

REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conforming as Conditioned

NC = Nonconforming

NA = Not Applicable

Decision Date: July 26, 2024

Findings Date: July 26, 2024

Project Analyst: Tanya M. Saporito

Co-Signer: Micheala Mitchell

Project ID #: J-12477-24

Facility: Wake Endoscopy Center-North

FID #: 240127

County: Wake

Applicant: Wake Endoscopy Center, LLC

Project: Develop a new ASF with no more than two GI endoscopy rooms

REVIEW CRITERIA

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

Wake Endoscopy Center, LLC (hereinafter referred to as “the applicant”, or WECLLC), proposes to develop a new ambulatory surgical facility (ASF), Wake Endoscopy Center-North (WEC-North), in Raleigh, Wake County with no more than two gastrointestinal endoscopy (GI) procedure rooms upon project completion.

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2024 SMFP,
- acquire any medical equipment for which there is a need determination in the 2024 SMFP,

- offer a new institutional health service for which there are any policies in the 2024 SMFP.

Therefore, 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- (2) Repealed effective July 1, 1987.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, persons with disabilities, the elderly, and other underserved groups are likely to have access to the services proposed.

C

WECLLC owns and operates two licensed ASFs in Wake County: WEC-Raleigh and WEC-Cary and was approved in 2023 to develop a third ASF in Wake County, WEC-Holly Springs, which is projected to begin operating at the end of 2024. WECLLC also co-owns and provides physician services to Wake Forest Endoscopy Center (WFEC). In this application, the applicant proposes to lease space in a previously-approved medical office building (MOB) currently under development in Raleigh and develop a new ASF with no more than two GI endoscopy procedure rooms upon project completion.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 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), defines the service area as “*the county where the proposed GI endoscopy room will be developed.*” The proposed facility will be developed in Wake County. Thus, the service area for the proposed facility is Wake County. Facilities may also serve residents of counties not included in their service area.

The applicant proposes to develop a new freestanding GI endoscopy facility; therefore, there is no historical patient origin to report.

In Section C, pages 31-32, the applicant provides the following table to illustrate projected patient origin, which includes 22 ZIP codes in northern Wake County and nine ZIP codes in southern Virginia:

COUNTY/ZIP	1 ST FULL FY (CY 2026)		2 ND FULL FY (CY 2027)		3 RD FULL FY (CY 2028)	
	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL	# PTS.	% OF TOTAL
23915, Baskerville, Mecklenburg Co., VA	4	0.2%	5	0.2%	5	0.2%
23917, Boydton, Mecklenburg Co., VA	11	0.4%	12	0.4%	13	0.4%
23919, Bracey, Mecklenburg Co., VA	10	0.4%	11	0.4%	12	0.4%
23920, Brodnax, Brunswick Co., VA	12	0.5%	14	0.5%	15	0.5%
23924, Chase City, Mecklenburg Co., VA	21	0.9%	24	0.9%	27	0.9%
23927, Clarksville, Mecklenburg Co., VA	18	0.7%	20	0.7%	22	0.7%
23944, Kenbridge, Lunenburg Co., VA	14	0.6%	16	0.6%	18	0.6%
23950, La Crosse, Mecklenburg Co., VA	12	0.5%	14	0.5%	15	0.5%
23970, South Hill, Mecklenburg Co., VA	31	1.3%	35	1.3%	40	1.3%
27508, Bunn, Franklin Co., NC	8	0.3%	9	0.3%	10	0.3%
27525, Franklinton, Franklin Co., NC	75	3.1%	86	3.2%	98	3.2%
27536, Henderson, Vance Co., NC	61	2.5%	69	2.5%	76	2.5%
27537, Henderson, Vance Co., NC	90	3.8%	102	3.7%	113	3.7%
27544, Kittrell, Vance Co., NC	15	0.6%	16	0.6%	18	0.6%
27545, Knightdale, Wake Co., NC	141	5.9%	162	5.9%	183	5.9%
27549, Louisburg, Franklin Co., NC	106	4.4%	121	4.4%	137	4.4%
27551, Macon, Warren Co., NC	9	0.4%	10	0.4%	11	0.4%
27553, Manson, Warren Co., NC	8	0.3%	9	0.3%	10	0.3%
27556 Middleburg, Vance Co., NC	0	0.0%	0	0.0%	0	0.0%
27563, Norlina, Warren Co., NC	19	0.8%	21	0.8%	23	0.8%
27571, Rolesville, Wake Co., NC	38	1.6%	43	1.6%	49	1.6%
27587, Wake Forest, Wake Co., NC	338	14.1%	389	14.2%	441	14.3%
27589, Warrenton, Warren Co., NC	26	1.1%	29	1.1%	33	1.1%
27591, Wendell, Wake Co., NC	110	4.6%	126	4.6%	143	4.6%
27596, Youngsville, Franklin Co., NC	87	3.6%	100	3.7%	114	3.7%
27597, Zebulon, Wake Co., NC	123	5.1%	141	5.1%	160	5.2%
27613, Raleigh, Wake Co., NC	189	7.9%	214	7.8%	240	7.8%
27614, Raleigh, Wake Co., NC	144	6.0%	164	6.0%	184	6.0%
27615, Raleigh, Wake Co., NC	173	7.2%	196	7.2%	219	7.1%
27616, Raleigh, Wake Co., NC	243	10.1%	277	10.1%	313	10.2%
27850, Littleton, Halifax Co., NC	24	1.0%	27	1.0%	30	1.0%
Other*	240	10.0%	274	10.0%	308	10.0%
Total	2,399	100.0%	2,736	100.0%	3,081	100.0%

*On page 32, the applicant states "other" includes "the remainder of North Carolina and Virginia, and all other states."

In Section C, page 32, the applicant provides assumptions and methodology used to project its patient origin. The applicant's assumptions are reasonable and adequately supported based on the following:

- Since the applicant proposes to develop the WEC-North facility in Raleigh near the existing Wake Forest facility, the applicant bases projected patient origin for the proposed facility on historical patient origin for the Wake Forest facility.

- The applicant projects patient origin based on its analysis of projected population growth in the proposed service area, high utilization of existing GI endoscopy procedure rooms, and the lack of sufficient GI endoscopy procedure room capacity

Analysis of Need

In Section C, pages 35-51, the applicant explains why it believes the population projected to be served by the proposed project needs the proposed services, as summarized below:

- GI endoscopy access issues – The applicant researched data from the Sheps Center Health Professional Database and determined there is a shortage of gastroenterologists throughout the state, including Wake County. The applicant states the same data shows there are no gastroenterologists in Franklin or Warren counties and only one in Vance County. Those counties are included in the applicant’s catchment area. Additionally, the applicant states reimbursement rates for GI endoscopy services vary and providing those services in a freestanding ASF allows for lower cost services for patients in need of GI endoscopy services (*pages 36-39*).
- Land development in northern Wake County and adjacent communities – The applicant states 2022 Wake County Planning Department data shows significant commercial and residential planning in the catchment area, particularly in the WEC-North catchment area, that indicates the catchment area has experienced and is projected to experience significant population growth. Additionally, the applicant states traffic congestion in the area and travel time within Wake County indicate a need for additional GI endoscopy services to serve residents of the proposed catchment area who otherwise must travel 45 minutes or more for those services (*pages 39-41*).
- Patient in-migration to Wake County for GI endoscopy services – The applicant states that, because of the lack of access to GI endoscopy services in rural and non-urban counties, many patients from counties surrounding Wake County travel to Wake County for GI endoscopy services (page 41).
- Wake County as a referral center – The applicant examined historical patient origin patterns for existing Wake County GI endoscopy providers and determined that in FY 2022, 25.2% of non-Wake County residents sought GI endoscopy services at a Wake County provider. The applicant also examined its FFY 2023 internal data and found that between 51.2% and 78.7% of all GI endoscopy procedures performed at a WECLLC facility in FFY 2023 were performed on non-Wake County residents (*pages 42-43*).
- Wake County and the catchment area population growth – The applicant examined population growth projections from the North Carolina Office of State Budget and Management (NCOSBM) which show the Wake County population is projected to increase by a compound annual growth rate (CAGR) of 2.0%

between CY 2024-2029, compared to a 1.1% CAGR in the state as a whole. The applicant calculated a GI endoscopy use rate per 1,000 for FY 2018-2021 of 79.95. Relying on that data, the performance standard of 1,500 GI endoscopy procedures per room and the projected Wake County population growth, the applicant determined that Wake County GI endoscopy utilization from FY 2024-2028 would support an additional five GI endoscopy procedure rooms. See the tables that illustrate the calculations on pages 43-44. The applicant also determined that the total catchment area population is projected to increase at the same rate as that of the state as a whole, further supporting the need for additional GI endoscopy capacity in the proposed service area. Additionally, according to the NCOSBM, the 45-74 age group in Wake County and the applicant's catchment area is projected to increase by a 2.4% and 1.2% CAGR, respectively. Typically, the older age cohorts are those people more likely to utilize GI endoscopy services (pages 43-46).

- Health status of Wake County and the proposed catchment area – The applicant states that WECLLC physicians specialize in colorectal cancer screening as well as prevention, diagnosis, treatment and management of digestive and liver disease, all of which are detectable through GI endoscopy services. The applicant states that although colon cancer is largely preventable, it was the leading cause of cancer deaths in many counties in North Carolina in 2018. Between 2016 and 2020, the applicant states colorectal cancer rates in Franklin, Halifax, Vance and Warren counties, which are partially in the applicant's catchment area and are largely rural, were higher than both the state and national rates. See the tables that illustrate historical and projected colorectal cancer rates on pages 46-50.
- The applicant states the need for GI endoscopy services in freestanding facilities in Wake County will continue to increase, particularly as the population of the county and the entire catchment area ages and grows. The applicant proposes a lower-cost freestanding GI endoscopy facility that will accommodate the increasing need (*page 51*).

The information is reasonable and adequately supported based on the following:

- The applicant provides reliable data to support its projections of population growth and aging in the proposed service area, as well as information regarding the health status of the proposed population to be served.
- The applicant adequately demonstrates how the proposed project will provide a more cost-effective option and improve geographical access in the proposed service area.

Projected Utilization

In Section Q, Forms C.3b, pages 119-123, the applicant provides projected utilization for all WECLLC facilities, as illustrated in the following tables:

WEC-RALEIGH	PARTIAL FY (10/1/25- 12/31/25)	1ST FULL FY (CY 2026)	2ND FULL FY (CY 2027)	3RD FULL FY (CY 2028)
# GI Endoscopy Rooms	4	4	4	4
# Procedures	2,708	10,830	10,830	10,830
Avg. # Procedures/Room	0.45	1.81	1.81	1.81

Source: Section Q, page 119

WAKE FOREST ENDOSCOPY CENTER	PARTIAL FY (10/1/25- 12/31/25)	1ST FULL FY (CY 2026)	2ND FULL FY (CY 2027)	3RD FULL FY (CY 2028)
# GI Endoscopy Rooms	3	3	3	3
# Procedures	1,231	4,923	4,923	4,923
Avg. # Procedures/Room	0.27	1.09	1.09	1.09

Source: Section Q, page 120

WEC-CARY	PARTIAL FY (10/1/25- 12/31/25)	1ST FULL FY (CY 2026)	2ND FULL FY (CY 2027)	3RD FULL FY (CY 2028)
# GI Endoscopy Rooms	3	3	3	3
# Procedures	1,186	4,820	4,820	4,820
Avg. # Procedures/Room	0.26	1.07	1.07	1.07

Source: Section Q, page 121

WEC-HOLLY SPRINGS	PARTIAL FY (10/1/25- 12/31/25)	1ST FULL FY (CY 2026)	2ND FULL FY (CY 2027)	3RD FULL FY (CY 2028)
# GI Endoscopy Rooms	2	2	2	2
# Procedures	570	3,073	3,105	3,105
Avg. # Procedures/Room	0.19	1.02	1.04	1.04

Source: Section Q, page 122

WEC-NORTH	PARTIAL FY (10/1/25- 12/31/25)	1ST FULL FY (CY 2026)	2ND FULL FY (CY 2027)	3RD FULL FY (CY 2028)
# GI Endoscopy Rooms	2	2	2	2
# Procedures	424	2,715	3,097	3,489
Avg. # Procedures/Room	0.14	0.91	1.03	1.16

Source: Section Q, page 123

In Section Q, page 124 the applicant states WECLLC operates on a calendar year. The project is projected to begin operating on October 1, 2025; therefore, the applicant's partial fiscal year is the last three months in 2025. In Section Q, pages 124-148, the

applicant provides the assumptions and methodology used to project utilization, as summarized below:

Forecast Need

Step 1: Determine WEC-North catchment area population by ZIP code through the first three operating years

The applicant states it has identified a catchment area of 31 ZIP codes in an area from northern Wake County to southern Virginia from which over 85% of its WFEC patients originate, based on internal data. The applicant states the proposed WEC-North will serve a similar patient base as WFEC facility, which currently has two licensed GI endoscopy procedure rooms and will not be able to effectively serve the volume of patients in the catchment area. The applicant provides a table on pages 125-126 that illustrates WFEC's procedure history by ZIP code from FFY 2021-2023, as well as the percentage of patients served from each of the 31 ZIP codes.

Step 2: Determine the population of the WEC-North catchment area from 2023-2028

The applicant estimated the annual population for the catchment area using Claritas Environics' ZIP-code population projections. Claritas provides data for the calendar years 2024 and 2029; therefore, the applicant calculated a five-year CAGR and interpolated the population in each ZIP code for each intervening year. The applicant states that by the first full project fiscal year, the projected service area will have an estimated population of 559,975. The applicant provides a table on pages 128-129 that illustrates the population data.

Step 3: Determine the North Carolina use rate for GI endoscopy procedures

The applicant estimated need for GI Endoscopy procedures in the catchment area, the Applicant used the 2019-2024 SMFPs and NCOSBM population data to calculate an average North Carolina GI procedure use rate for the years 2018 through 2022 of 66.74 GI endoscopy procedures per 1,000 population. The applicant omitted FFY 2020 to eliminate the impact of the COVID-19 pandemic and states the state use rate smooths differences among counties and smooths for delayed procedures that occurred in years following the pandemic. See the table showing the calculations on page 130.

Step 4: Forecast GI endoscopy procedures in the proposed catchment area for the years 2023-2028

The applicant applied the use rate of 66.74 from Step 3 to the projected population in the catchment area to estimate the total number of GI endoscopy procedures in the catchment area from FFY 2024-2029. The applicant provides a table on page 131 to illustrate the calculations.

Step 5: Estimate the number of GI endoscopy procedure rooms justified in the WEC-North catchment area

The performance standard in 10A NCAC 14C .3903 requires an applicant to project that each GI endoscopy procedure room will perform at least 1,500 GI endoscopy procedures per room in the third full fiscal year of operation. Therefore, the applicant divided the total projected catchment area procedures from *Step 4* by 1,500 and subtracted the number of existing and approved GI endoscopy procedure rooms in the catchment area. The applicant states the calculations show a “deficit” of 12 GI endoscopy procedure rooms in the catchment area in FFY 2028, which involves no in-or out-migration to or from the catchment area. See the table that illustrates the calculations on page 132.

Forecast Utilization

Having calculated a projected deficit of up to 12 GI endoscopy procedure rooms in the proposed catchment area by FY 2028, the applicant projects utilization as follows:

Step 6: Determine GI endoscopy procedures performed in existing WEC procedure rooms from 2019-2023

The applicant calculates the historical utilization of all licensed GI endoscopy procedure rooms in facilities owned or operated by WECLLC, using historical data from WECLLC LRAs and SMFPs. The following table illustrates historical utilization at all WECLLC facilities:

WEC SITE	FFY 2019	FFY 2020	FFY 2021	FFY 2022	FFY 2023
WEC-Raleigh	10,576	9,176	10,794	11,652	10,830
WFEC	4,364	4,697	4,861	5,720	4,923
WEC-Cary*	--	--	--	--	1,975
WEC-Holly Springs^	--	--	--	--	--
Total	14,940	13,864	15,655	17,372	17,728

*The applicant states on Application page 133 that WEC-Cary was licensed in January 2024. The data provided in the table shows procedures performed from June-September 2023.

^The applicant states WEC-Holly Springs is still under development.

The applicant states the decrease in the number of procedures performed at WEC-Raleigh and WFEC in FFYs 2022-2023 reflects a slight shift of patients from those facilities to WEC-Cary. The applicant states total utilization of all WEC facilities continued to increase.

Step 7: Forecast GI endoscopy procedures at existing and approved WEC facilities from 2023-2028

The applicant projects utilization for each facility individually, and adjusts its historical data from a FFY to a CY to align its projections with the pro formas in Section Q. See the table that illustrates these projections on page 134. The applicant provides the following specific assumptions on page 135:

- *“WEC-Raleigh and WFEC forecasts are constant at the FFY 2023 procedures; this is reasonable because those locations are operating at or above the performance standard of 1,500 procedures per room, and Wake County and NC populations are growing.*
- *WEC-Cary projections are constant from 2026 at third year forecast from its CON. Original forecasts were reasonable. Since 2019, the WEC-Cary service area has continued to grow and age....*
- *WEC-Holly Springs is not yet operational. Forecasts are based on 2022 CON projections. WEC-Holly Springs is maintaining a development schedule on par with the CON....”*

Step 8: Determine percentage of WEC-North catchment area procedures performed at existing and approved WECLLC Wake County facilities, 2021-2023

The applicant states its internal data show that existing WECLLC GI endoscopy rooms serve patients from the ZIP codes that comprise the catchment area; thus, the applicant determined the percentage of each site’s procedures that originated from the catchment area. The applicant determined that an average of 24.7% of procedures from the catchment area would be served by WEC-Raleigh and 84.3% would be served by WFEC. The applicant assumes no procedures from the catchment area will be performed in the WECLLC GI endoscopy rooms in either WEC-Cary or WEC-Holly Springs.

Step 9: Estimate the number of WEC-North catchment area procedures served at existing or approved WECLLC Wake County facilities from 2023-2028

To project the number of WEC-North catchment area procedures served by existing and approved WECLLC Wake County facilities, the applicant multiplied the percent by site from *Step 8* by the total number of available procedures in the catchment area from *Step 4*. The applicant provides a table that illustrates the calculations on page 137.

Step 10: Estimate the WEC-North market share of remaining catchment area procedures from 2023-2028

The applicant states that approximately 60% of the catchment area population lives in Wake Forest, in northern Wake County, and in areas north of Wake Forest. Therefore, the applicant’s proposed facility is projected to serve the following market share of remaining catchment area procedures not served by other WECLLC facilities that could be served by WEC-North:

	JULY-DEC. 2025*	1 ST PY (CY 2026)	2 ND PY (CY 2027)	3 RD PY (CY 2028)
WEC-North Market Share Increase	5.0%	8.0%	9.0%	10.0%

*This is the applicant’s interim year, July 2025-December 2025.

Step 11: Estimate the number of WEC-North catchment area procedures served at WEC-North from 2023-2028

The applicant projected the number of GI endoscopy procedures to be served by WEC-North from the catchment area by multiplying the estimated market share from *Step 10* by the remaining catchment area procedures from *Step 9*. The applicant then summed WEC procedures by year from *Step 9* and *Step 11* and divided the total WECLLC catchment area procedures by the estimated total catchment area procedures from *Step 4*. The applicant states WEC-North and WFEC will operate 62.5% of the Wake Forest and north catchment area freestanding GI endoscopy procedure rooms. The applicant provides a table to show the calculations on page 139.

Step 12: Estimate the total procedures at WEC-North with in-migration from 2023-2028

The applicant projects to serve 10% of patients from the rest of the state and from other states at WEC-North. The applicant states the two facilities will serve a similar population, and the historical average in-migration of patients served at WFEC from outside the catchment area is 15.7%. The applicant provides a table to show the calculations on page 140.

Step 13: Determine if WECLLC Wake County GI endoscopy procedure rooms meet the performance standard

The applicant provides a table on page 141 that summarizes the assumptions and methodology from *Steps 1-11*, as shown below:

WECLLC Wake County Facilities Total GI Procedures per GI Endoscopy Procedure Room, 2023-2028

	LOCATION	FFY 2024	FFY 2025	OCT.-DEC. 2025	PY 1 CY 2026	PY 2 CY 2027	PY 3 CY 2028
a	WEC-Raleigh	10,830	10,830	2,708	10,830	10,830	10,830
b	WFEC	4,923	4,923	1,231	4,923	4,923	4,923
c	WEC-Cary	4,671	4,745	1,186	4,820	4,820	4,820
d	WEC-Holly Springs	--	2,281	570	3,073	3,105	3,105
e	WEC-North	--	--	424	2,715	3,097	3,489
f	Total	20,424	22,779	6,119	26,361	26,775	27,167

Step 14: Determine population distribution by WEC-North catchment area ZIP code each year from 2025-2028

The applicant projects that GI endoscopy procedures in the catchment area in each of the first three project years will be distributed in proportion to the percent distribution of the population calculated in *Step 2*. The applicant provides a table to illustrate the percent distribution on pages 143-144.

Step 15: Estimate WEC-North GI endoscopy procedures by ZIP code

To project the number of procedures by ZIP code that will be performed at WEC-North, the applicant multiplied the total projected catchment area procedures from *Step 11* by the percent distribution from *Step 14* for all three project years, CYs 2026-2028. The applicant provides a table to illustrate the calculations on pages 144-145.

Step 16: Estimate WEC-North GI endoscopy cases from 2025-2028

The applicant examined its FY 2022 data and determined that WFEC performed 1.17 procedures per patient. Since the applicant relies on WFEC data to support its projections at the proposed WEC-North, the applicant divided the procedures by ZIP code from *Step 15* by 1.17 to project the number of cases at WEC-North. The applicant provides a table to illustrate the calculations on pages 146-147.

Next, the applicant divided the number of cases by ZIP code by the total estimated number of cases to determine the percent distribution by ZIP code of projected WEC-North GI endoscopy cases. The applicant provides a table to illustrate the calculations on pages 147-148.

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

- Projected utilization is based on WEC's historical GI endoscopy data for its existing Wake County GI endoscopy procedure rooms; specifically WFEC, since the proposed facility will be located in northern Wake County.
- The applicant's growth rates used to project utilization at WEC-North are conservative and supported by the growing population in all of Wake County and surrounding areas, cancer incidence, prevalence rates for gastrointestinal conditions, and the increased focus on preventive screening for colorectal cancer.
- The applicant provides letters of support in Exhibit I.2 which demonstrate support for the project and projected physician referrals based on referral history.
- The applicant's assumptions are based on WECLLC utilization, documented data regarding population growth and reliable population projections.
- The assumptions used to project the market share of GI endoscopy procedures projected to be performed at WEC-Holly Springs are reasonable and adequately supported.

Access to Medically Underserved Groups

In Section C, page 56, the applicant states that WECLLC will provide "*accessible care to medically underserved groups, including low-income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved persons including the medically indigent, uninsured, or underinsured.*" The applicant provides additional information regarding access to specific groups in Section C, pages 56-57.

On page 58, the applicant provides the estimated percentage for each medically underserved group for the third full fiscal year, as shown in the following table.

MEDICALLY UNDERSERVED GROUPS	PERCENTAGE OF TOTAL PATIENTS
Low income persons	2.30%
Racial and ethnic minorities	41.7%
Women	54.1%
Persons with Disabilities	12.1%
Persons 65 and older	38.8%
Medicare beneficiaries	36.6%
Medicaid recipients	0.7%

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

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information publicly available during the review and used by the Agency
- Supplemental information provided at the Agency's request

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

- (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, persons with disabilities, and other underserved groups and the elderly to obtain needed health care.

NA

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

The applicant does not propose to reduce a service, eliminate a service or relocate a facility or service. Therefore, Criterion (3a) is not applicable to this review.

- (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 develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

In Section E, pages 65-67, 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 alternative would eliminate capital costs involved in developing a new facility. However, it would not provide a long term effective solution for projected demand for GI endoscopy services in the applicant’s service area, given the existing wait times and current utilization.
- Increase hours of operation at existing facilities - The applicant states increasing operating hours at existing facilities would expand existing capacity, provide a short-term solution to address existing demand and would save on capital costs associated with developing a new facility. However, this is not a sustainable solution for projected demand in the service area and would ultimately have a negative impact on both patients and staff.
- Expand by fewer GI endoscopy procedure rooms – The applicant states it considered applying for fewer GI endoscopy procedure rooms, which would lower construction costs. However, operating a facility with only one GI endoscopy procedure room would not efficiently address patient throughput and physician times and would likely result in increased wait times for patients. \
- Expand in place – The applicant considered adding rooms to one of its current locations rather than developing a new facility. However, the applicant states the existing locations that could serve the proposed service area do not have a design footprint that would do not adapt well to this alternative, since the current location is on the second floor of a leased multi-complex and there is no space within which to expand.

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

- The proposal will provide needed access to GI Endoscopy services in northern Wake County while meeting the needs of a growing population.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- 1. Wake Endoscopy Center, LLC (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop a freestanding GI endoscopy, Wake Endoscopy Center-North, with no more than two licensed GI endoscopy procedure rooms.**
- 3. Upon project completion, Wake Endoscopy Center-North shall be licensed for no more than two GI endoscopy rooms.**

Progress Reports:

- a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.**
 - b. The certificate holder shall complete all sections of the Progress Report form.**
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.**
 - d. The first progress report shall be due on December 1, 2024.**
- 4. The certificate holder shall receive accreditation from the Joint Commission for the Accreditation of Healthcare Organizations, the Accreditation Association for Ambulatory Health Care or a comparable accreditation authority within two years following licensure of the facility.**
 - 5. For the first three years of operation following completion of the project, the certificate holder 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 fiscal years of operation following initiation of the services authorized by this certificate of need, the certificate holder 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 certificate holder shall not acquire as part of this project any equipment that is not included in the project's proposed capital expenditures in Section Q of the application and that would otherwise require a certificate of need.**
8. **The certificate holder shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Agency in writing prior to issuance of the certificate of need.**

- (5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1.b, the applicant projects the total capital cost of the project, as shown in the following table:

	TOTAL
Construction Costs	\$1,632,735
Medical Equipment	\$595,675
Miscellaneous Costs	\$645,556
Total	\$2,869,970

In Section Q, page 150, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions because it is based on the estimated cost to develop a freestanding GI endoscopy center and acquire the necessary equipment, based on the applicant’s experience with similar projects. The applicant also provides supporting information regarding costs in Exhibits F.1 and K.3.

In Section F.3, page 70, the applicant projects that start-up costs will be \$85,588 and initial operating expenses will be \$270,483 for a total working capital of \$356,070. In Section Q, pages 154-155 and referenced exhibits, the applicant provides the assumptions and methodology used to project the working capital needs of the project. The applicant adequately demonstrates that the projected working capital needs of the project are based on reasonable and adequately supported assumptions because they are based on the applicant’s experience developing and operating similar facilities.

Availability of Funds

In Section F, page 64, the applicant states that the capital cost will be funded as shown in the following table:

Sources of Capital Cost Financing

TYPE	WAKE ENDOSCOPY CENTER, LLC	TOTAL
Loans	\$2,869,970	\$2,869,970
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total Financing	\$2,869,970	\$2,869,970

* OE = Owner’s Equity

In Section F, page 71, the applicant states that the working capital needs of the project will be funded as shown in the following table:

Sources of Working Capital Financing

TYPE	WAKE ENDOSCOPY CENTER, LLC	TOTAL
Loans	\$356,070	\$356,070
Accumulated reserves or OE *	\$0	\$0
Bonds	\$0	\$0
Other (Specify)	\$0	\$0
Total	\$356,070	\$356,070

* OE = Owner’s Equity

Exhibit F.2 contains a letter from the Senior Vice President of First Citizens Bank that documents the bank’s intent to consider a loan for up to \$3.5 million for the WEC-North

project. Exhibit F.2 also contains a letter dated February 1, 2024 from the GI Administrator of WECLLC, committing the loan funds to the proposed project..

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal year following project completion, as shown in the following table:

WEC-NORTH	PARTIAL YEAR (10/1/25- 12/31/25)	1 ST FULL FY CY 2026	2 ND FULL FY CY 2027	3 RD FULL FY CY 2028
Total Procedures (from Form C.3b)	424	2,715	3,097	3,489
Total Gross Revenues (Charges)	\$945,456	\$6,050,919	\$6,901,358	\$7,774,398
Total Net Revenue	\$470,155	\$3,008,989	\$3,431,894	\$3,866,037
Average Net Revenue / Procedure	\$1,109	\$1,108	\$1,108	\$1,108
Total Operating Expenses (Costs)	\$579,793	\$2,912,196	\$3,159,230	\$3,420,871
Average Operating Expense / Procedure	\$1,367	\$1,073	\$1,020	\$980
Net Income	(\$109,638)	\$96,793	\$272,664	\$445,166

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- Payor mix, used to calculate gross revenue, is based on the applicant’s experience operating other similar facilities in Wake County.
- The assumptions used to project revenues and expenses are likewise based on the applicant's experience with other similar facilities in Wake County.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions for all the reasons described above.

- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 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), defines the service area as “*...the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Wake County. Thus, the service area for this facility is Wake County. Facilities may also serve residents of counties not included in their service area.

Table 6D on page 92 of the 2024 SMFP shows there are 46 existing GI endoscopy rooms in Wake County and 19 GI endoscopy procedure rooms that have been approved but are not developed, for a total of 65 GI endoscopy procedure rooms in Wake County [46 + 19 = 65].

In Section G, pages 80-82, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Wake County, summarizing procedure volume and population information provided in Section C and reiterating the increasing demand for GI endoscopy services in northern Wake County. The applicant states:

“In the aggregate, licensed and approved Wake County GI endoscopy rooms are operating at 119.1% of the performance standard in 10 NCAC 14C .3903.”

The applicant provides additional information regarding utilization of existing GI endoscopy services and the lack of sufficient access to GI endoscopy services in northern Wake County.

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved GI endoscopy services in the service area based on the following:

- The applicant adequately demonstrates that the proposed of GI endoscopy rooms are needed in addition to the existing or approved of GI endoscopy rooms in the proposed service area.
- The proposal will enhance accessibility to residents in need of GI endoscopy services, while providing those services in a cost-effective setting.
- The proposal will decrease existing wait times, travel times and other accessibility issues currently faced by existing and projected GI endoscopy patients, thereby allowing the applicant to provide a higher quality of GI endoscopy services to those patients.

Conclusion

The Agency reviewed the:

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

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

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

C

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

In Section Q, Form H, page 156 the applicant projects full-time equivalent (FTE) staffing for the proposed services for each of the three project years, as illustrated in the following table:

Wake Endoscopy Center-North Projected Staffing

POSITION	PARTIAL YEAR (6 MONTHS)	1 ST FULL FY CY 2026	2 ND FULL FY CY 2027	3 RD FULL FY CY 2028
Registered Nurse	0.50	2.00	2.00	2.00
Licensed Practical Nurse	0.25	1.00	1.00	1.00
Assistant Director of Nursing	0.13	0.50	0.50	0.50
Surgical Technician	0.50	2.00	2.00	2.00
Administrator/CEO	0.05	0.20	0.20	0.20
Clerical	0.25	1.00	1.00	1.00
Central Sterile Supply	0.25	1.00	1.00	1.00
Other (Physicians)	0.27	1.73	1.97	1.00
Total	2.20	9.43	9.67	9.92

The assumptions and methodology used to project staffing are provided in Section Q. page 157. Adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, page 84, the applicant describes the methods used to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- As an established employer in Wake County and current provider of GI endoscopy services, the applicant states it will actively recruit the necessary staff for the facility. The applicant states some existing employees have expressed interest in the anticipated positions in Raleigh.
- The facility will require all clinical staff to complete orientation and training specific to their position, maintain licensure and certification, and provide annual evidence of continued qualifications.
- The facility will require all clinical staff to attend continuing education programs and regular in-service training.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary

and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

Ancillary and Support Services

In Section I, page 86, the applicant identifies the necessary ancillary and support services for the proposed GI endoscopy services. On pages 87-88, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in referenced exhibits. The applicant adequately demonstrates that the necessary ancillary and support services will be made available because the applicant currently provides GI endoscopy services in Wake County and has the ancillary and support services available. The applicant states those services will be available at the new proposed facility.

Coordination

In Section I, page 88, the applicant describes its existing and proposed relationships with other local health care and social service providers. The applicant provides supporting documentation in Exhibit I.2. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the applicant's established relationships with local health care and social service providers, which will be extended to WEC-North when the facility is developed.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

In Section K, page 92, the applicant states that the project involves renovating 5,200 square feet of existing space in a physician office building that is currently under development by a third party from whom WECLLC will lease space for the proposed facility. Line drawings showing the areas to be renovated are provided in Exhibit K.2.

On pages 95-96, the applicant identifies the proposed site and provides information about the zoning and special use permits, and the availability of water, sewer and waste disposal

and power at the site. Supporting documentation is provided in Exhibit K.3. The site appears to be suitable for the proposed GI endoscopy facility based on the applicant's representations and supporting documentation.

On pages 93-94, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal based on the following:

- The applicant states it will lease space and thus the only costs it will incur are those related to upfit and lease expenses.
- The applicant's architecture and design staff will design the layout to maximize space and include several cost-saving elements, thus lowering patient cost and increasing efficiency.
- The architecture and construction teams are familiar with North Carolina health care construction standards and will ensure that the facility is built to the latest standards.
- The architecture and construction teams are familiar with ASC construction and have been involved in previous projects with the applicant.

On page 94, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed GI endoscopy services or the costs and charges to the public for the proposed services. A freestanding facility can provide GI endoscopy services at a lower cost and avoid other costs associated with a hospital-based facility, saving the patient, government, and third-party payors money.

On page 94, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 persons with disabilities, 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

The applicant proposes to develop a new facility. Therefore, there is no historical payor mix to report. In Section L, page 97, the applicant provides the historical payor mix for its other existing GI endoscopy facilities in Wake County during calendar year (CY) 2023, as shown in the following table:

WAKE ENDOSCOPY CENTER, LLC	
HISTORICAL PAYOR MIX, CY 2023 ALL WAKE COUNTY FACILITIES	
PAYOR CATEGORY	GI ENDOSCOPY SERVICES AS PERCENT OF TOTAL
Self-Pay	1.6%
Charity Care*	--
Medicare**	27.2%
Medicaid**	0.8%
Insurance**	70.0%
Other (TRICARE, MCST, Projecta, RRMCRE)	0.5%
Total	100.0%

*The applicant states charity care is 1% of gross revenue and not a payor category.

**Includes managed care plans.

In Section L, page 98, the applicant states patient demographic data is based on historical percentages from its Wake Forest facility and Claritas data. The applicant provides this data on page 99 to make the following comparison for the last full FY prior to submission of the application:

WAKE ENDOSCOPY CENTER, LLC	PERCENTAGE OF TOTAL PATIENTS SERVED BY THE FACILITY OR CAMPUS DURING THE LAST FULL FY	PERCENTAGE OF THE POPULATION OF THE SERVICE AREA
Female	54.1%	51.3%
Male	45.9%	48.7%
Unknown	NA	NA
64 and Younger	61.2%	77.2%
65 and Older	38.8%	22.8%
American Indian	0.1%	2.5%
Asian	0.1%	4.1%
Black or African-American	2.0%	21.5%
Native Hawaiian or Pacific Islander	NA	2.1%
White or Caucasian	8.5%	57.5%
Other Race	NA	12.3%
Declined / Unavailable	89.3%	--

The Agency reviewed the:

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

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

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

C

In Section L, page 100, the applicant states that the proposed facility is not obligated under any applicable federal regulations to provide uncompensated care, community service or access by minorities and persons with disabilities.

In Section L, page 100 the applicant states the proposed project does not involve an existing facility and thus has no civil rights access complaints.

The Agency reviewed the:

- Application
- 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 101, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation (CY 2028) following project completion, as shown in the following table:

WAKE ENDOSCOPY CENTER-NORTH 3 RD FULL FY, CY2028	
PAYOR CATEGORY	GI ENDOSCOPY SERVICES AS PERCENT OF TOTAL
Self-Pay	2.5%
Charity Care*	--
Medicare**	36.6%
Medicaid**	0.7%
Insurance**	59.3%
Other (TRICARE, MCST, Projecta, RRMCRE)	0.8%
Total	100.0%

*The applicant states charity care is 1% of gross revenue and not a payor category.

**Includes managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.5% of total services will be provided to self-pay patients, 36.6% to Medicare patients and 0.7% to Medicaid patients.

On page 101, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following project completion. The projected payor mix is reasonable and adequately supported because it is based on its historical payor mix at the applicant's existing Wake County GI endoscopy facilities.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 103, the applicant adequately describes the range of means by which patients will have access to the proposed GI endoscopy services.

The Agency reviewed the:

- Application
- 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

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

In Section M, page 104, the applicant describes the extent to which health professional training programs in the area will have access to the proposed facility for clinical training purposes. The applicant adequately demonstrates that health professional training programs in the area will have access to the facility for training purposes based on the following:

- WECLLC has established clinical education agreements with existing community colleges and universities and will include WEC-North when that facility becomes operational.
- In Exhibit M.1 the applicant provides copies of letters to area colleges and universities from the WECLLC GI Administrator offering to provide clinical training at the proposed facility.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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 develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2024 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), defines the service area as “*...the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Wake County. Thus, the service area for this facility is Wake County. Facilities may also serve residents of counties not included in their service area.

Table 6D on page 92 of the 2024 SMFP shows there are 46 existing GI endoscopy rooms in Wake County and 19 GI endoscopy procedure rooms that have been approved but are not developed, for a total of 65 GI endoscopy procedure rooms in Wake County [46 + 19 = 65].

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 105, the applicant states:

“The proposed facility will increase competition in the proposed catchment area. It will provide a new access location for freestanding GI endoscopy procedures. ... there are other freestanding ASFs in the proposed catchment

area, including one operated by WECLLC. However, most options are in the southern part of the catchment area. From the outer beltline, Interstate 540, north to Richmond Virginia, the three GI endoscopy procedure rooms at WFEC in Wake Forest are the only freestanding facility options.

...

The proposed project will strengthen WECLLC's ability to continue offering low-cost, price competitive GI endoscopy services. WECLLC is not the only provider of freestanding GI Endoscopy services. But, to thousands of patients in Wake County and north, WECLLC is the provider of choice. A new location that offers these competitive prices and quality care will serve to encourage competition in the proposed catchment area and Wake County."

Regarding the impact of the proposal on cost effectiveness, in Section N, page 106, the applicant states:

"...freestanding GI endoscopy centers are more cost-effective than those in hospitals. Hospital-based GI endoscopy rooms have more expensive rates. Medicare, the benchmark for payment structures, establishes a higher fee rate for the same GI endoscopy service when it occurs in a hospital.

Consumers of GI endoscopy services are becoming more value conscious. Aided by the internet, consumers are better informed, and are willing to shop for providers that offer lower out-of-pocket costs, especially for planned procedures like screening colonoscopies. Providing additional access to a low-cost, high-quality provider will help to ensure that Wake County and catchment area residents will seek the preventive care they need."

See also Sections C, F, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 106, the applicant states:

"All [Raleigh Medical Group] physicians are board-certified and benchmark themselves to national standards. The proposed new facility will maintain the same standards.

WEC-North will be subject to third-party oversight. It will be accredited by the AAAHC, licensed by the State of North Carolina and certified by CMS for Medicare and Medicaid participation.

Staff and patient safety are designed into the patient flow. The facility will be staffed to minimize turnover time while providing patients time to recover and understand discharge instructions at their own pace."

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 107, the applicant states:

“WECLLC has a policy of accepting low-income persons, racial and/or ethnic minorities, women, handicapped persons, the elderly, or other underserved persons including the medically indigent, uninsured or underinsured.”

See also Sections C and L of the application and any referenced exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost-effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant’s representations about how it will ensure the quality of the proposed services and the applicant’s record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant’s representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that the application is conforming to this criterion based on all the reasons described 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.

The applicant proposes to develop a new ASF in Raleigh with no more than two GI endoscopy procedure rooms upon project completion.

In Section O, page 108, the applicant identifies the acute care and ambulatory surgical facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of six of this type of facility located in three counties in North Carolina.

In Section O, page 109, the applicant states that, during the 18 months immediately preceding the submittal of the application, all WEC facilities listed in Section O did not have any deficiencies in quality of care at any of its licensed facilities. In Exhibit I.1, the applicant provides a letter dated February 1, 2024 from the GI Administrator of Wake Endoscopy Center, LLC, confirming that all of WEC's facilities have provided quality care and have not received any violations or Civil Rights access complaints during the 18 months preceding application submission. After reviewing and considering the information provided by the applicant and considering the quality of care provided, 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.

G.S. 131E-183 (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 Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities, promulgated in 10A NCAC 14C .3903, are applicable to this review.

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

.3903 PERFORMANCE STANDARDS

An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:

(1) *identify the proposed service area;*

-C- In Section C, page 60, the applicant identifies the service area for WEC-North as Wake County.

- (2) *identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area;*
- C- In Section C, page 60, the applicant states that WECLLC or a related entity owns or operates 12 GI endoscopy procedure rooms in Wake County.
- (3) *provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule;*
- C- In Section Q, Forms C.3b, pages 119-123 the applicant provides projected utilization for each of the existing WECLLC GI endoscopy procedure rooms located in Wake County.
- (4) *project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and*
- C- In Sections C and Q, the applicant projects to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy procedure room during the third full fiscal year of operation following project completion.
- (5) *provide the assumptions and methodology used to project the utilization required by this Rule.*
- C- In Section Q, pages 124-148, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at the proposed and existing facilities. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.