adequately demonstrates the extent to which all residents of the service area, including underserved groups, are likely to have access to its services.

Conclusion

In summary, the applicant adequately identifies the population to be served, demonstrates the need the population has for an additional GI endoscopy procedure room, and demonstrates the extent to which all residents of the area, including underserved groups, are likely to have access to the services proposed. Therefore, 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.

NA

- (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 16-17, the applicant describes the alternatives considered prior to submitting this application for the proposed project, which include:

- Maintain the Status Quo –The applicant states that this alternative was dismissed due to the growth rate of the patient population at WCEC and because it will hit its physical capacity of 3,000 cases per year in the current year (2016).
- Use Local Hospital GI Endoscopy Procedure Rooms – The applicant states this alternative was dismissed because freestanding GI endoscopy centers provide services at a lower cost than hospitals.
- Engage in a Joint Venture/Build a Separate GI Endoscopy Center – The applicant states this alternative was dismissed as cost prohibitive since the facility was built new in 2014 and its design had incorporated a second GI endoscopy procedure room (identical to the licensed room) in the event additional capacity was needed.

After considering those alternatives, the applicant states 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 applicant adequately demonstrates that the proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions.

1. **Western Carolina Endoscopy Center, LLC shall materially comply with all representations made in the certificate of need application and supplemental information received June 21, 2016. In those instances where representations conflict, Western Carolina Endoscopy Center, LLC shall materially comply with the last made representation.**
2. **Western Carolina Endoscopy Center, LLC shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **Western Carolina Endoscopy Center, LLC shall develop no more than one additional gastrointestinal endoscopy procedure room and shall be licensed for a total of no more than two gastrointestinal endoscopy procedure rooms at Western Carolina Endoscopy Center following project completion.**
 4. **Prior to the issuance of a certificate of need, Western Carolina Endoscopy Center, LLC shall provide to the Agency documentation of an attempt to establish a relationship or an established relationship with at least one health professional training program in the area as required by G.S. 131E-183(a)(14).**
 5. **Western Carolina Endoscopy Center, LLC 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 develop a second GI endoscopy procedure room in existing space at its current location.

Capital and Working Capital Costs

In Section VIII.2, pages 35-37, the applicant states that the projected capital cost is \$196,539, which includes \$122,504 for endoscopic equipment, \$23,000 for construction, \$25,035 in miscellaneous project costs (such as furniture and landscaping), and \$26,000 for contingency funds.

In supplemental information received June 21, 2016, the applicant projects working capital costs of \$6,413 for one month of training for an additional endoscopy technician and registered nurse.

Availability of Funds

In Section VIII.3, page 37, and Section IX.2, page 41, the applicant states that cash reserves/owner's equity is being used to finance the proposed project. Exhibit 25 contains a March 7, 2016 letter from Dr. Philip Stack, a Member Manager of Western Carolina, which states:

"This letter serves as a commitment that \$220,000 in cash is available and has been set aside in an account within Western Carolina Endoscopy Center that will be [sic] solely be used to complete the proposed endoscopy room project.

Exhibit 29 contains an unaudited balance sheet for WCEC from 2014. According to the balance sheet, in 2014 Western Carolina Endoscopy Center, LLC had \$17,000 in cash and cash equivalents, \$542,287 in total assets and \$299,963 in net assets (contained in a fund balance). The applicant adequately demonstrates the availability of funds for the capital needs of the project.

Financial Feasibility

The applicant provides pro forma financial statements for the first two years of the project. In the pro forma financial statement (Form B), the applicant projects that revenues will exceed operating expenses in the first two operating years of the project, as shown in the table below.

Projected Revenues and Operating Expenses		
WCEC	Operating Year 1 FY 2017	Operating Year 2 FY 2018
Gross Patient Revenue	\$2,501,324	\$2,892,102
Deductions from Gross Patient Revenue	(\$1,100,484)	(\$1,270,343)
Net Patient Revenue	\$1,400,840	\$1,621,759
Total Operating Expenses	\$1,198,005	\$1,230,693
Net Income/Profit	\$202,835	\$391,066

The applicant’s projections of treatments and revenues are reasonable based on the number of patients projected for the first two operating years. See the financial section of the application for the assumptions used regarding costs and charges. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

In Section VII.2, pages 29-30, the applicant provides projected staffing and salaries. Form B in the pro formas section shows budgeted operating costs adequate to cover the projected staffing. The discussion regarding staffing found in Criterion (7) is incorporated herein by reference.

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges.

Conclusion

In summary, the applicant adequately demonstrates 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.

C

WCEC is an existing, licensed ambulatory surgery center located in Franklin, Macon County, which operates one GI endoscopy procedure room. WCEC proposes to develop a second GI endoscopy procedure room in existing space.

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 Cherokee, Clay, Graham, Haywood, Jackson, Macon, and Swain counties. The applicant may also serve residents of counties not included in its service area.

The applicant is one of seven providers of GI endoscopy services in its defined service area. The table below lists information about all providers of GI endoscopy services in the applicant's identified service area (taken from Table 6F, pages 93-102, of the 2016 SMFP).

GI Endoscopy Service Providers in Cherokee, Clay, Graham, Haywood, Jackson, Macon, & Swain Counties (FY 2014 data)				
Provider	County	Type of Facility	# of Endoscopy Rooms	# of Procedures
Murphy Medical Center	Cherokee	Hospital	2	905
Haywood Regional Medical Center	Haywood	Hospital	3	2,866
Harris Regional Hospital	Jackson	Hospital	1	2,739
Angel Medical Center	Macon	Hospital	2	635
Highlands-Cashiers Hospital	Macon	Hospital	2	110
Western Carolina Endoscopy Center	Macon	Freestanding	1	1,981
Swain Community Hospital	Swain	Hospital	1	0
Total			12	9,236

WCEC is the only freestanding GI endoscopy provider in its service area. In Section III.9, pages 17-18, the applicant states that hospital-based providers of GI endoscopy services are unable to provide the most cost-effective and efficient care for patients as compared to private or freestanding GI endoscopy providers. Exhibit 17 contains a cost estimate from Blue Cross/Blue Shield of North Carolina (BCBSNC), showing the average patient costs for a colonoscopy with biopsy for WCEC and for Harris Regional Hospital in Jackson County. According to the cost estimate, the total average BCBSNC patient cost of this specific procedure is \$1,713 at WCEC and \$5,842 at Harris Regional Hospital.

The applicant states that the need for an additional GI endoscopy procedure room is based on increasing utilization. In FY 2015, the applicant exceeded the performance threshold by almost double (2,734 procedures / 1,500 procedures per room = 1.82; 1.82 / 1 = 1.82 or 182 percent). The applicant projects to be performing 4,049 GI endoscopy procedures in two GI endoscopy procedure rooms during the second year following project completion, or 2,024 procedures

per room. This exceeds the minimum of 1,500 GI endoscopy procedures per room per year as of the end of the second operating year as required by 10A NCAC 14C .3903(b).

The applicant adequately demonstrates the need to develop a second GI endoscopy procedure room based on the number of patients it currently serves and proposes to serve. Projected utilization is based on reasonable and adequately supported assumptions regarding continued growth. The discussion regarding analysis of need found in Criterion (3) is incorporated herein by reference.

The applicant adequately demonstrates that the proposal will not result in the unnecessary duplication of existing or approved health service capabilities or facilities in the defined service area. Consequently, 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 Sections VII.1 and VII.2, pages 29-30, the applicant provides the current and proposed staffing for its GI endoscopy services for the first full fiscal year, FY 2017, as illustrated in the table below:

WCEC Staffing – Current & Projected (First FFY)			
Position	Current Staff (FTEs)	Projected Staff Additions (FTEs)	Total Projected Staff (FTEs) Project Year 1 FY 2017
Administrator	1.54	0.0	1.54
Registered Nurse (RN)	3.0	1.0	4.0
Endoscopy Technician	2.0	1.0	3.0
Medical Records/Admin.	0.2	0.0	0.2
Non-health/technical personnel	2.6	0.07	2.67
Totals	9.34	2.07	11.41

WCEC will add one additional full-time Registered Nurse and one additional full-time Endoscopy Technician to its staff to accommodate the proposed project. In Section VII.7, page 33, the applicant states that management often initiates contact with potential employees but it will use outside services as well as local training centers to recruit staff. In Section VII.7, page 33, the applicant states that Dr. Philip Stack will continue to serve as the Medical Director at WCEC.

The applicant adequately documents the availability of sufficient health manpower and management personnel to staff the proposed new GI endoscopy procedure room at WCEC. 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, pages 7-8, the applicant discusses all of the ancillary and support services it provides and will continue to provide for the proposed GI endoscopy services. A table is provided on page 7 that lists all of the services needed and indicates the in-house staff and contracted providers who will provide each of the services. Exhibit 7 contains a more detailed list of all ancillary and support service provider information. On page 7, the applicant states that it has a transfer agreement with Angel Medical Center to provide emergency services if required. The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed 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

The applicant proposes to develop a second GI endoscopy procedure room in existing space. In Section XI, pages 47-50, the applicant states that the existing space is already constructed and needs only minor finishing work and equipment installed to complete the project. The discussion regarding costs and charges found in Criterion (5) is incorporated herein by reference. Therefore, this criterion is not applicable to this review.

- (13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:
- (a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section VI.12, page 26, the applicant reports that 24 percent of the patients who received services at WCEC had some or all of their services paid for by Medicare or Medicaid in CY 2015. The historical payor mix for patients as a percent of total cases is shown in the table below.

WCEC Historical Payor Mix – CY 2015	
Payor	% of Procedures
Self-Pay/Indigent	1%
Commercial	70%
Medicare/Medicare Managed Care	21%
Medicaid	3%
Other – Gov't	5%
Total	100%

In supplemental information received June 21, 2016, the applicant states that some of the patients reported under the Commercial payor mix are Medicare patients who are on Medicare-replacement plans (such as Medicare Part C plans).

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**
Cherokee	27%	51%	8%	21%	15%	22%
Clay	28%	51%	6%	19%	11%	22%
Graham	22%	51%	13%	21%	7%	22%
Haywood	24%	52%	7%	15%	11%	19%
Jackson	18%	51%	19%	24%	9%	25%
Macon	26%	51%	10%	18%	12%	25%
Swain	19%	52%	36%	19%	9%	23%
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

In Section VI.11, page 26, the applicant states that it has no obligation to provide uncompensated care or community service under federal regulations. In Section VI.10, page 26, the applicant states there have been no civil rights access complaints filed within the last five years. Therefore, 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 27, the applicant projects that 24 percent of the patients who will receive treatments at WCEC in the second operating year (FY 2018) will have some or all of their services paid for by Medicare or Medicaid. The table below shows the projected OY2 payor mix for the facility.

WCEC Projected Payor Mix – FY 2018	
Payor	% of Procedures
Self-Pay/Indigent	1%
Commercial	70%
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Medicaid	3%
Other – Gov't	5%
Total	100%

In supplemental information received June 21, 2016, the applicant states that some of the patients reported under the Commercial payor mix are Medicare patients who are on Medicare-replacement plans (such as Medicare Part C plans).

The applicant demonstrates that medically underserved groups will have adequate access to the services offered at WCEC. 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, pages 25-26, the applicant describes the range of means by which a person will have access to the GI endoscopy services at WCEC, including referrals from physicians at several types of medical practices. The applicant adequately demonstrates that the facility will offer a range of means by which patients will have access to GI endoscopy 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.

CA

In Section V.1, page 20, the applicant states that it has informal relationships with Western Carolina University and Southwestern Community College and that formal relationships will be developed to allow for student access to the facility and its providers. The applicant states that

Dr. Philip Stack and Dr. Charles Barrier both currently teach students at Western Carolina University and Southwestern Community College; however, there is no relevant documentation found in the application to demonstrate the existence of a relationship between the applicant and health professional training programs in the area. The application is conforming to this criterion, subject to the applicant demonstrating the existence of a relationship or attempts to establish a relationship with health professional training programs in the area. See Criterion (4) Condition 4.

- (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

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The applicant is one of seven providers of GI endoscopy services in its defined service area. The table below lists information about all providers of GI endoscopy services in the applicant's identified service area (taken from Table 6F, pages 93-102, of the 2016 SMFP).

GI Endoscopy Service Providers in Cherokee, Clay, Graham, Haywood, Jackson, Macon, & Swain Counties (FY 2014 data)				
Provider	County	Type of Facility	# of Endoscopy Rooms	# of Procedures
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Haywood Regional Medical Center	Haywood	Hospital	3	2,866
Harris Regional Hospital	Jackson	Hospital	1	2,739
Angel Medical Center	Macon	Hospital	2	635
Highlands-Cashiers Hospital	Macon	Hospital	2	110
Western Carolina Endoscopy Center	Macon	Freestanding	1	1,981
Swain Community Hospital	Swain	Hospital	1	0
Total			12	9,236

WCEC is the only freestanding GI endoscopy provider in its service area. In Section III.9, pages 17-18, the applicant states that hospital-based providers of GI endoscopy services are unable to provide the most cost-effective and efficient care for patients as compared to private or freestanding GI endoscopy providers. Exhibit 17 contains a cost estimate from Blue Cross/Blue Shield of North Carolina (BCBSNC), showing the average patient costs for a colonoscopy with biopsy for WCEC and for Harris Regional Hospital in Jackson County. According to the cost estimate, the total average BCBSNC patient cost of this specific procedure is \$1,713 at WCEC and \$5,842 at Harris Regional Hospital.

In Section V.7, page 22, the applicant discusses 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 applicant discusses the impact of the project on cost effectiveness, quality, and access.

The information provided by the applicant 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 applicant adequately demonstrates 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 applicant adequately demonstrates it will provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant demonstrates that it 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

WCEC is accredited by The Joint Commission and is certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, no incidents occurred at the facility within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State on any facility owned and operated by WCEC in North Carolina. 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.

C

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

.3903 PERFORMANCE STANDARDS

- (a) *In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays.*

-NA- The applicant does not propose to operate any surgical operating rooms. In Section II, page 8, the applicant states that WCEC hours of operation are 6:30 a.m. to 5:00 p.m. Monday through Friday.

- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project.*
- C- In Section IV, page 19, the applicant projects that WCEC will perform 4,049 GI endoscopy procedures during Project Year Two, FY 2017, using two GI endoscopy procedure rooms, which is an average of 2,025 procedures per room (4,049 procedures / 2 GI endoscopy procedure rooms = 2,024.5 procedures per room).

The applicant provides the assumptions and methodology used to project utilization on page 19. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section II, page 11, the applicant lists several types of procedures it currently performs and states it will continue to provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at WCEC.
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.*
- NA- In Section II, page 12, the applicant states that it does not own or operate any surgical operating rooms in the proposed service area.

- (e) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule.*
- C- In Section IV, page 19, the applicant describes the assumptions and methodology it uses to project GI endoscopy procedures. The discussion regarding the projected utilization found in Criterion (3) is incorporated herein by reference.