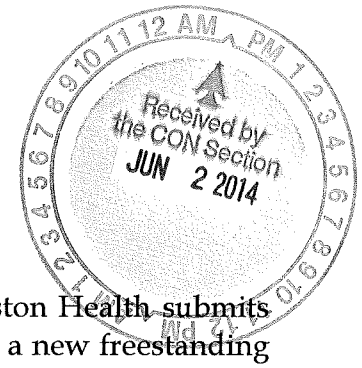


Comments on Clayton Endoscopy

submitted by

Johnston Health

In accordance with N.C. GEN. STAT. § 131E-185(a1)(1), Johnston Health submits the following comments related to an application to develop a new freestanding GI endoscopy center in Johnston County. Johnston Health's comments 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). In order to facilitate the Agency's review of these comments, Johnston Health has organized its discussion by issue, noting some of the general CON statutory review criteria and specific regulatory criteria and standards creating the non-conformity relative to each issue, as they relate to the following application:

- **Clayton Endoscopy, Project ID # J-10281-14**

Clayton Endoscopy's application should not be approved as proposed. Johnston Health has identified the following specific issues, each of which contributes to Clayton Endoscopy's non-conformity:

(1) Failure to Demonstrate the Proposed Service Will Be Coordinated with the Existing Healthcare System;
(2) Failure to Reasonably Identify the Population to be Served by the Project;
(3) Failure to Demonstrate the Need for the Proposed Project;
(4) Failure to Demonstrate that Payor Mix Assumptions are Reasonable and Supported; and,
(5) Failure to Provide Required Financial Information and Demonstrate that Financial Assumptions are Reasonable.

Each of the issues listed above are discussed in turn below. Please note that relative to each issue, Johnston Health has identified the statutory review criteria and specific regulatory criteria and standards creating the non-conformity.

<u>Failure to Demonstrate the Proposed Service Will Be Coordinated with the Existing Healthcare System</u>

Johnston Health is the primary provider of healthcare services in Johnston County and serves as the sole provider of several services including emergency, acute care, inpatient surgery, outpatient surgery, radiation oncology, and medical oncology, among others. Johnston Health operates Johnston Medical

Center-Smithfield (JMC-Smithfield), a full-service acute care facility in Smithfield, and Johnston Medical Center-Clayton (JMC-Clayton), a freestanding outpatient healthplex in Clayton with emergency, surgery, and diagnostic services that is currently developing inpatient acute care services approved under Project ID # J-8848-12.

As the primary provider of healthcare services in the county, it is concerning that Clayton Endoscopy had no communication at all with Johnston Health prior to filing its proposed application. Given the lack of any attempt to coordinate with Johnston Health, there has clearly been insufficient coordination between Clayton Endoscopy's proposed project and the existing healthcare system in Johnston County. Clayton Endoscopy proposes to locate its GI endoscopy center in Clayton. The majority of Clayton Endoscopy's physicians practice at a clinic located in a medical office building on JMC-Clayton's campus. Two of Clayton Endoscopy's physicians perform GI endoscopy procedures at Johnston Health, which offers GI endoscopy services at both of its campuses. Despite the proximity of its location and the historical relationship with its physicians, Clayton Endoscopy is proceeding with its project without any coordination with Johnston Health or other Johnston County providers. In fact, Clayton Endoscopy's only transfer agreement is with Rex Hospital in Wake County, which is a 27 minute drive (without traffic) from the proposed facility according to Google Maps. By contrast, JMC-Clayton, which offers a freestanding emergency department and is developing inpatient acute care services, is a three minute drive without traffic from the proposed facility. If, as Clayton Endoscopy argues, local GI endoscopy access is needed in Johnston County, then it should also be true that patients who have a medical emergency receiving that care should not be transferred to an acute care facility 30 minutes away in another county. This proposed lack of coordination significantly undermines Clayton Endoscopy's claims that it is offering local access to patients. Furthermore, Dr. Lee, the physician who is expected to perform the 2nd highest number of procedures (per page 60 of the application), does not appear to have privileges at Rex Hospital; thus, in the event that any of his patients required transfer to Rex, he would not be able to admit or follow his patients there, which further undermines the ability to coordinate care.

Johnston Health also directs Project Access in Johnston County. Although Clayton Endoscopy's application states on page 75 that it intends to develop a relationship with Project Access in Johnston County, given the lack of any attempt to communicate with Johnston Health as well as the lack of any specific commitment to care for Project Access patients, it is questionable at best whether or not the applicant is genuinely interested in working with this program in Johnston County.

Clayton Endoscopy's failure to coordinate with the existing healthcare system is also evident in its failure to consider a joint venture. Clayton Endoscopy states that "[a] *joint venture is not a realistic option for the proposed project*" (page 67). This is simply false. There are numerous examples of joint ventures between private physician practices and healthcare systems for GI endoscopy centers. Notably, Carolina Endoscopy Center has three locations in Mecklenburg County (Huntersville, Pineville, and University) that are joint ventures between Carolinas HealthCare System and Carolina Digestive Health Associates, PA (per the 2014 Hospital License Renewal Applications for these facilities). Joint venture agreements between different providers in a given healthcare system can offer significant benefits to patients and physicians. Clayton Endoscopy's deliberate unwillingness to consider such an option is also a failure to demonstrate that the least costly or most effective alternative has been proposed.

As a result, the application should not be approved, and is non-conforming with Criteria 4 and 8.

Failure to Reasonably Identify the Population to be Served by the Project

In its application, Clayton Endoscopy unreasonably projects that 100 percent of its patients will originate from Johnston County. This inaccuracy is important for two reasons. First, by failing to include other counties from which its patients will originate, Clayton Endoscopy has failed to reasonably identify the population to be served. Second, Clayton Endoscopy has artificially restricted its service area to Johnston County alone, apparently in order to circumvent the performance standards for Gastrointestinal Endoscopy Procedure Rooms (10A NCAC 14C .3903). The discussion below demonstrates the fallacy of Clayton Endoscopy's assumption and these two issues in detail.

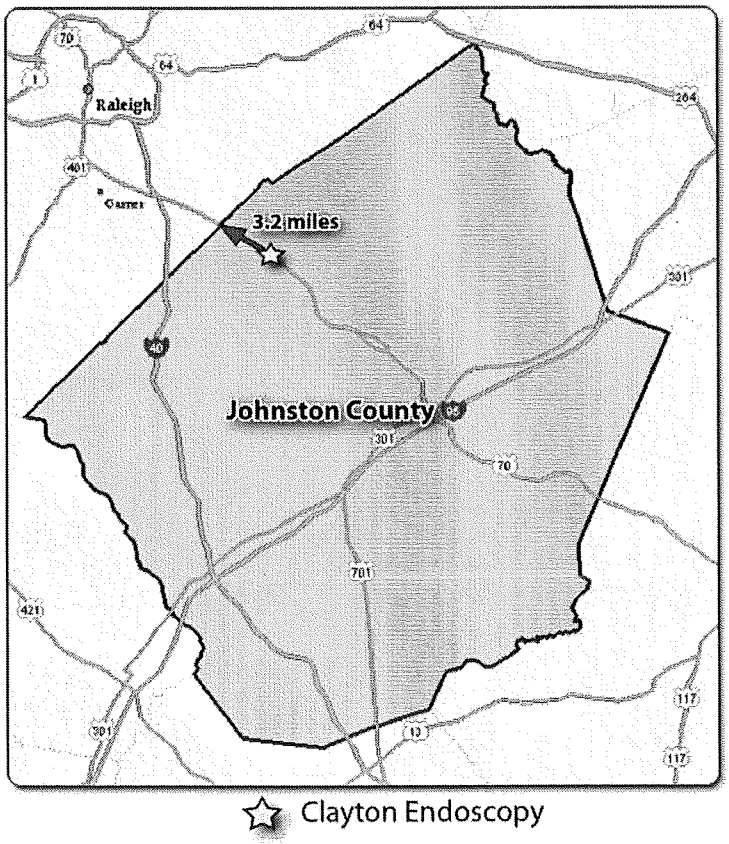
On its face, Clayton Endoscopy's assumption that it will serve patients only from Johnston County is unreasonable. According to the 2012 Ambulatory Surgery Facility database provided by the Medical Facilities Planning Section, no freestanding GI endoscopy center in the entire state served patients from only one county. Of the 74 total freestanding GI endoscopy centers statewide, only six served patients from five or fewer counties:

Facility	*Counties Served*
Kurt G. Vernon, MD PA	2
Center for Digestive Diseases & Cary Endoscopy Center, PC	3
Endoscopy Center of Lake Norman, LLC	3
Surgery Center of Wilson, LLC	4
CaroMont Health Services, Inc.	4
Wake Endoscopy Center, LLC	5

Note: Caromont Endoscopy Center and Endoscopy Center of Lake Norman are included in this discussion; however, they each served fewer than 20 patients in total in 2012 and this low utilization would likely serve to depress the breadth of their patient origin. Thus, excluding severely underutilized facilities, only four freestanding GI endoscopy centers statewide served patients from five or fewer counties.

Thus, there is no other facility in the entire state which could serve as a basis for Clayton Endoscopy's assumption.

Further, Clayton Endoscopy proposes to develop a new freestanding GI endoscopy center in Clayton, which is only 3.2 miles from the Johnston County border with Wake County.



Healthcare services in Clayton serve numerous patients from outside Johnston County, including Wake County. JMC-Clayton and JMC-Smithfield both offer GI endoscopy services. In Federal Fiscal Year (FFY) 2013, JMC-Clayton served GI endoscopy patients from 15 counties in North Carolina and Virginia and only 70 percent originated from Johnston County.

FFY 2013 JMC-Clayton GI Endo Patient Origin

County	*Patients*	*% of Total*
Johnston	420	70%
Wake	126	21%
Harnett	26	4%
Sampson	5	1%
Wayne	5	1%
Duplin	3	1%
Haywood	2	<1%
Robeson	2	<1%
Cumberland	1	<1%
Dawson	1	<1%
Fairfax (VA)	1	<1%
Franklin (VA)	1	<1%
Granville	1	<1%
Moore	1	<1%
Pitt	1	<1%
Total	**596**	**100%**

Source: Johnston Health internal data.

In FFY 2013, JMC-Smithfield served GI endoscopy patients from 19 counties in four states and only 85 percent originated from Johnston County.

FFY 2013 JMC-Smithfield GI Endo Patient Origin

County	*Patients*	*% of Total*
Johnston	1,773	85%
Wake	152	7%
Wayne	61	3%
Harnett	53	3%
Sampson	25	1%
Wilson	4	<1%
Bladen	1	<1%
Buncombe	1	<1%
Cabell (WV)	1	<1%
Columbus	1	<1%

County	*Patients*	*% of Total*
Cumberland	1	<1%
Duplin	1	<1%
Durham	1	<1%
Guilford	1	<1%
Kent (MI)	1	<1%
Nash	1	<1%
Pitt	1	<1%
Talbot (MD)	1	<1%
Union	1	<1%
Total	**2,081**	**100%**

Source: Johnston Health internal data.

As shown, Johnston Health's GI endoscopy service currently serves nearly 280 patients annually from Wake County. Also, JMC-Clayton serves a higher percentage of patients from outside of Johnston County than does JMC-Smithfield, owing to Clayton's proximity to the county border. Clearly, Johnston Health's experience demonstrates that numerous patients from outside of the county access healthcare services in Johnston County and that healthcare facilities in Clayton, given their proximity to Wake County, serve a greater proportion of non-Johnston County patients. Johnston Health believes it is unreasonable and inaccurate to assume that Clayton Endoscopy will only serve Johnston County patients.

In fact, Clayton Endoscopy has access to its own historical data which could have been used to more accurately project its future patient origin. The majority of Clayton Endoscopy's physicians currently practice at a clinic in Clayton. The patient origin of this clinic should have been examined in order to project the patient origin for Clayton Endoscopy's proposed facility. Moreover, two of Clayton Endoscopy's physicians have privileges and practice at Johnston Health facilities. According to Johnston Health data (shown below), Drs. Lee and Whitt served over 100 patients in FFY 2013 who resided outside of Johnston County and 70 of those were Wake County residents.

FFY 2013 Johnston Health GI Endo Patient Origin For Drs. Lee and Whitt

County	*Dr. Whitt*	*Dr. Lee*	*Total*
Johnston	130	311	441
Wake	38	32	70
Harnett	7	13	20
Wayne	1	6	7
Sampson	3	3	6
Buncombe	0	1	1
Cumberland	1	0	1
Duplin	1	0	1
Franklin	1	0	1
Moore	0	1	1
Robeson	1	0	1
Total	**183**	**367**	**550**

Source: Johnston Health internal data.

The physician letters of support, which include projected volumes, provide no indication that the patients to be served will only be Johnston County patients, which is consistent with Johnston Health's assertion that all of the Clayton Endoscopy physicians currently serve patients from outside of the county.

In its approved application to develop a one room GI endoscopy center in Robeson County (Project ID N-8361-09), Robeson Digestive Diseases (RDD) projected that its patients would originate from Robeson County (90 percent), Bladen County (seven percent), and Columbus County (three percent) based on the historical patient origin of patients treated by RDD's physician owner, Dr. Locklear. Dr. Locklear had previously performed GI endoscopy procedures at Southeastern Regional Medical Center in Robeson County and utilized that experience in projecting future patient origin. The Agency found that RDD had adequately identified the population to be served by the project. A similar approach could have been utilized by Clayton Endoscopy in order to reasonably project its patient origin. The RDD application serves to reinforce the unreasonableness of Clayton Endoscopy's patient origin projections. RDD proposed its facility in Lumberton which is centrally located within a county that spans 949 square miles (per the U.S. Census Bureau) and reasonably projected to serve 10 percent of its patients from adjacent counties. Clayton Endoscopy proposes to build its facility only 3.2 miles from the border of Johnston County which spans only 791 square miles and assumes that 100 percent of its patients will originate from within Johnston County.

In addition, other recent CON applications for new GI Endoscopy ASCs have more reasonably relied on the patient origin of the physician(s) practicing near the proposed facility, and none of those projected patients from only the county in which the facility would be located. In fact, WEC's prior application for a new facility in Wake Forest, Wake Endoscopy Center projected patient origin based on the historical experience of its physicians and included Wake and Franklin counties, stating: "*WEC projects that the Wake Forest GI endoscopy procedures will shift from its existing Lake Drive facility to the proposed new facility. WEC also received letters from two additional physicians with a large patient base in Wake Forest that will utilize the proposed facility. Therefore, WEC's projected patient origin is based on its large base of patients that reside in the Wake Forest and surrounding areas, and that will shift to the proposed new facility. Historically, WEC has also served a small portion of patients from Franklin County. WEC projects these patients will utilize the proposed Wake Forest location due to its improved proximity to Franklin County*" (page 57).

It is clear that Clayton Endoscopy will serve patients from outside of Johnston County based on the experience of other Clayton providers as well its own physicians. As such, Clayton Endoscopy has failed to accurately identify the population to be served by its facility. Further, by failing to correctly include Wake County patients in its patient origin projections, Clayton Endoscopy has circumvented the performance standards for Gastrointestinal Endoscopy Procedure Rooms (10A NCAC 14C .3903) in relation to the utilization of related entities in Wake County.

Specifically, Wake Endoscopy, the proposed owner of Clayton Endoscopy, owns a majority share in W.F. Endoscopy Center, LLC (WFEC) located in Wake Forest, NC in Wake County. WFEC is currently underutilized (according to its 2014 License Renewal Application, it provided 2,230 procedures in its two existing rooms in FFY 2013) and is approved to develop an additional GI endoscopy room (pursuant to a settlement agreement of Project ID # J-8822-12). Clayton Endoscopy states in its application that it "*intends to develop its previously approved GI endoscopy room in WFEC during 2014 and anticipates utilizing the facility at practice capacity within two years*" (page 9). If Clayton Endoscopy had included Wake County in its patient origin projections, it would have been required to demonstrate that WFEC will perform at least 1,500 GI endoscopy procedures per room and all the assumptions and the methodology used in those projections [pursuant to 10 NCAC 14C .3903 (b) and (e)]. As noted above, WFEC currently operates at only 1,115 GI endoscopy procedures per room and is approved to develop an additional room.

In its original application to develop GI endoscopy services in Wake Forest, WFEC estimated that its procedures would be performed by Drs. Schwarz, Battagalino, and Sachdeva. All of these physicians have included letters of

support in Clayton Endoscopy's application indicating their intent to perform procedures at the Clayton facility. It is impossible to determine whether Clayton Endoscopy is double-counting the procedures of these physicians and using their volume to justify the utilization of two different GI endoscopy centers, one in Wake Forest (north of Raleigh) and one in Clayton. These unanswered questions must be considered as Clayton Endoscopy's owner, Wake Endoscopy, has almost doubled its GI endoscopy rooms since 2012. At the start of 2012, Wake Endoscopy operated three GI endoscopy rooms at its Lake Drive facility. It was subsequently approved and developed one additional room at Lake Drive. As noted above, Wake Endoscopy acquired two existing rooms at WFEC and is approved to develop an additional room. Finally, the Clayton Endoscopy project seeks to add two more GI endoscopy rooms. Thus, if Clayton Endoscopy is approved, Wake Endoscopy will have increased its capacity from three GI endoscopy rooms in 2012 to nine rooms in 2016. By falsely assuming that it will not serve Wake County patients, Clayton Endoscopy is able to circumvent the GI endoscopy facility performance standards and avoid scrutiny of whether it can effectively utilize its approved and proposed capacity.

Additionally, throughout its application, Clayton Endoscopy asserts that its project is needed in order to provide the population of Johnston County with access to a freestanding GI endoscopy facility. It is curious then, that Clayton Endoscopy has chosen to locate its facility at the edge of Johnston County, rather than a more central location, which would be more accessible to the entire Johnston County population. As will be discussed in detail later in these comments, Clayton Endoscopy has chosen a location in a more affluent location in the county which is inconsistent with its goal of providing greater economic access. Further, Clayton Endoscopy fails to account for the existing availability of freestanding GI endoscopy services in Johnston County provided by Jordan & Associates Gastroenterology, P.A.

As a result, the application should not be approved, and is non-conforming with Criterion 3 and fails to comply with 10 NCAC 14C .3903.

Failure to Demonstrate the Need for the Proposed Project

In its application, Clayton Endoscopy relies upon unsupported use rate, market share, and patient access assumptions to demonstrate the need for the proposed project.

On page 55 of the application, Clayton Endoscopy states "[t]*he FY2012 GI endoscopy use rate for Johnston County is lower compared to the State GI endoscopy use rate. This is due to the lack of local access to more cost effective licensed freestanding GI*

endoscopy rooms." While Clayton Endoscopy states this cause and effect as fact, it is not fact; rather, it is an unsubstantiated assumption. On this basis, Clayton Endoscopy's methodology assumes that "[g]*iven local access to more cost effective, licensed freestanding GI endoscopy services, WEC reasonably assumes the Johnston County GI endoscopy use rate will gradually increase to a rate more comparable to the North Carolina GI endoscopy utilization rate*" (page 55). While this assumption at first glance appears reasonable based on the small increase in the use rate, the actual increase in GI endoscopy procedures projected for Johnston County is substantial and unreasonable. As shown below, GI endoscopy procedures in Johnston County are projected to increase 13 percent in a single year (from 2016 to 2017).

	2014	2015	2016	2017	2018
Projected Johnston County GI Endo Procedures	8,544	8,647	9,245	10,453	10,573
Annual Growth	NA	1.2%	6.9%	13.1%	1.1%

Source: Clayton Endoscopy Application page 56.

Clayton Endoscopy provides no evidence that this level of increase is reasonable or supported. Since 2007, statewide GI endoscopy volume has grown annually at no more than 6.2 percent and volume has stabilized in recent years.

	2007	2008	2009	2010	2011	2012
North Carolina Total GI Endo Procedures	546,634	580,707	589,388	564,997	574,908	579,316
Annual Growth		6.2%	1.5%	-4.1%	1.8%	0.8%

Source: Table 6D, State Medical Facilities Plan.

Clayton Endoscopy's assumed use rate increase and the resulting increase in Johnston County GI endoscopy procedures is speculative and the application fails to include data that would support the substantial increase in utilization that results.

On page 59 of its application, Clayton Endoscopy provides its assumptions for increased market share in Johnston County. Clayton Endoscopy assumes its market share will increase by 15.0 percentage points in its first year of operation and by 20.0 percentage points in the second and third years of operation. Clayton Endoscopy provides no quantitative supportive for these market share assumptions and appears to have chosen them in order to ensure that its total GI endoscopy procedures would exceed 3,000 cases annually so that it would meet the applicable performance standard. Clayton Endoscopy cites the letters of support from physicians, which include projected procedure estimates. However, the volume included in these letters is inconsistent with data

presented by Clayton Endoscopy as well as with Johnston Health's historical data.

All of Clayton Endoscopy's physicians, with the exception of Dr. Lee, are WEC physicians. According to the table on page 60 of the application, these six WEC physicians anticipate providing 2,500 procedures at the proposed facility (as shown below) and based on the assumptions provided in the application, all of these procedures are expected to be performed on Johnston County residents.

WEC Physician Projected GI Endoscopy Procedures

Physician	*# of GI Endo Procedures*
Kerry Whitt, MD	1,500
Subhash Gruber, MD	200
Neeraj Sachdeva, MD	200
Michael Mattaglino, MD	200
Indira Reddy, MD	200
Christopher Schwartz, MD	200
Total WEC Physicians	**2,500**

Source: Clayton Endoscopy Application (page 60).

According to Johnston Health data, Dr. Whitt is the only WEC physician who performs procedures from WEC in a Johnston Health GI endoscopy room. In 2013, Dr. Whitt performed 226 GI endoscopy procedures at JMC-Clayton. The remainder of Dr. Whitt's procedures were likely performed at WEC's Lake Drive facility. Similarly, the procedures for the other five WEC physicians are assumed to have historically been performed at WEC's Lake Drive facility. Based on this information, Johnston Health infers that the physician letters totaled above indicate that approximately 2,274 procedures (2,500 total - 226 at Johnston Health) were performed on Johnston County patients at WEC's Lake Drive facility. However, Clayton Endoscopy clearly states in its application that "[d]*uring 2013, WEC's Lake Drive facility performed approximately 1,034 GI endoscopy procedures on Johnston County residents*" (page 56). As such, the physician letters have overstated the Johnston County volume for WEC physicians by approximately 2,239 procedures (2,274 procedures projected to be performed by WEC according to letters - 1,034 actually performed by WEC in 2013 per the application page 56). Given this overstatement, the physician letters of support do not provide reasonable support for Clayton Endoscopy's market share assumptions.

Similarly, Dr. Lee, the only non-WEC physician, provided a letter of support indicating that he intended to perform 1,200 procedures annually at the proposed facility. However, Johnston Health internal data shows that Dr. Lee

performed only 367 procedures at JMC-Smithfield and JMC-Clayton combined in 2013. As such, Dr. Lee's volume may also be significantly overstated (by 833 procedures). Again, given this overstatement of volume in the physician letters, they cannot be used as a reasonable basis to support Clayton Endoscopy's market share assumptions.

As a result, the application should not be approved, and is non-conforming with Criterion 3.

Failure to Demonstrate that Payor Mix Assumptions Are Reasonable and Supported

On pages 85-86 of its application, Clayton Endoscopy provides its payor mix assumptions and the basis for those assumptions. Notably, Clayton Endoscopy projects to provide 4.1 percent of its services to Medicaid patients. Historically, Wake Endoscopy's facilities in Wake County have provided only 1.0 to 1.3 percent of their services to Medicaid patients. Thus, Clayton Endoscopy's projection represents a 300 to 400 percent increase over the past experience of other facilities under the same ownership. As part of the basis for its projections, Clayton Endoscopy reviewed the payor mix for all HSA IV GI endoscopy centers. On average, these centers provided only 1.4 percent of their services to Medicaid patients. Thus, Clayton Endoscopy is projecting to provide nearly 300 percent more of its services to Medicaid patients than HSA IV facilities on average. Clayton Endoscopy notes that "[a]*ccording to the Division of Medial Assistance, Wake County's 2013 Medicaid-eligible population was 9.3%. By comparison, Johnston County's 2013 Medicaid-eligible population was 17.3%*" (page 86). As such, Johnston County's Medicaid-eligible population is 186 percent greater than Wake County's. However, this disparity is certainly not sufficient to explain the 300 to 400 percent increase over the experience of other providers that Clayton Endoscopy is projecting. Clayton Endoscopy's projected Medicaid payor mix is simply not supported by the data provided, and is therefore unsubstantiated and unreasonable.

Clayton Endoscopy argues that it "*seeks to increase access for Medicaid patients in Johnston County. WEC will actively market Medicaid patients and referral sources* [sic]. *Based on its experience working with Project Access of Wake County, WEC's physician owners will strive to identify and coordinate with similar Johnston County programs to make Clayton Endoscopy available to medically indigent patients who need GI endoscopy services*" (page 86). These statements are nothing more than lip service. The experience of Clayton Endoscopy's owner in Wake County suggests that it has historically provided below average access to Medicaid patients. Furthermore, the reference to Clayton Endoscopy's desire to coordinate with programs in

Johnston County similar to Project Access is particularly disingenuous. Johnston Health operates Project Access in Johnston County. As previously noted, Clayton Endoscopy made no effort prior to filing this application to coordinate with Johnston Health.

Finally, Clayton Endoscopy's payor mix is unsupported by its proposed location. According to U.S. Census Bureau, the town of Clayton, the proposed location for Clayton Endoscopy, is more affluent than Johnston County as a whole. Clayton's median household income is $61,218, which is 22 percent higher than Johnston County as a whole ($50,132). Moreover, 10.9 percent of Clayton's population lives below the poverty level compared to 16.1 percent for Johnston County as a whole. As such, the proposed location for Clayton Endoscopy suggests that its payor mix will include fewer Medicaid persons than if the facility were located in a more central Johnston County location.

In addition to unsupported projection of Medicaid patients, Clayton Endoscopy misrepresents its prepayment requirements. On page 79 and 80 of its application, Clayton Endoscopy states that it "*will not turn away any patient for not having the ability to pay his or her cost share or deductible at the time of service. If Medicare, Medicaid, or any other third-party payor does not cover a patient, WEC establishes appropriate payment arrangements. Please see Exhibit 12 for a copy of the relevant patient financial policies. The underlying principle upon which WEC operates is that no patient is denied needed treatment based upon the inability to pay*" [emphasis added]. However, Clayton Endoscopy's Self Pay Patients Policy and Procedure in Exhibit 12 states that "[i]*f a patient can not 'pay in full' then the patient must be rescheduled. If a patient has been given the fee for self-pay and is unable to pay and has been referred by a Referring MD for a problem it will be up to the MD to determine if the patient can be seen.*" Clayton Endoscopy's policy makes clear that patients are not seen regardless of their ability to pay, in fact, they are rescheduled if they cannot pay and whether or not they receive treatment is at the discretion of the physician. These policies indicate a lack of commitment to treating the underserved.

As a result, the application should not be approved, and is non-conforming with Criterion 13.

Failure to Provide Required Financial Information and Demonstrate that Financial Assumptions are Reasonable

On page 21 of its application, Clayton Endoscopy provides its projected procedures by CPT code. Clayton Endoscopy projects to provide CPT Code 43760, or "Change Sastrostomy Tube Percutaneous W/O Guide" four to six times annually, making that code one of its Top 10 codes in volume annually. 10

NCAC 14C .3902 (6) requires the applicant to report "the type and projected average facility charge for the 10 GI endoscopy procedures which the applicant projects will be performed most often in the facility." In its response, Clayton Endoscopy did not include the charge for CPT Code 43760. Similarly, in its response to 10 NCAC 14C .3902 (10), Clayton Endoscopy failed to include the average reimbursement projected for CPT Code 43760.

In fact, Clayton Endoscopy's reimbursement projections are entirely inconsistent with its financial statements. As shown in the table below, the projected reimbursement for its top 10 procedures when aggregated exceeds its total projected reimbursement as shown on Form E in each of the three project years.

Project Year One Overstatement of Revenue

	Annual Reimbursement per Response to 10A NCAC 14C .3902 (1)	*PY1 Volume per Response to 10A NCAC 14C .3902 (2) (D)*	*Net Revenue*
45378	$663	862	$571,506
45385	$841	676	$568,516
45380	$733	352	$258,016
43239	$462	297	$137,214
43235	$482	81	$39,042
43248	$520	59	$30,680
45331	$516	11	$5,676
45330	$450	11	$4,950
43249	$462	4	$1,848
43245	$881	1	$881
TOTAL			$1,618,329
Form E Total Net Revenue			$1,405,750
Overstatement of Revenue			**$212, 579**

Project Year Two Overstatement of Revenue

	Annual Reimbursement per Response to 10A NCAC 14C .3902 (1)	*PY1 Volume per Response to 10A NCAC 14C .3902 (2) (D)*	*Net Revenue*
45378	$663	1,118	$741,234
45385	$841	877	$737,557
45380	$733	456	$334,248
43239	$462	385	$177,870
43235	$482	105	$50,610
43248	$520	77	$40,040
45331	$516	14	$7,224
45330	$450	14	$6,300
43249	$462	6	$2,772
43245	$881	2	$1,762
TOTAL			$2,099,617
Form E Total Net Revenue			$1,823,453
Overstatement of Revenue			**$276,164**

Project Year Three Overstatement of Revenue

	Annual Reimbursement per Response to 10A NCAC 14C .3902 (1)	*PY1 Volume per Response to 10A NCAC 14C .3902 (2) (D)*	*Net Revenue*
45378	$663	1,126	$746,538
45385	$841	884	$743,444
45380	$733	460	$337,180
43239	$462	388	$179,256
43235	$482	106	$51,092
43248	$520	77	$40,040
45331	$516	14	$7,224
45330	$450	14	$6,300
43249	$462	6	$2,772
43245	$881	2	$1,762
TOTAL			$2,115,608
Form E Total Net Revenue			$1,837,762
Overstatement of Revenue			**$277,846**

As a result, the application should not be approved, and is non-conforming with Criterion 5.