Comments on Wake Endoscopy Center-Holly Springs GI Endoscopy ASF

Project ID #J-12250-22

October 3, 2022

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Rex Hospital, Inc. d/b/a UNC Health Rex (Rex) hereby submits the following comments related to an application to develop a new GI endoscopy ambulatory surgical facility (ASF) in Wake County. Rex's comments on this application include "*discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with the relevant review criteria, plans and standards*." *See* N.C. GEN. STAT. § 131E-185(a1)(1)(c). To facilitate the Agency's review of these comments, Rex has organized its discussion by issue, noting some of the general Certificate of Need (CON) statutory review criteria and specific regulatory criteria and standards creating the non-conformity on the following application:

- **Wake Endoscopy Center, LLC, (WEC) Project ID # J-12250-22** (proposal to develop a new ASF with two licensed GI endoscopy rooms in Holly Springs)

GENERAL COMMENT:

While Rex understands that there is no need determination for GI endoscopy rooms, and therefore no determinative limit on the number of rooms that *may* be approved, applicants must still demonstrate conformity with the applicable statutory review criteria and the performance standards in order to be approved. While Rex appreciates the need for sufficient access to GI endoscopy services in Wake County, it believes that the application fails to demonstrate the need for the proposed project and is based on wholly unsupported utilization projections for a service area from which the applicant currently performs only a modest number of procedures. The lack of sufficient support for the utilization projections, combined with inconsistencies and unreasonable assumptions render the application non-conforming with multiple statutory and regulatory criteria.

ISSUE-SPECIFIC COMMENTS:

1. <u>The application's patient origin assumptions are not based on reasonable and adequately supported assumptions</u>.

   As a foundational matter, although the applicant has existing and approved facilities in Wake County, it does not reference any historical information regarding the number of patients it has served from in and around the proposed site to support its project. As shown in Exhibit C.5 of the application, page 18, in FFY 2021, the applicant treated only 814 patients from the proposed service area at its existing facilities, and it projects to continue to serve that number of patients at its existing facilities in Raleigh and Wake Forest (i.e., it does not use those patients as a basis for its projected utilization in Holly Springs, or as a "shift"). As shown in Exhibit C.5 of this application, in demonstrating need for its approved Cary facility, the applicant documented specific physicians that were to shift their practices to the Cary location along with their associated volumes. No such analysis was provided in the current application to develop a new facility in Holly Springs, and, as noted above, all of the projected volume for the Holly Springs facility would be incremental to the practice—no "shifted" volume was assumed.

   Next, the applicant admits that its approved and soon to be operational facility in Cary was approved on the basis of serving ZIP codes included in the service area for this Holly Springs application, including the two largest ZIP codes that comprise over 60 percent of the service area population, 27526 and 27540. Given the pending opening of the Cary facility with three GI endoscopy rooms, the approved service area's inclusion of over 60 percent of the service area for the Holly Springs facility proposed in the instant application, and the available capacity in a three-room GI ASF that has yet to open, it is simply not reasonable to assume that the applicant needs both facilities to serve largely the same patient population.

   The patient origin projections are also unreasonable because of the basis for calculating the percentage by ZIP code. In Exhibit C.5 of the application, the percentage of total population for each ZIP code is applied to the projected total patients and the applicant assumes that patient origin will be identically proportional to the population of each ZIP code. This assumption is not reasonable in this situation, however, for a few reasons. First, as noted above, the applicant is already approved to serve patients from the two largest ZIP codes at its facility in Cary; thus, the patients that will originate from these ZIP codes, at a minimum, will be diminished by the impact

of the Cary facility. Second, the application inappropriately uses the total population of each ZIP code to calculate the portion of the total service area population each represents; however, given the applicant states that the proposed service is intended to serve the population age 45-74, and as such, that is the population it should have used as the basis for calculating the patients it will serve by ZIP code. Next, despite making several arguments around accessibility to the proposed service, the patient origin assumptions make no adjustment for the distance of the ZIP codes to the proposed facility, or the impact of other facilities in and around the proposed service area. For example, the applicant projects that the plurality of its patients will originate from the Fuquay-Varina ZIP code, despite the existence of another GI endoscopy ASF in that ZIP code and despite the proposed location in the Holly Springs ZIP code. The applicant attempted no analysis or evaluation of the impact that the distance patients would travel might have on its patient origin. The proposed service area is also not reasonable based on travel patterns, existing roads and other facilities in the region. For example, the application states on page 110 that the Chatham ZIP code (27559) is reasonable, because it straddles Route 1, "a major highway with direct access to Holly Springs." This statement is incorrect; Highway 1 runs between Sanford in Lee County, where an existing GI endoscopy ASF is located, and New Hill and Apex in Wake County, before going into Cary, less than one mile from the approved WEC-Cary location. It does not provide direct access to Holly Springs. In addition, some of the ZIP codes include portions of other (non-Wake) counties, including Johnston County, where WEC owns a GI endoscopy facility, Clayton Endoscopy Center, that included all of Johnston County in its approved service area. Finally, the assumption of 10 percent inmigration is also unreasonable because the methodology used in the application already includes inmigration; that is, it is based on patients served in Wake County, not just from Wake County. By including the inmigration percentage, the applicant double counts patients that are already accounted for in its projected number of patients. Please see the discussion below for additional analysis of this issue.

The methodology developed by the applicant has several critical flaws as applied to projected utilization for the proposed project. The methodology uses a calculated "in Wake County" use rate; in other words, the use rate it uses includes all patients served in Wake County, not just from Wake County. While a more precise use rate for Wake County residents could be obtained using aggregated data from Medical Facilities Planning[1], since the applicant chose to calculate a use rate that contains not just Wake County residents but inmigrating patients as well, the calculated volume already includes inmigration. Thus, adding more inmigration results in an overcounting of projected procedures. This issue can be easily identified by comparing the "in county" use rate calculated in the application with the Wake County resident use rate, calculated using the data from Medical Facilities Planning referenced above. According to the table on page 112 of the application, the "in Wake County" volume for FFY 2021 is 75,419 cases resulting in a use rate per 1,000 of 65.23. Using the data for just Wake County residents for FFY 2021, the volume is 64,321 resulting in a use rate per 1,000 of 55.62. The same calculation for the other years used in the applicant's average can be made with similar results: 43.43 in 2020, 52.65 in 2019, and 50.17 in 2018, which average to 50.47, significantly lower than the use rate used to project the number of cases in the service area.

	2018	***2019***	***2020***	***2021***	***4-Year Average Use Rate***
"In Wake County" Cases/Use Rate (includes inmigration)	84,628/77.39	88,637/79.51	72,881/64.22	75,419/65.23	76.38
Wake County Only Cases/Use Rate (no inmigration)	54,861/50.17	58,704/52.65	49,286/43.43	64,321/55.62	50.47

Source: Application, page 112 and Medical Facilities Planning patient origin reports (https://info.ncdhhs.gov/dhsr/mfp/publications.html#por)

[1] https://info.ncdhhs.gov/dhsr/mfp/pdf/por/2022/12-PatientOrigin_GI-2022.pdf

Given the clear difference in these data, the application of the use rate to calculate volume in the service area already includes patients from outside the service area that would be served in the service area. While the applicant may elect such an approach, it has failed to recognize that the use rate already includes inmigration—in this case, patients from other ZIP codes that are projected to be served in the ZIP code service area. As such, the application errs when it further increases the volume by assuming a 10 percent "inmigration" factor. This volume is already included in its use rate as demonstrated above. In fact, from an analytical perspective, the use rate applied in the application has a nearly 23 percent inmigration factor (65.23 "in county" use rate – 50.47 Wake County only use rate = 14.76 ÷ 65.23 = 22.6 percent). Of note, this percentage corresponds with the applicant's own analysis on page 42, Table 6, which shows that 23.9 percent of patients served in Wake County are from other counties. Applying the 65.23 use rate to a population, in this case an aggregated ZIP code population, therefore already includes patients from outside that geographic area that are coming into the area for the proposed service, and the addition of another inmigration factor overstates the projected utilization and is unreasonable. Moreover, the ZIP code service area already includes unenumerated portions of other counties, including Harnett, Johnston and Chatham. As such, patients from other counties/ZIP codes are accounted for in multiple ways and should not be added on top of the "in county" use rate.

Step 4 of the "need" analysis on page 114 is similarly flawed, in that it calculates the need within the selected ZIP codes but fails to acknowledge that patients travel outside the service area for GI endoscopy services, not only by choice, but by design of the applicant's approved project, the WEC-Cary facility. As noted above, that facility, which the application states will open early 2023, proposed to serve the ZIP codes comprising the majority of the WEC-Holly Springs population; as such, the applicant believes that the "need" of patients within a particular ZIP code can be met effectively outside that ZIP code.

The inconsistent and flawed analysis can also be demonstrated by examining the tables used to project utilization and patient origin. Page 34 shows the projected patient origin, which is 2,389 patients in Year 3, of which 2,150 are identified from the service area ZIP codes. Page 3 of Exhibit C.3 shows how this figure was calculated, assuming 3,105 procedures and a case adjustment of 1.3 procedures per patient. In other words, the 2,389 patients equate to 3,105 procedures. Page 119 of the application shows how the 3,105 procedures were projected by applying the "in county" use rate to the service area ZIP codes. As described above, however, the "in county" use rate analysis already assumes a 23 percent inmigration factor; thus, no other inmigration should be expected.

As a result of these issues, the **application should be found non-conforming with Criteria 1, 3, 4, 5, 6 and 18a and the performance standards for GI endoscopy rooms at 10A NCAC 14C .3903.**

2. The application fails to demonstrate that the utilization projections are based on reasonable and adequately supported assumptions.

Unreasonable projections for its existing/approved facilities

As an applicant with existing and approved facilities in Wake County, WEC-Holly Springs must demonstrate that its proposed two GI endoscopy rooms are needed in addition to the existing and approved rooms. The application's analysis to attempt to demonstrate this is inconsistent with its previous projections for the approved WEC-Cary facility and overstates the projected volume for its existing and approved facilities. On page 115 of the application, the applicant projects utilization for its three existing/approved facilities, as shown below:

Table 5: Actual and Forecast GI Procedures Performed at Existing/ Approved WEC Facilities in Wake County through Third Operating Fiscal Year, FY 27

Notes	Facility	Actual				Forecast					
		FFY18	FFY19	FFY20	FFY21	FY22	FY23	FY24	FY25	FY26	FY27
a	WEC	10,782	10,576	9,167	10,794	10,794	10,794	10,794	10,794	10,794	10,794
b	WFEC	2,959	4,364	4,697	4,861	4,861	4,861	4,861	4,861	4,861	4,861
c	WEC-Cary	-	-	-	-	-	4,671	4,745	4,820	4,820	4,820
d	*Total*	*13,741*	*14,940*	*13,864*	*15,655*	*15,655*	*20,326*	*20,400*	*20,475*	*20,475*	*20,475*

The applicant states that it is "conservative" by holding utilization at each facility constant, and that it bases the projections for WEC-Cary on that 2019 application. These prevaricated statements do not align with the WEC-Cary application, however, as shown in Exhibit C.5 of the Holly Springs application. As noted above, utilization projections in the WEC-Cary application were based on shifting a substantial number of procedures from the existing WEC facilities in Raleigh and Wake Forest to the Cary location. The projections shown in Table 5 (reproduced above) fail to make this adjustment, resulting in overstated utilization. Step 4 of the WEC-Cary application, which is included in Exhibit C.5 of the Holly Springs application, demonstrates this flaw and is shown below:

Step 4: Determine Procedures Remaining at WEC after Three WEC Docs Become Exclusive at WEC–Cary

The applicant shows the impact that these WEC physicians will have on WEC once they move to WEC–Cary. This step shows how many procedures will be performed at WEC after these physicians relocate to WEC–Cary. Table 10 shows the procedures remaining at WEC.

Table 10: GI Procedures Remaining at WEC after Deduction of Procedures for WEC–Cary, FY2019-FY2023

Notes		FY2019	FY2020	FY2021	FY2022	FY2023
a	Forecast Total Annual GI Procedures at WEC, all physicians	11,055	11,279	11,507	11,739	11,976
b	Projected Annual Procedures for 3 Physicians Exclusive to WEC–Cary	3,501	3,572	3,644	3,718	3,793
c	Annual Procedures Remaining at WEC	7,554	7,707	7,862	8,021	8,183

Notes:

As shown, the methodology for WEC-Cary assumed that volume would shift to the Cary facility, based on the physicians that would relocate there to practice, <u>resulting in a decrease in procedures performed at the WEC facility in Raleigh</u>. It also projected other procedures would shift to Cary based on patients living in that service area (which, of note, includes ZIP codes 27540 and 27526). This step further reduced the utilization for WEC, shown below, from page 7 of Exhibit C.5 of the Holly Springs application:

Table 12: Procedures Available at WEC for Shift to WEC–Cary and WFEC, Partial FY2020 to FY2023

Notes		Partial FY (Jun-Dec 2020)	FY2021	FY2022	FY2023
a	Total Annual Forecast GI Procedures at WEC, all docs	4,496	7,862	8,021	8,183
b	35% of Cary WEC Procedures Shifted WEC–Cary	599	1,027	1,027	1,027
c	15% of Wake Forest WEC Procedures shifted to WFEC	336	577	577	577
d	Remaining Procedures at WEC after Shifts to other Locations	3,560	6,259	6,418	6,580

Thus, WEC projected only 6,580 procedures at its Raleigh facility in FY 2023, after the shifts that it projected and upon which the approval of its Cary facility was based. The Holly Springs application provides no assumptions to support a growth of over 4,000 procedures at the WEC facility, particularly since the actual impact of the development of the Cary facility has not yet occurred.

Based on this issue, **the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, and 18a, and the performance standards for GI endoscopy rooms at 10A NCAC 14C .3903.**

Unrealistic market share and volume projections for WEC-Holly Springs

While the projected utilization for the existing/approved facilities is clearly unreasonable, so, too, is the projected utilization of the Holly Springs facility. As noted above, unlike the Cary facility, to which WEC projected shifting a significant volume of patients it was already serving, WEC physicians are currently performing few procedures from the Holly Springs service area. Page 18 of Exhibit C.5 in the application demonstrates that in FY 2021, WEC physicians performed only 806 procedures from the service area, which equates to approximately seven percent of the service area procedures estimated in the application. Of note, the application does not propose that these procedures will shift to the proposed facility; to the contrary, the application projects (page 118) that these procedures (grown to 1,133 by FY 2027) will remain at the Cary facility. The applicant assumes that its projected utilization at the Holly Springs facility will be completely new (incremental) market share, gained from unnamed existing providers. Step 4/Table 9 of the application projects 30 percent market share by Project Year 3, without any data or analysis to support that assumed market share. When added to the 1,133 procedures projected at the Cary facility, WEC assumes that it will perform 4,238 procedures (3,105 at Holly Springs, plus 1,133 at Cary), which equates to a market share of 36.9 percent in Year 3. Thus, without any analysis to demonstrate its existing market share at other facilities or any reasonable proxy or other basis, the applicant projects that WEC will achieve more than one-third of the market share for the service area within three years of opening the proposed facility. A review of data from the *Proposed 2023 SMFP* shows that in the competitive Wake County market, WEC currently has less than one-half that market share, 15.7 percent, based on 15,655 procedures performed out of 99,271 in Wake County. Although the application used a different methodology, the projections for WEC-Cary, found in Exhibit C.5, page 16 of the Holly Springs application, resulted in a market share projection of only 13.4 percent in its third year, which is more consistent with WEC's overall market share in Wake County. Clearly if a more reasonable and supportable market share percentage were used, the application would not meet the minimum required utilization to demonstrate need and conformity with the performance standards.

Even apart from this analysis, the market share assumptions are unsupported by other factors. As noted above, in the Cary application, WEC stated that three specific physicians would relocate to the proposed facility and demonstrated that the historical volume of these physicians would also shift to the facility. No such analysis is provided in the Holly Springs application, and there are no support letters from referring physicians outside of the applicant's own group[2] that would be necessary to support such a significant increase in volume and market share. When the expected referrals to the Holly Springs facility from the letters are totaled, the result is 58 referrals per month, or only 696 per year. Of note, all of the referring physicians are at the Cary location of the parent of WEC, which is located less than one mile from the approved WEC-Cary location[3], so it is certainly reasonable that most of the referrals from those physicians will be to the WEC-Cary location. Indeed, most of the letters of support indicate that their referrals to the Holly Springs location will, at best, be only a portion of their historical referrals to WEC facilities. Further, the application states on page 26 that five Raleigh Medical Group (RMG) physicians will practice at the proposed facility; however, only two practicing gastroenterologists provided letters of support, Drs. Jagannath and Reddy, and both of them state that they intend to continue practicing at WEC as well, so they will not be dedicated to the Holly Springs location. No other information is provided to affirm the statements in

[2] Note that WEC is owned by Raleigh Medical Group, of which Cary Medical Group is a part. See page 16 of the application for the reference to Raleigh Medical Group as the parent of WEC.

[3] Based on driving distance from 530 New Waverly Place, Cary to 1805 Kildare Farm Road, Cary.

the application regarding the number of physicians that will practice in Holly Springs. This is in stark contrast with the Cary application, as noted in Exhibit C.5 of the Holly Springs application. Table 9 of that Exhibit, reproduced below, projects volume for its Cary facility based on the expected shift from three existing gastroenterologists relocating full time to the Cary location:

Table 9: GI Procedures Associated with Three Full Time GIs Going to WEC–Cary, FY2019-FY2024

Notes		FY2019	FY2020	FY2021	FY2022	FY2023
a	Number of WEC Physicians going to WEC–Cary	3	3	3	3	3
b	Average Number of Procedures per WEC Physician per month	97	99	101	103	105
c	Projected Procedures Per Year going to WEC–Cary	3,501	3,572	3,644	3,718	3,793

Thus, the information provided in Exhibit C.5 of the Holly Springs application shows that WEC physicians average approximately 105 procedures per month; the projected 3,105 procedures at WEC-Holly Springs would require at least 2.5 full time equivalent physicians, therefore, and the application lacks support from any full time physician, and only two part time physicians. The staffing assumptions in Form H also assume fewer physicians than are needed to perform the projected number of procedures, only 1.98 physicians in the third project year.

Based on this issue, **the application should be found non-conforming with Criteria 1, 3, 4, 5, 6, 7, and 18a, and the performance standards for GI endoscopy rooms at 10A NCAC 14C .3903.**

3. The application fails to demonstrate that its projected utilization conforms with the GI endoscopy rules.

WEC-Holly Springs is applying for a new GI endoscopy ASF with two licensed GI endoscopy rooms. Per the definition in NCGS 131E-176(7d), a "gastrointestinal endoscopy room" is for "the performance of procedures the require the insertion of a flexible endoscope into a gastrointestinal orifice to visualize the gastrointestinal lining and adjacent organs for diagnostic or therapeutic purposes." Page 55 of the application includes the definitions in 10A NCAC 14C .3901, including (3) which defines "GI endoscopy procedure" as, "each upper endoscopy, esophagoscopy, or colonoscopy procedure performed on a patient during a single visit to the licensed health service facility." (emphasis added) Thus, the procedures performed in the proposed ASF should conform with the definitions in the statute and the administrative rules, including a projection of at least 1,500 GI endoscopy procedures (as defined above) by Year 3. While the application states on page 56 that it is consistent with these rules, no other statements in the response to the rules support this assertion, and evidence in the application actually contradicts this claim as well as conformity with the statutory definition. The application does not identify the volume of the various types of procedures to be performed at the facility (and, of note, it is not required to do so per se, but it must demonstrate that its projections are reasonable), but page 27 lists the types of procedures provided by existing physicians at WEC, including colonoscopy, capsule endoscopy, PEG replacement and removal, abdominal paracentesis, endoscopic retrograde cholangiopancreatography, endoscopic ultrasound, and small bowel enteroscopy. While some of these procedures fall into one of the three categories listed in the definition of "GI endoscopy procedure," and while some do involve the insertion of an endoscope into a GI orifice some do not. Specifically, capsule endoscopies involve a camera swallowed by the patient and do not involve the insertion of a scope like traditional endoscopies do. Abdominal paracentesis also does not typically involve a scope or an existing orifice, but instead requires an incision or tap to remove fluid from the abdomen. Finally, while both endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound use a scope, neither are typically provided in an ambulatory setting due to equipment costs and the limited number of patients that can be treated in that setting.

Based on the discussion in the application, it appears that the applicant is projecting some number of procedures that would not meet the statutory and/or regulatory definition of GI endoscopy and should not be used to

determine conformity with the performance standards. Without detailed data from the applicant, it is impossible to determine how many of these procedures are included in the projected utilization, and **the application should be found non-conforming with the performance standards for GI endoscopy rooms at 10A NCAC 14C .3903, as well as Criteria 1, 3, 4, 5, 6, and 18a.**