ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

DATE OF DECISION: August 15, 2013
FINDINGS DATE: August 15, 2013

PROJECT ANALYST: Celia C. Inman
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: #O-10143-13 / Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center / Develop a second gastrointestinal endoscopy room in an existing licensed facility/ Brunswick County

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

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

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

NA

Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center (NHBMC) is an existing, licensed, and accredited North Carolina acute care hospital located at 240 Hospital Drive NE, Bolivia, in Brunswick County. NHBMC proposes to develop a second GI endoscopy procedure room at the existing facility.

The total capital expenditure for the proposed project is less than $2 million. There are no policies or need determinations in the 2013 State Medical Facilities Plan applicable to the review of applications for GI endoscopy rooms. Therefore, this criterion is not applicable in this review.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic

minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

NHBMC is an existing, licensed, and accredited North Carolina acute care hospital located at 240 Hospital Drive NE, Bolivia, in Brunswick County. NHBMC proposes to add one GI endoscopy room to the existing facility for a total of two GI endoscopy rooms.

Population to be Served

In Sections III.6 and III.7, pages 62-63, the applicant provides the current and projected patient origin for GI endoscopy services at NHBMC, as illustrated in the following table.

COUNTY	CURRENT (FFY 2012)	PROJECTED	
		YEAR ONE (FFY 2015)	YEAR TWO (FFY 2016)
Brunswick	95.5%	95.5%	95.5%
Other	4.5%	4.5%	4.5%
Total	**100.0%**	**100.0%**	**100.0%**

Per the corrected 2013 License Renewal Application submitted by NHBMC and provided in Exhibit 2, page 0168, "Other" in the above table includes: Bladen, Columbus, Durham, Forsyth, Granville, Mecklenburg, Moore, New Hanover, Northampton, Onslow, Pender, Richmond, Wake, Georgia, South Carolina, Tennessee, Virginia, and other states.

On page 62, the applicant states that projected patient origin is based on its historical GI patient origin. The applicant adequately identifies the population proposed to be served.

Need for the Proposal

In Section III.1, page 39, the applicant states the following factors support the need to develop one additional GI endoscopy room at NHBMC in Brunswick County:

- NHBMC growth in hospital utilization,
- Utilization of existing GI endoscopy resources at NHBMC,
- Utilization of existing GI endoscopy resources at Wilmington Gastroenterology Associates, PA,
- Growth in population and GI endoscopy use rate for Brunswick County residents ages 55+,
- Prevalence of gastrointestinal disorders,
- Importance of early detection of colorectal cancer, and
- The Patient Protection and Affordable Care Act of 2010.

Growth in Hospital Utilization

NHBMC's new replacement hospital facility opened in August 2011, during the last quarter of FFY2011. In Section III.1, page 39, the applicant states, *"In one year, the new facility has been successful in recapturing significant volumes previously leaving the county to seek health care services in New Hanover County."* The applicant further states that NHBMC market share of Brunswick County inpatient admissions, inpatient surgery and outpatient surgery increased 5.8%, 0.7% and 0.2%, respectively in the one year since opening.

Utilization of NHBMC GI Endoscopy Resources

The approval of the CON Project I.D. # O-7767-06 to build the NHBMC replacement hospital contained a condition that reduced the number of GI endoscopy procedure rooms at the facility from two to one. In Section III.1, page 40, the applicant states NHBMC showed a steady increase in annual GI endoscopy procedure volume during the last three fiscal years, with a compound annual growth rate (CAGR) in procedures of 4.3%, as shown in the table below.

Historical Utilization of NHBMC GI Cases and Procedures

	FFY2010	**FFY2011**	**FFY2012**	**CAGR 2010-2013**
GI Endoscopy Cases	1,777	1,781	1,716	
GI Endoscopy Procedures	2,010	2,121	2,187	4.3%
Average Procedures per Case	1.1	1.2	1.3	
GI Endoscopy Rooms Needed at 1,500 Procedures/Year	1.3	1.4	1.5	

The table above shows procedures per case has steadily increased from 2010 through 2012. Also shown in the table, NHBMC has sufficient GI endoscopy procedure volume in FFY2012 to support 1.5 GI endoscopy rooms at the planning capacity of 1,500 procedures per year.

The applicant also provides the NHBMC GI endoscopy cases performed during FFY 2013 from October through March (annualized) at 1,782 cases, a 0.1% CAGR in cases for 2010 through 2013. The number of annualized cases FFY2013 is an increase of 3.8% over FFY2012.

The following table shows a comparison of GI endoscopy case volume at NHBMC in the last two years beginning April 2011 through March 2013, which the applicant states is the most current data available.

Historical NHBMC GI Endoscopy Cases April 2011 – March 2013

	April 2011-March 2012	April 2012-March 2013	Percent Increase
GI Endoscopy Inpatient Cases	126	148	17.5%
GI Endoscopy Outpatient Cases	1,488	1,665	11.9%
Total GI Endoscopy Cases	1,614	1,813	12.3%

The applicant also provides data on page 41 showing NHBMC's utilization in cases increased significantly each quarter in the April 2012–March 2013 year over the same quarters in the April 2011-March 2012 year. The applicant states, *"Also shown in the previous table, NHBMC has GI endoscopy volume in April 2012-March 2013 to support more than one GI endoscopy procedure room, assuming an average of 1.3 procedures per case and a planning target of 1,500 procedures per room per year."* Based on the performance standard promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility is currently operating at 157.1% of capacity [1,813 cases x 1.3 = 2,357 procedures / 1,500 = 1.5713].

Utilization of Wilmington Gastroenterology Associates, PA GI Endoscopy Resources

Seven gastroenterologists comprise a physician practice called Wilmington Gastroenterology Associates, PA (WGA) in Wilmington NC. WGA owns and operates a freestanding ambulatory surgery center with four licensed GI endoscopy procedure rooms in Wilmington, NC. The 2013 State Medical Facilities Plan (SMFP) reports WGA performed 11,450 procedures in the four GI endoscopy procedure rooms during FY2011. Based on the performance standard promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility was operating at 190.9% of capacity [(11,450 procedures / 4 rooms = 2,863 procedures per room) / 1,500 = 1.9086]. The applicant provides data on page 42 that shows a 13.1% CAGR in GI endoscopy procedures performed at WGA between FY2010 and FY2012.

In Section III.1, page 42, the applicant states that two WGA gastroenterologists began performing GI endoscopy cases at NHBMC in February 2013. The applicant further states that those physicians have expressed interest in expanding the number of GI endoscopy cases they perform at NHBMC and that other WGA gastroenterologists are also considering seeking privileges to practice at the NHBMC GI Endoscopy suite when a second room is available. See Exhibit 5, pages 0615-0616 for WGA physician letters documenting their interest in scheduling more procedures at NHBMC and their support of the proposed project.

In Section III.1, page 43, the applicant presents the following table to demonstrate the number of Brunswick County patients who received GI endoscopy procedures at WGA in New Hanover County.

Wilmington Gastroenterology Associates, PA
Brunswick County Patients GI Endoscopy Cases: FFYs2010-2012

Oct - Sept	FFY2010	FFY2011	FFY2012
Brunswick County Patients	1,447	1,419	1,883
Total WGA Patients	8,314	8,038	10,158
Brunswick County Patients as % of Total WGA Patients	17.4%	17.7%	18.5%

As shown in the table above, WGA provides GI endoscopy services to a large number of Brunswick County patients; in fact, more than 18% of WGA's patients are from Brunswick County. In addition, Exhibit 3, Table 4 (page 0206) data from the DHSR Planning Section, demonstrates that WGA's market share of Brunswick County GI endoscopy procedures was 19.9%, 21%, and 28.7%, for FFYs 2010, 2011 and 2012, respectively. The applicant states that a second GI endoscopy procedure room at NHBMC would allow WGA physicians to perform more GI endoscopy procedures at NHBMC. The applicant further states that additional capacity at NHBMC will allow Brunswick County patients to have their GI endoscopy procedures performed by a WGA physician practicing in the patient's county of residence.

Growth in Population and GI Endoscopy Use Rate for Residents 55+

On pages 43-45, the applicant provides demographic data for Brunswick County. On page 43, the applicant states, "*Brunswick County's total population grew from 73,143 to 107,431 between 2000 and 2010, an increase of 46.9%. Brunswick County is the 37th fastest growing county in the country.*" The applicant states that a large contributor to the growth in Brunswick County is that it is a popular retirement destination with beautiful weather, great beaches and endless activities.

On page 44 and in Exhibit 3, page 0207, the applicant provides data on the steady growth of the total population of Brunswick County and of the population aged 55 and older, the age group that the applicant states is most likely to utilize GI endoscopy services. The data is summarized in the table below.

Brunswick County Population

Year	Total Population	Population Age 55+
2010	108,064	43,013
2011	110,312	44,685
2012	112,597	46,354
2013	114,882	47,982
2014	117,168	49,537
2015	119,451	51,148
2016	121,737	52,653
2017	124,022	54,104
2010-2013 CAGR	2.06%	3.71%
2013-2017 Projected CAGR	1.93%	3.05%

Source: Applicant: NCOSBM, last updated 4/18/13

As shown in the table above, the population aged 55+ grew at a CAGR of 3.71% between 2010 and 2013. The population is projected to have a CAGR of 3.1% from 2013 through 2017.

Prevalence of Gastrointestinal Disorder

In Section III.1, page 45, the applicant provides information from a June 2005 national study reported in Clinical Gastroenterology and Hepatology that concluded that 44.9% of U.S. adults had gastrointestinal symptoms over a three month period.[1] The applicant further states:

> *"Based upon those statistics, in 2013, there are over 21,500 residents ages 55+ (44.9% x 47,982) in Brunswick County struggling with gastrointestinal issues. GI endoscopy is a major tool in determining underlying disease issues for many of those GI disorders."*

Importance of Early Detection of Colorectal Cancer

In Section III.1, page 46, the applicant states, *"The American Cancer Society (ACS) has actively pursued increased screening for colon cancer for years, including the use of outpatient GI endoscopy."* The applicant further states that colonoscopy is the definitive test for colorectal cancer screening. On page 49, the applicant states,

> *"By Project Year 2 (FFY 2016), it is estimated that the population of those over 55 years of age within Brunswick County, who should receive screening exams for colon cancer, will increase by approximately 39% as reflected in Exhibit 3, Table 8*

[1] http://www.ncbi.nlm.nih.gov/pubmed/15952096

for Brunswick County population. The age of residents in Brunswick County supports the need for easily accessible, high quality GI endoscopy services."

The Patient Protection and Affordable Care Act of 2010

In Section III.1, page 50, the applicant provides information on The Patient Protection and Affordable Care Act of 2010 (PPACA), stating that the act, along with recent reimbursement changes, will lead to a growing number of colorectal cancer screening procedures through 2017. The applicant states,

"Under the PPACA, all new health insurance policies must cover preventative exams, including colonoscopies, without charging out-of-packet fees such as co-payments or deductibles. As of January 1, 2011, colorectal cancer screening colonoscopies are fully covered for all Medicare beneficiaries with no out-of-pocket fees. The expanded coverage of colorectal cancer screening procedures will increase the number of colonoscopies performed over the next five years.[2] That expected growth supports the development of a second GI endoscopy procedure room at NHBMC."

Historical and Projected Utilization

The following table illustrates the applicant's historical and projected utilization of the existing and proposed GI endoscopy procedure rooms at NHBMC, as reported by the applicant in Sections IV.1 and IV.2, pages 66-67.

NHBMC GI Endoscopy Volume: FFYs 2011-2017

	Actual		Projected				
	FFY2011	**FFY2012**	**FFY2013**	**FFY2014**	**FFY2015**	**FFY2016**	**FFY2017**
Inpatient	157	180	186	192	201	207	207
Outpatient	1,964	2,007	2,077	2,145	2,502	2,824	2,908
Total Procedures	2,121	2,187	2,263	2,337	2,703	3,031	3,114
# of GI Endoscopy Procedure Rooms	1	1	1	1	2	2	2
Average # of Procedures per Room	2,121	2,187	2,263	2,337	1,352	1,516	1,557
Percent of Capacity	1.41	1.46	1.51	1.56	0.90	1.01	1.04

Sums may not total due to rounding.

As shown in the above table, in FFY2011, NHBMC performed 2,121 GI endoscopy procedures in one procedure room, which is 141% of capacity. In the second full operating year after project completion, NHBMC projects performing 3,031 GI endoscopy procedures in the two procedure rooms, which exceeds the minimal threshold of 1,500 procedures per room.

[2] http://www.endonurse.com/news/2010/08/new-screening-coverage-will-boost-gi-endoscopy-market.aspx

The applicant's assumptions and methodology used to project utilization are provided in Section III.1, pages 50-57, and are summarized below.

Step 1: Determine Base Volume for Use in Projections

The applicant states that it reviewed internal Trendstar data for the most recent three fiscal years to assure the reliability of the internal database and to confirm the accuracy of data reported on its 2011-2013 License Renewal Applications. The applicant further states that NHBMC determined it underreported GI endoscopy volume and therefore submitted corrected 2011-2013 License Renewal Applications to the DHSR Licensure Section. The applicant included the corrected applications in Exhibit 2 of the application and provided the following table on page 51.

Novant Health Brunswick Medical Center
GI Endoscopy Volume: FFYs 2010-2012

Oct-Sept	***FFY2010***	***FFY2011***	***FFY2012***
GI Endoscopy Cases	*1,777*	*1,781*	*1,716*
GI Endoscopy Procedures	*2,010*	*2,121*	*2,187*
Average Procedures per Case	*1.1*	*1.2*	*1.3*

Source: Exhibit 3, Table 1

On page 51, the applicant states, *"NHBMC determined that FFY 2012 data is the most current and reasonable data to use as a base to project future GI endoscopy utilization."*

Step 2: Determine GI Endoscopy Use Rate for Brunswick County

In Section III, page 51, the applicant states,

> *"NHBMC analyzed GI endoscopy data reported on the DHSR Medical Facilities Planning Branch GI Endoscopy Facility Reports for 2011-2012 (included in Exhibit 3) and 2013 LRA on Annual Hospital and Ambulatory Surgical Centers-Endo Only Licensure Renewal Applications to determine the number of Brunswick County residents who received GI endoscopy services from a licensed facility in FFY 2010-FFY 2012, respectively, as shown in the following table.*

Brunswick County Residents
GI Endoscopy Cases: FFYs 2010-2012

Oct-Sept	*FFY2010*	*FFY2011*	*FFY2012*
Hospital	*4,062*	*3,937*	*3,414*
Freestanding	*3,211*	*2,824*	*3,145*
Total	*7,273*	*6,761*	*6,559*

Source: Exhibit 3, Table 5

…

Use rate is calculated by dividing annual GI endoscopy cases by county population 55+ and then multiplying the quotient by 1,000."

NHBMC provides the GI endoscopy use rates for the Brunswick County population aged 55+ on page 44 and in Exhibit 3, Table 9 on page 0207. The applicant names the tables in the application as Use Rate but labels the figures as Cases, as shown in the following table.

Brunswick County
GI Endoscopy Use Rate for Population 55+: FYs 2010-2012

Brunswick	***2010***	***2011***	***2012***	***Three Year Average***
Hospital Cases [use rate]	*94.44*	*88.11*	*73.65*	*85.40*
Freestanding Cases [use rate]	*74.65*	*63.20*	*67.85*	*68.57*
Total Cases [use rate]	*169.09*	*151.30*	*141.50*	*153.96*

Source: Exhibit 3, Table 9

In the Use Rate table above, and on page 44, the applicant adds together the number labeled Hospital Cases to the number labeled Freestanding Cases to attain Total Cases. Then, on page 52, the applicant uses the sum as the GI endoscopy use rate for the population 55+ to calculate projected cases. In supplemental information requested by the CON Project Analyst and submitted by NHBMC during the expedited review of this application, the applicant confirmed the labels were meant to be "Use Rate", not "Cases". Additional analysis of the data provided shows that if one divides the total number of 2012 Brunswick County GI endoscopy cases (shown in Exhibit 3, Table 7, page 0207) by the 2012 population 55+ (shown in Exhibit 3, Table 8, page 0207) and multiplies it by 1000, the result is a use rate of 141.5 (6,559 / 46,354 x 1000 = 141.49) for the population 55+, agreeing with the 2012 use rate in table above. Thus, the numbers in the table above appear to be reasonable use rates for the population 55 years and older.

On page 52 of the application, the applicant states, *"Persons 55+ are the age group most likely to utilize GI endoscopy services. NHBMC, therefore, believes use of the 55+ use rate is reasonable and yields an accurate projection of GI endoscopy volume for Brunswick County."* The applicant provides supporting documentation for the assumption on pages

47-49 and in supplemental information, showing that persons 50 years and older are the age group most likely to utilize the proposed services. However, the NC Office of State Budget & Management (OSBM) breaks its population projections down based on the population 55+; therefore, proxy use of the 55+ population appears to be a reasonable assumption for the applicant's projections.

Step 3: Calculate Expected Brunswick County GI Endoscopy Cases

The applicant calculated expected Brunswick County GI endoscopy cases by multiplying the FFY 2012 GI endoscopy use rate for the population 55+ (Step 2) by annual projected county population 55+ divided by 1,000, as shown in the following table and on page 52 of the application.

Brunswick County
Expected GI Endoscopy Cases: FFYs 2012-2017

Brunswick County	***FFY2012***	***FFY2013***	***FFY2014***	***FFY2015***	***FFY2016***	***FFY2017***
Population 55+	*46,354*	*47,982*	*49,537*	*51,148*	*52,653*	*54,104*
GI endoscopy Use Rate 55+	*141.5*	*141.5*	*141.5*	*141.5*	*141.5*	*141.5*
Expected GI Endoscopy Cases	*6,559*	*6,789*	*7,009*	*7,237*	*7,450*	*7,656*

Source: Exhibit 3, Table 11

The above table shows the applicant used the 2012 use rate of 141.5, rather than the higher three-year average use rate of 153.9; thus, resulting in a more conservative projection.

In Section III.1, pages 44-45, the applicant discusses the possible reasons for the decline in the GI endoscopy use rate over the last few years and provides sources that attribute the decline to the global economic crisis. On page 53, the applicant states,

> *"NHBMC held the FFY 2012 total GI endoscopy use rate constant through FFY 2017 based on its reasonable belief that the 55+ use rate will no longer decrease and may increase as a result of the expanded coverage of colorectal cancer screening procedures under the PPACA."*

Step 4: Determine NHBMC Market Share of Brunswick County GI Endoscopy Cases

In Section III, page 53, the applicant states,

> *"NHBMC used the DHSR Planning Branch GI Endoscopy Facility Reports (2011-2012) and 2013 LRAs to determine the number of GI endoscopy cases performed at hospitals and freestanding facilities for Brunswick County residents."*

The applicant includes copies of the reports mentioned above in Exhibit 3. Based on that data, NHBMC calculated its market share of total GI endoscopy cases in Brunswick County, as shown below from Table 4 of Exhibit 3.

Table 4. GI Endoscopy Market Share of Brunswick County Residents

GI Endoscopy Cases	*FY 2010*		*FY 2011*		*FY 2012*		*Three-Yr Average*
NHBMC*	***1,710***	***23.5%***	***1,707***	***25.2%***	***1,639***	***25.0%***	***24.6%***
Wilmington Gastroenterology	*1,444*	*19.9%*	*1,419*	*21.0%*	*1,883*	*28.7%*	*23.2%*
NHRMC	*909*	*12.5%*	*1,098*	*16.2%*	*682*	*10.4%*	*13.0%*
Endoscopy Center of NHMRC	*0*	*0.0%*	*0*	*0.0%*	*753*	*11.5%*	*3.8%*
Dosher	*831*	*11.4%*	*889*	*13.1%*	*787*	*12.0%*	*12.2%*
Wilmington Health	*318*	*4.4%*	*329*	*4.9%*	*400*	*6.1%*	*5.1%*
UNC Hospitals	*133*	*1.8%*	*126*	*1.9%*	*116*	*1.8%*	*1.8%*
Duke University	*51*	*0.7%*	*42*	*0.6%*	*69*	*1.1%*	*0.8%*
Wimington SurgCare	*62*	*0.9%*	*62*	*0.9%*	*59*	*0.9%*	*0.9%*
Columbus Regional	*58*	*0.8%*	*24*	*0.4%*	*47*	*0.7%*	*0.6%*
Atlantic Surgery Center	*0*	*0.0%*	*120*	*1.8%*	*0*	*0.0%*	*0.6%*
All Other	*1,757*	*24.2%*	*945*	*14.0%*	*124*	*1.9%*	*13.3%*
Grand Total	*7,273*	*100.0%*	*6,761*	*100.0%*	*6,559*	*100.0%*	*100.0%*

Source: Planning Branch GI Encoscopy Facility Reports (2011-2012); 2013 LRAs
**Revised data to be reported to Licensure Section on Revised 2011, 2012, 2013 LRAs*
Note: Facilities that reported more than 50 GI endoscopy cases(=patients)
Note: Atlantic Surgery Center delicensed in 10/1/2012

As the table above demonstrates, NHBMC has averaged a 25% market share over the last three years, with only Wilmington Gastroenterology (WGA) surpassing its market share with 28.7% in FY2012. On page 53, the applicant states,

> *"As documented in the physician letters included in Exhibit 5, the existing two gastroenterologists practicing at the NHBMC GI Endoscopy Suite and WGA physicians reasonably expect that some Brunswick County patients currently seeking GI Endoscopy procedures outside Brunswick County, especially in New Hanover County, will choose in the future to seek GI Endoscopy services at NHBMC after the second GI Endoscopy room becomes operational in October 2014. That transition is projected to increase market share at NHBMC as shown in the following table.*

Novant Health Brunswick Medical Center
Brunswick County Market Share: FFYs2012-2017

Oct-Sept	***FFY 2012***	***FFY 2013***	***FFY 2014***	***PY1: FFY 2015***	***PY2: FFY 2016***	***PY3: FFY 2017***
Market Share	*25.0%*	*25.0%*	*25.0%*	*28.0%*	*30.5%*	*30.5%*
Net Increase				*3.0%*	*2.5%*	

Source: Exhibit 3, Table 11

> *As shown in the previous table, NHBMC reasonably assumes that its market share will increase a total of 5.5% as a result of a shift of outpatient GI endoscopy cases*

performed on Brunswick County residents from New Hanover health service facilities to NHBMC."

Step 5: Calculate Projected Brunswick County GI Endoscopy Cases at NHBMC

The applicant states that NHBMC determined its projected number of Brunswick County GI endoscopy cases by multiplying the expected Brunswick County GI endoscopy cases (Step 3) by NHBMC's projected market share of Brunswick County cases (Step 4), as discussed in the application on pages 54 through 56.

NHBMC Projected Brunswick County GI Endoscopy Cases

Brunswick County	FFY 2012 Actual	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Expected Brunswick County GI Endoscopy Cases	6,559	6,789	7,009	7,237	7,450	7,656
NHBMC Market Share	25.0%	25.0%	25.0%	25.0%	25.0%	25.0%
Projected Cases @ 25% Share	1,639	1,697	1,752	1,809	1,862	1,913
Increase in Market Share %				3.0%	5.5%	5.5%
Increase in Market Share Cases				217	410	421
NHBMC Projected Brunswick County GI Endoscopy Cases				2,026	2,271	2,334

Source: Exhibit 3, Table 11
Sums may not total due to rounding.

On Page 55, the applicant states,

"It is important to note that NHBMC is projecting an increase in outpatient GI endoscopy cases only as a result of volumes shifting from Wilmington health service facilities to NHBMC beginning in FFY 2015, when there is more GI Endoscopy capacity available due to the opening of NHBMC's second GI Endoscopy Room."

Letters in Exhibit 5 from WGA physicians demonstrate support for the applicant's expectations.

Step 6: Calculate Total GI Endoscopy Cases at NHBMC

The applicant states that NHBMC anticipates that 95.5% of its GI endoscopy cases will be Brunswick County patients and 4.5% of its GI endoscopy cases will be performed on patients who in-migrate from other North Carolina Counties and other states, based on its 2012 historical patient origin as presented in Exhibit 2. The applicant further states that one GI endoscopy case is equal to one GI endoscopy patient. The applicant projects total GI endoscopy cases as presented on page 56 and in the following table.

NHBMC Projected Total GI Endoscopy Cases

October - September	FFY 2012 Actual	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Brunswick County GI Endoscopy Cases	95.5%	1,697	1,752	2,026	2,271	2,334
All Other In-migration GI Endoscopy Cases	4.5%	80	82	95	107	110
Total GI Endoscopy Cases	100.0%	1,776	1,834	2,121	2,378	2,444

Source: Exhibit 3, Table 11
Sums may not total due to rounding.

Step 7: Calculate Total GI Endoscopy Procedures at NHBMC

The applicant states that NHBMC determined the number of GI endoscopy procedures per case based on the facility's historical experience of 1.3 procedures per case in FFY 2012. In the following table, the applicant multiplies the total number of GI endoscopy cases projected in Step 6 by 1.3 and determines the number of GI endoscopy procedure rooms needed to support its projected volume.

NHBMC Projected GI Endoscopy Procedures: FFYs 2013-2017

Oct-Sept	FFY 2013	FFY 2014	FFY 2015	FFY 2016	FFY 2017
Total GI Endoscopy Cases	1,776	1,834	2,121	2,378	2,444
Average Procedures / Case	1.3	1.3	1.3	1.3	1.3
Total GI Endoscopy Procedures	2,264	2,337	2,703	3,031	3,114
Procedure Rooms Needed at 1,500 Procedures/Year	1.5	1.6	1.8	2.0	2.1
NHBMC Projected Licensed GI Endoscopy Procedure Rooms	1	1	2	2	2

Source: Exhibit 3, Table 11
Sums may not total due to rounding.

On pages 56-57, the applicant states, *"The previous table shows that NHBMC projects GI endoscopy volume sufficient to support two GI endoscopy procedures rooms at a planning target of 1,500 GI endoscopy procedures per room per year by the end of Project Year 2."*

The applicant adequately demonstrates that it is reasonable to assume that it will perform 3,031 GI endoscopy procedures in the two GI endoscopy rooms in the second operating year, which is an average of 1,515 procedures per room [3,031 procedures / 2 rooms = 1,515.5 procedures per room]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room as required by 10A NCAC 14C .3903(b).

Access to the Proposed Services

In Section VI, page 82, the applicant states,

> *"It is the policy of all the Novant Health facilities and programs, including Novant Health Brunswick Medical Center to provide necessary services to all individuals without regard to race, creed, color, or handicap. Novant Health facilities and programs do not discriminate against the above-listed persons, or other medically underserved persons, regardless of their ability to pay."*

In Section VI, page 98, the applicant demonstrates its projected GI endoscopy payor mix will mirror its current GI endoscopy payor mix, with 71.3% of its GI endoscopy cases being Medicare and Medicaid.

Exhibit 6 contains a copy of the Novant Health Charity Care policies, the Novant Medical Group Charity Care Policy and the Financial Assistance Policy. The applicant states that these policies will continue to apply at NHBMC, and to the Novant Health Medical Group surgeons, gastroenterologists, and other physicians associated with the NHBMC GI Endoscopy program. The applicant further describes its charity and financial payment policies on pages 82-93. NHBMC projects that it will provide over $300,000 (19.49%) in charity care and close to $100,000 (6.02%) in bad debt services to GI endoscopy patients in each of its first two years of operation of the project.

On page 87, the applicant states there are no specific "admission requirements" for either inpatient or outpatient GI endoscopy procedures at NHBMC, other than a physician referral.

In summary, the applicant adequately identified the population to be served and demonstrates the need the population proposed to be served has for one additional GI endoscopy procedure room at NHBMC. The applicant also adequately demonstrates that all residents of the area, in particular, the underserved, will have adequate access to the proposed services. Consequently, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.8, pages 63-64, the applicant describes the alternatives considered, which include: 1) maintain the status quo; 2) develop a new GI endoscopy procedure room in a freestanding ambulatory surgery center in Brunswick County with one GI endoscopy procedure room; and 3) develop a second GI endoscopy procedure room at NHBMC, as proposed.

The applicant states that maintaining the status quo is not an effective alternative because the growth following the opening of the replacement hospital facility in Bolivia makes it necessary to add capacity for GI endoscopy procedures. The one GI endoscopy procedure room at NHBMC is fully utilized. The facility does not have current capacity sufficient to meet the demand of its existing practicing physicians. The applicant states, *"Quality, patient safety, efficiency, local access, and the needs of physicians, staff, and patients make continuing the status quo an unacceptable alternative."*

Regarding developing a new GI endoscopy procedure room to establish a freestanding ambulatory surgery center, the applicant states that a freestanding ambulatory surgery center with only one GI procedure room may not be financially sustainable and would not address the capacity crunch that exists at the one GI endoscopy room at NHBMC. In addition, the applicant states that the capital expenditure associated with the development of a new freestanding ambulatory surgical facility is considerably more than expanding the GI endoscopy suite at NHBMC. Moreover, having two single room endoscopy programs would require the endoscopy physicians to travel between the two sites, and require two separate sets of GI endoscopy staff in two different physical locations, which the applicant says would result in more costly and less efficient care delivery.

The applicant states that adding a second GI endoscopy room, as proposed, is a low cost project which will improve access to GI endoscopy services for the residents of Brunswick County. The one existing NHBMC GI endoscopy room is operated at capacity and there is no time available for additional GI endoscopy procedures. The applicant further states,

> *"The renovation of existing space at NHBMC to expand the existing GI Endoscopy program can be accomplished much more expeditiously than a project involving the construction of a new facility containing new GI endoscopy capacity. Therefore, adding a second GI endoscopy procedure room at NHBMC is the most reasonable alternative."*

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria. See Criteria (3), (5), (6), (7), (8), (13), (14), (18a), (20) and 10A NCAC 14C .3900.

The applicant adequately demonstrates that the proposal to develop a second GI endoscopy procedure room at the existing facility is the most effective or least costly alternative to meet the need for additional capacity at NHBMC now and in the near future. Consequently, the application is conforming to this criterion, and is approved subject to the following conditions:

1. **Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center shall materially comply with all representations made in the certificate of need application and supplemental information provided. In those instances where representations conflict, Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center shall materially comply with the last made representations.**

2. **Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application or that would otherwise require a certificate of need.**

3. **Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center shall develop no more than one additional gastrointestinal endoscopy room and shall be licensed for a total of no more than two gastrointestinal endoscopy rooms upon completion of the project.**

4. **Brunswick Community Hospital d/b/a Novant Health Brunswick Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Certificate of Need Section in writing prior to issuance of the certificate of need.**

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

C

In Section VIII.3, page 111, the applicant projects the total capital cost for the project will be $459,856. On page 112, the applicant states the capital cost will be financed through Novant Health's accumulated reserves and provides the projected interest expense in the pro forma assumptions on pages 140-141. In Section IX, page 120, the applicant states there will be no start up or initial operating expenses.

Exhibit 7 contains a May 28, 2013 letter from Novant Health's Senior Vice President Operational Finance stating Novant Health will provide funding for the proposed project. The exhibit also contains a letter from NHBMC President which demonstrates NHBMC's commitment to receive funds from Novant Health for the proposed project, stating,

"At the time that the capital funding arrangements for this project are finalized, we will execute the appropriate internal documents to indicate that the applicant NHBMC will incur the obligation for the capital expenditure for this project. This is also documented as part of the NHKMC [sic] *Pro Forma Income statement and assumptions in our CON Application."*

The pro forma assumptions, provided on pages 140-141 of the application, include the interest amortization schedule associated with the financing of the projected $459,856 capital expenditure. Exhibit 7 also contains Novant Health, Inc. and Affiliates Combined Financial Statements documenting available funds for the project. Both of the letters mentioned above state that at the time the capital is required, a decision may be made to fund all or part of the proposed capital expenditure using tax-exempt bond proceeds.

The applicant provided pro forma financial statements for the first three years of the project. The applicant projects revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below.

NHBMC GI Endoscopy Services	Project Year 1	Project Year 2	Project Year 3
Projected # of Procedures	2,703	3,031	3,114
Projected Average Charge	$ 1,885	$ 1,941	$ 2,000
Gross Patient Revenue	$ 5,095,646	$5,884,474	$6,229,228
Deductions from Gross Patient Revenue	$ 3,488,028	$4,027,986	$4,263,974
Net Patient Revenue	$ 1,607,621	$1,856,488	$1,965,254
Total Expenses	$ 814,337	$ 890,498	$ 917,627
Net Income	$ 793,284	$ 965,990	$1,047,626

The applicant also projects a positive net income for the entire facility in each of the first three operating years of the project. The applicant provides the projected average facility charge per case for the ten most commonly performed GI endoscopy procedures on page 27 of the application. From data provided in the pro forma Forms C and D, the analyst calculated the average facility charge per procedure during each of the first three operating years as $1,885, $1,941, and $2,000, respectively. The professional fees for the gastroenterologist, general surgeon, anesthesiologist, and pathologist are billed separately by those physicians' offices. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See the Pro Forma tab for the assumptions regarding costs and charges. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if fully set forth herein. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges, and therefore, the application is conforming to this criterion.

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

C

NHBMC owns and operates one existing licensed GI endoscopy procedure room at the hospital located in Bolivia, in Brunswick County. The applicant proposes to add one GI endoscopy procedure room to the existing facility for a total of two GI endoscopy rooms.

Regarding utilization of the existing GI endoscopy room at NHBMC, on page 40, the applicant states that utilization based on procedures has increased 4.3% per year (CAGR) between FFY 2010 and FFY 2012. In FFY 2012, 2,187 procedures were performed in the one existing GI endoscopy room. Based on the performance standard promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility operated at 145.8% of capacity [2,187 / 1,500 = 1.458]. The applicant also provides data on page 41 showing NHBMC's utilization in cases increased significantly each quarter in the April 2012 – March 2013 year over the same quarters in the April 2011-March 2012 year. The applicant states, *"Also shown in the previous table, NHBMC has GI endoscopy volume in April 2012-March 2013 to support more than one GI endoscopy procedure room, assuming an average of 1.3 procedures per case and a planning target of 1,500 procedures per room per year."* Based on the performance standard promulgated in G.S. 131E-182(a) and 10A NCAC 14C .3903(b), the facility is currently operating at 157.1% of capacity [1,813 cases x 1.3 = 2,357 procedures / 1,500 = 1.5713].

On pages 64-65, the applicant provides information regarding number of cases performed in the existing and approved GI endoscopy rooms in Brunswick County, as shown in the following table.

Brunswick County Facility	**GI Endoscopy Cases FFY 2012**
NHBMC	1,716
Dosher Memorial Hospital	807

The 2013 Hospital License Renewal Applications provide information on procedures as follows:

Brunswick County Facility	**GI Endoscopy Procedure Rooms**	**GI Endoscopy Procedures FFY 2012**
NHBMC*	1	2,187
Dosher Memorial Hospital	2	807
Total Brunswick County	**3**	**2,994**
# of Procedures / # of Rooms		**998**
% of Capacity per 10A NCAC 14C .3903(b)		**66.5%**

* From 2013 Corrected License Renewal Application, as submitted by NHBMC and provided in Exhibit 2.

There are three hospital-based GI endoscopy procedure rooms in Brunswick County, two at Dosher Memorial Hospital (DMH) and one at NHBMC. There are no freestanding ambulatory GI endoscopy services in Brunswick County. Assuming each of Brunswick County's three GI endoscopy procedure room performs at the performance standard of 1,500 procedures per year, only 2 are needed. However, that assumption does not take into account that the hospital based GI endoscopy rooms are used by inpatients and high-risk patients. These procedures may take longer, and thus, hospital based GI endoscopy rooms could have a lower practical capacity. Nor does it take into account that NHBMC is operating at capacity while DMH is operating at only 27% of capacity (807 / 2 = 403.5 / 1500 = 26.9%).

It also fails to recognize that DMH's two endoscopy procedure rooms have been chronically underutilized since 2006, falling from operating at 43.8% of capacity in 2006 to 26.9% in 2012, and never operating above 43.9% of capacity during that period. DMH is located in Southport, on the Intracoastal Waterway in the most eastern tip of Brunswick County. The only highway, other than beach roads, with direct accessibility to Southport is NC Highway 211, and NC Highways 87 and 133 by way of NC 211. The geographic inaccessibility of DMH likely contributes to its lower utilization.

Brunswick County residents living anywhere other than in the immediate proximity of DMH would likely find it easier and less time consuming to seek services at New Hanover Regional Medical Center in Wilmington or NHBMC in Bolivia. Residents in eastern and northern Brunswick County can easily reach New Hanover Regional Medical Center and other GI Endoscopy services in Wilmington. Furthermore, residents in western Brunswick would not likely bypass NHBMC in Bolivia to get to DMH in Southport.

The following tables analyze where Brunswick County residents seek medical services based on FY2012 data from 2013 Licensure Renewal Applications.

Market Share of Brunswick County Patients

Provider	GI Endo Services	GI Endo %	AmSurg Services	AmSurg %	Acute Care	Acute Care %	AC Inpt Surgical	AC Inpt Surg %
NHBMC	1,576	23.8%	2,752	29.7%	2,962	25.3%	802	22.7%
DMH	889	13.4%	995	10.7%	1,112	9.5%	293	8.3%
Total Treated in Brunswick	2,465	37.2%	3,747	40.5%	4,074	34.8%	1,095	31.0%
Other	4,164	62.8%	5,510	59.5%	7,643	65.2%	2,437	69.0%
Total Brunswick Patients Treated	6,629	100.0%	9,257	100.0%	11,717	100.0%	3,532	100.0%

As the above table illustrates, 30% to 40% of Brunswick County residents stay in Brunswick County for their healthcare needs. Of the 60% to 70% of Brunswick County residents who seek care outside of Brunswick County, approximately 55% seek medical care in New Hanover County.

The following table shows the Brunswick County providers' market shares of the Brunswick County residents who seek care in Brunswick County.

Brunswick County Providers' Market Share of Brunswick County Patients

Provider	GI Endo Services	GI Endo %	AmSurg Services	AmSurg %	Acute Care	Acute Care %	AC Inpt Surgical	AC Inpt Surg %
NHBMC	1,576	63.9%	2,752	73.4%	2,962	72.7%	802	73.2%
DMH	889	36.1%	995	26.6%	1,112	27.3%	293	26.8%
Total Brunswick Patients Treated in Brunswick	2,465	100.0%	3,747	100.0%	4,074	100.0%	1,095	100.0%

Of the Brunswick County residents who seek medical care in Brunswick County, the above table shows that 64% to 73% are treated at Novant Health Brunswick Medical Center. NHBMC's market share of Brunswick residents is 73% for ambulatory services, acute care inpatient services and acute care inpatient surgical services. Its market share of GI endoscopy is only 64%. NHBMC's GI endoscopy service is operating at capacity as stated in the need analysis in Criterion (3). One would expect, with the number of gastroenterologists and surgeons performing GI endoscopies at NHBMC, that the GI endoscopy market share would be at least as much as that of the other medical services, if capacity allowed.

The assumption also fails to acknowledge that more than 50% of Brunswick County patients currently seek GI endoscopy services outside Brunswick County, with more than 18% of Brunswick County GI endoscopy patients served at WGA in Wilmington. See Exhibit 2, Table 4. Also see Criterion (3) for the discussion on NHBMC's proposed utilization, based on projected population increases and increased use by WGA physicians, which is hereby incorporated as if fully set forth herein.

Given that the population age 55 and older is projected to increase 3% per year between 2013 and 2017 and the request for additional surgery time at NHBMC by WGA physicians, it is reasonable to assume an additional GI endoscopy room will be needed at NHBMC, regardless of the under-utilized capacity at Dosher Memorial Hospital. NHBMC, the only other GI endoscopy provider in the county is fully utilized and has demonstrated the need for additional capacity based on existing utilization and future physician commitments.

In Section III.9, page 65, the applicant states the purpose of the proposed project is to allow NHBMC to develop a second GI endoscopy procedure room in order to meet current and future patient and physician demand at its existing facility. The facility does not have current capacity sufficient to meet the demand of its existing practicing gastroenterologists.

The applicant adequately demonstrates that developing one additional GI endoscopy room at NHBMC would improve access to GI endoscopy services in Brunswick County,

allowing more Brunswick County patients the opportunity to stay at home for their GI endoscopy services.

Furthermore, the applicant adequately demonstrates that one additional GI endoscopy room is needed at NHBMC based on current utilization as well as projected utilization. In FFY 2012, NHBMC operated at 145.8% of capacity [2,187 procedures / 1,500 procedures per room per year = 1.458]. In Project Year 2, the facility is projected to operate at 101% of capacity [3,031 procedures / 2 rooms / 1,500 procedures per room per year = 1.01].

In summary, the proposal will not result in the unnecessary duplication of existing or approved GI endoscopy rooms in Brunswick County. Therefore, the application is conforming to this criterion.

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

C

The following table illustrates the current and projected staffing at NHBMC during the second operating year, as reported by the applicant in Sections VII.1 and VII.2, pages 100-101.

POSITION	# OF FULL-TIME EQUIVALENT POSITIONS (FTES)	
	CURRENT STAFF FFY 2012	PROJECTED STAFF YEAR 2 FFY 2016
Registered Nurses (RNs)	1.0	3.0
Surgical/Endoscopy Technicians	1.8	2.8
Manager, Surgical Services	0.5	0.5
Data Specialist	0.2	0.2
Total	3.5	6.5

The following table illustrates the projected staffing at NHBMC by functional area, as reported by the applicant in Section VII.7, page 105.

FUNCTIONAL AREA	TYPE	# OF FTE POSITIONS
Administration	Manager, Surgical Services	0.25
Preoperative	RNs	0.50
Postoperative	RNs	0.50
GI Endoscopy Rooms	RNs	2.00
	Surgical/Endoscopy Technicians	2.00
Equipment cleaning, safety & maintenance [1]		
Other	Total	1.25
	Surgical Technicians	0.80
	Manager, Surgical Services	0.25
	Data Specialist	0.20

[1]The table in Section VII.7, page 105, does not have a column labeled "Equipment cleaning, safety and maintenance." The applicant includes the 0.8 FTE surgical technician positions in the Other column. A review of the job description for the endoscopy technician position provided in Exhibit 13 documents that a primary responsibility of the endoscopy technician is equipment cleaning, safety and maintenance.

In Section VII.7(a), page 106, the applicant states it anticipates no difficulty in recruiting the additional FTEs. The applicant projects sufficient RNs so that there will be at least one RN in each of the two GI endoscopy rooms during a procedure and adequate coverage in the preoperative and postoperative areas. Exhibit 4 contains a letter signed by Richard Scallion, M.D., and his curriculum vitae which document that Dr. Scallion is board-certified and has agreed to continue to serve as Medical Director for Surgical Services at NHBMC and the GI Endoscopy program. The applicant adequately documents the availability of sufficient health manpower and management personnel to provide the proposed GI endoscopy services. Therefore, the application is conforming to this criterion.

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

C

The applicant identifies the necessary ancillary and support services in Section II.2, page 9. The applicant discusses coordination with the existing health care system in Sections V.2-V.6, pages 69-73. The applicant provides supporting documentation of coordination and support from hospital board members and administration and area physicians in Exhibits 1, 4, 5, 8 and 15. The information provided in those sections and exhibits is reasonable and credible and supports a finding of conformity with this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in

adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates:

(a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and
(b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:
    (i) would be available under a contract of at least 5 years duration;
    (ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
    (iii) would cost no more than if the services were provided by the HMO; and
    (iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

The applicant proposes to renovate existing hospital space.

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose

of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

The following table illustrates the current payor mix for NHBMC, as reported by the applicant in Section VI.12, page 97.

PAYOR	PERCENT OF TOTAL
Self Pay / Indigent / Charity	12.97%
Commercial Insurance	2.11%
Medicare	37.26%
Medicaid	20.97%
Managed Care	24.62%
Other (Other Gov't, Workers' Comp)	2.07%
Total	**100.00%**

The applicant reports the payor mix for NHBMC GI Endoscopy services for FFY2012 in Section VI.13, page 97 as shown below.

PAYOR	PERCENT OF TOTAL
Self Pay / Indigent / Charity	1.22%
Commercial Insurance	1.87%
Medicare	62.07%
Medicaid	4.73%
Managed Care	29.03%
Other (Other Gov't, Workers' Comp)	1.11%
Total	**100.00%**

Exhibit 6 contains a copy of Novant Charity Care policies. Section VI.2, pages 82-86, contains additional discussion on charity care, financial payment policies, and handicap access.

The Division of Medical Assistance (DMA) maintains a website which offers information regarding the number of persons eligible for Medicaid assistance and

estimates of the percentage of uninsured for each county in North Carolina. The following table illustrates those percentages for Brunswick County and statewide.

	2010 Total # of Medicaid Eligibles as % of Total Population *	2010 Total # of Medicaid Eligibles Age 21 and older as % of Total Population *	CY2008-2009 % Uninsured (Estimate by Cecil G. Sheps Center) *
Brunswick County	7%	2.8%	19.8%
Statewide	17%	6.7%	19.7%

*More current data, particularly with regard to the estimated uninsured percentages, was not available.

The majority of Medicaid eligibles are children under the age of 21. This age group would not typically utilize the health services proposed in this application.

Moreover, the number of persons eligible for Medicaid assistance may be greater than the number of Medicaid eligibles who actually utilize health services. The DMA website includes information regarding dental services which illustrates this point. For dental services only, DMA provides a comparison of the number of persons eligible for dental services with the number actually receiving services. The statewide percentage of persons eligible to receive dental services who actually received dental services was 48.6% for those age 20 and younger and 31.6% for those age 21 and older. Similar information is not provided on the website for other types of services covered by Medicaid. However, it is reasonable to assume that the percentage of those actually receiving other types of health services covered by Medicaid is less than the percentage that is eligible for those services.

The OSBM maintains a website which provides historical and projected population data for each county in North Carolina. In addition, data is available by age, race or gender. However, a direct comparison to the applicant's current payor mix would be of little value. The population data by age, race or gender does not include information on the number of elderly, minorities or women utilizing health services. Furthermore, OSBM's website does not include information on the number of handicapped persons.

The applicant demonstrates that medically underserved populations have adequate access to existing services; therefore, the application is conforming to this criterion.

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

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, pages 95-96, the applicant states, *"Novant Health's tertiary hospitals (Novant Health Forsyth Medical Center and Novant Health Presbyterian Medical Center) fulfilled their Hill-Burton obligations long ago. … NHBMC and all Novant Health facilities in North Carolina continue to comply with the community service obligation and there is no denial, restriction, or limitation of access to minorities or handicapped persons."* The applicant also states that Novant Health's Charity Care policies (Exhibit 6) are among the most generous in North Carolina. In Section VI.10, page 95, the applicant states that it is not aware of any documented civil rights equal access complaints or violations filed against Novant Health, NHBMC, or other Novant Health Acute Care hospitals in North Carolina in the last five years. The application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

The following table illustrates the projected payor mix for NHBMC GI endoscopy services during the second operating year, as reported by the applicant in Section VI.14, page 98.

PAYOR	PERCENT OF TOTAL
Self Pay / Indigent / Charity	1.82%
Commercial Insurance	0.91%
Medicare	67.20%
Medicaid	4.10%
Managed Care	24.15%
Other (Other Gov't, Workers' Comp)	1.82%
Total	**100.00%**

In Section VI.4, page 87, the applicant states *"Yes, all persons will continue to have access to the proposed Novant Health Brunswick Medical Center GI Endoscopy program regardless of their ability to pay."* Exhibit 6 contains a copy of the Novant Charity Care policies and the Novant Health Financial Navigator program. Section VI.2, pages 82-86, contains additional discussion on charity care, financial payment policies, and handicap access.

In Section VI.3, page 87, the applicant states that NHBMC will continue to provide services in a manner that is consistent with:

- Title VI of the Civil Rights Act of 1963 (and any applicable amendments);
- Section 504 of the Rehabilitation Act of 1973 (and any applicable amendments);
- The Age Discrimination Act of 1975 (and any applicable amendments);
- The Americans with Disabilities Act of 1990 (and any applicable amendments).

The applicant demonstrates that medically underserved populations will continue to have adequate access to the facility's services and the application is conforming to this criterion.

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

C

See Section VI.9, pages 93-94 for documentation of the range of means by which patients have access to the services provided at NHBMC. The applicant states:

> *"Patients will have access to the GI Endoscopy program at NHBMC by one or more of the following means:*
> - *Referral and written order from a physician on the NHBMC medical staff;*
> - *Request from a non-staff physician by referral and written order from a member of the NHBMC medical staff; and/or*
> - *Referral and written order from a* [sic] *NHBMC emergency department physicians or the hospitalist physicians assigning the patient to the physician on call for the particular service to which the patient is admitted."*

The information provided is reasonable and credible and supports a finding of conformity with 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

See Section V.1 and Exhibit 16 for documentation that NHBMC currently accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. The information provided is reasonable and credible and supports a finding of conformity with this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

NHBMC proposes to add one GI endoscopy procedure room to the existing facility for a total of two GI endoscopy procedure rooms.

The following table lists the existing providers of GI endoscopy services in Brunswick County.

Brunswick County Facility	**GI Endoscopy Cases FFY 2012**
NHBMC	1,716
Dosher Memorial Hospital	807

In Section III.9, page 65, the applicant states the purpose of the proposed project is to allow NHBMC to develop a second GI endoscopy procedure room in order to meet current and future patient and physician demand at its existing facility. The facility does not have current capacity sufficient to meet the demand of its existing practicing gastroenterologists.

In Section V.7, pages 73-81, the applicant discusses the impact of the proposed project on competition in the service area as it relates to promoting cost-effectiveness, quality and access. On page 73, the applicant states, "*Competition in healthcare is encouraged by containing costs, improving quality and patient safety, and ensuring access to services. Novant Health and NHBMC are committed to fostering competition through these factors.*" In the pages that follow, the applicant gives multiple examples of how it encourages cost effectiveness in operating costs and capital expenditures, and promotes quality and safety in the delivery of health care services. See also Sections II, III, V, VI and VII where the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and credible and adequately demonstrates that the expected effects of the proposal on competition in the service area include a positive impact on cost-effectiveness, quality and access to the

proposed services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need to add one GI endoscopy procedure room for a total of two GI endoscopy procedure rooms at NHBMC and that it is a cost-effective alternative;
- The applicant adequately demonstrates that it will continue to provide quality services; and
- The applicant demonstrates that it will continue to provide adequate access to medically underserved populations.

Therefore, the application is conforming to this criterion.

The application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

NHBMC is accredited by The Joint Commission on Accreditation of Healthcare Organizations and is certified for Medicare and Medicaid participation. According to the records in the Acute and Home Care Licensure and Certification Section of the Division of Health Service Regulation, no incidents have occurred at the facility within the eighteen months immediately preceding the date of this decision for which any sanctions or penalties related to quality of care were imposed by the State. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

C

The proposal submitted by NHBMC is conforming or conditionally conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900. The specific criteria are discussed below.

.3902 INFORMATION REQUIRED OF APPLICANT

.3902(a)(1) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: (1) the counties included in the applicant's proposed service area, as defined in 10A NCAC 14C .3906."*

-C- In Section III.6, page 62, the applicant identifies the service area as Brunswick County, stating that 95.5% of its patients originate from Brunswick County. The applicant states,

> *"NHBMC determined the geographic boundaries of the service area based on internal data for its GI endoscopy patients. The proposed patient origin is based upon the historical GI patient origin reported in the annual NHBMC Hospital Licensure Renewal Applications and is consistent with the service area served by NHBMC."*

.3902(a)(2)(A) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2) with regard to services provided in the applicant's GI endoscopy rooms, identify: (A) the number of existing and proposed GI endoscopy rooms in the licensed health service facility in which the proposed rooms will be located."*

-C- NHBMC is currently licensed with one GI endoscopy procedure room. The applicant proposes to develop one additional GI endoscopy procedure room for a total of two.

.3902(a)(2)(B) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (B) the number of existing or approved GI endoscopy rooms in any other licensed health service facility in which the applicant or a related entity has a controlling interest that is located in the applicant's proposed service area."*

-NA- Neither the applicant nor a related entity has another licensed health service facility in the proposed service area.

.3902(a)(2)(C) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (C) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, performed in the applicant's licensed or non-licensed GI endoscopy rooms in the last 12 months."*

-C- In Section II.11, page 22, the applicant provides the number of GI endoscopy procedures (2,187), identified by ICD-9-CM procedure code, performed in the applicant's endoscopy room FFY2012 (10/1/11 through 9/30/12).

.3902(a)(2)(D) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (D) the number of GI endoscopy procedures, identified by CPT code or ICD-9-CM procedure code, projected to be performed in the GI endoscopy rooms in each of the first three operating years of the project."*

-C- In Section II.11, page 23, the applicant provides the number of GI endoscopy procedures, identified by ICD-9-CM procedure code, projected to be performed in the applicant's licensed endoscopy rooms in each of the first three operating years of the project. See Criterion (3) for discussion of the reasonableness of projections which is hereby incorporated as if fully set forth herein.

.3902(a)(2)(E) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months."*

-NA- In Section II.11, page 24, the applicant states that no procedures other than GI endoscopy procedures were performed in NHBMC's GI endoscopy procedure room in the last 12 months.

.3902(a)(2)(F) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (F) the number of procedures by type, other than GI endoscopy procedures, projected to*

be performed in the GI endoscopy rooms in each of the first three operating years of the project."

-NA- In Section II.11, page 24, the applicant states that no procedures other than GI endoscopy procedures will be performed in the GI endoscopy procedure rooms at NHBMC in the first three years of operation.

.3902(a)(2)(G) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months."*

-C- In Section II.11, page 24, the applicant states that 1,716 patients were served in the one licensed NHBMC GI endoscopy procedure room between October 1, 2011 and September 30, 2012.

.3902(a)(2)(H) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (2): … (H)* the *number of patients projected to be served in the GI endoscopy rooms in each of the first three operating years of the project."*

-C- In Section II.11, pages 24-25, the applicant projects 2,121 patients will be served in Year 1, 2,378 patients in Year 2 and 2,444 patients in Year 3.

.3902(a)(3)(A) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (3) with regard to services provided in the applicant's operating rooms identify: (A) the number of existing operating rooms in the facility."*

-C- In Section II.11, page 25, the applicant states NHBMC has five licensed operating rooms: four shared operating rooms and one dedicated C-Section operating room.

.3902(a)(3)(B) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (3) with regard to services provided in the applicant's operating rooms identify: … (B) the number of procedures by type performed in the operating rooms in the last 12 months."*

-C- In Section II.11, page 25, the applicant states NHBMC performed 879 inpatient surgical procedures and 2,927 outpatient surgical procedures in its five licensed operating rooms. Exhibit 3, Table 14 provides the numbers of procedures by type.

.3902(a)(3)(C) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (3) with regard to services provided in the applicant's operating rooms identify: … (C) the number of procedures by type projected to be performed in the operating rooms in each of the first three operating years of the project."*

-C- In Exhibit 3, Table 14, the applicant projects the number of inpatient and outpatient procedures by type to be performed in the first three operating years of the project.

.3902(a)(4) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (4) the days and hours of operation of the facility in which the GI endoscopy rooms will be located."*

-C- In Section II.11, page 26, the applicant states that the facility will be operated Monday through Friday from 7:30 AM to 3:15 PM. Staff will stay in the GI Endoscopy Suite until all cases are completed and the last patient is fully recovered, sometimes requiring the staff to work until 5:00 PM.

.3902(a)(5) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (5) if an applicant is an existing facility, the type and average facility charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months."*

-C- In Section II.11, page 26, the applicant provides the facility charges by ICD-9-CM procedure code during CY 2012 for the ten procedures performed most often at NHBMC.

.3902(a)(6) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service*

facility shall provide the following information: … (6) 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."

-C- In Section II.11, page 27, the applicant provides the projected facility charges by ICD-9-CM procedure code for the ten procedures projected to be performed most often at NHBMC during the first three operating years.

.3902(a)(7) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (7) a list of all services and items included in each charge, and a description of the bases on which these costs are included in the charge."*

-C- In Section II.11, page 27, the applicant states *"The Novant Health Brunswick Medical Center facility charge for the GI Endoscopy department is based on the acuity of the GI procedure and the duration /length of time of the procedure."* The applicant further states the facility charge includes items such as: sponges, drapes, suction canisters, syringes, nasal cannulas, grounding pads, the use of scopes, medications and lab tests. The applicant states that the facility fee will sometimes include a technical charge for anesthesia services when a Certified Nurse Anesthetist or Anesthesiologist is present in the GI endoscopy procedure room at the time of the procedures.

The applicant states NHBMC's technical charge items include such items as anesthesia mask, circuit tubing used on the anesthesia machine, oxygen, gases, and monitoring devices. Professional fees are billed separately by the physicians' offices.

.3902(a)(8) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (8) identification of all services and items (e.g., medications, anesthesia) that will not be included in the facility's charges."*

-C- In Section II.11, page 28, the applicant states *"The professional fees for the endoscopy physician (gastroenterologist or general surgeon), anesthesiologist, and pathologist are billed separately by those physicians' offices. The professional fees are not part of the NHBMC GI Endoscopy facility or technical charges."* NHBMC does not charge for sedation if the anesthesiologist administers the sedation.

.3902(a)(9) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (9) if an applicant is an existing facility, the average reimbursement received per procedure for each of the ten GI endoscopy procedures most commonly performed in the facility during the preceding 12 months."*

-C- In Section II.11, page 28, the applicant provides the average reimbursement received per procedure during CY 2012 for the ten procedures performed most often at NFBMC.

.3902(a)(10) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the following information: … (10) the average reimbursement projected to be received for each of the ten GI endoscopy procedures which the applicant projects will be performed most frequently in the facility."*

-C- In Section II.11, pages 28-29, the applicant provides the average reimbursement received for the ten GI endoscopy procedures performed most often at NHBMC during CY2012. In supplemental information received during the expedited review of this application, the applicant provides the average reimbursement projected to be received for each of the ten most frequently performed GI endoscopy procedures at NHBMC for the first three fiscal years of operation following the completion of the project.

.3902(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for provision of GI endoscopy procedures shall submit the following information: (1) a copy of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, religion, disability or the patient's ability to pay; (2) a written commitment to participate in and comply with conditions of participation in the Medicare and Medicaid programs within three months after licensure of the facility; (3) a description of strategies to be used and activities to be undertaken by the applicant to assure the proposed services will be accessible by indigent patients without regard to their ability to pay; (4) a written description of patient selection criteria including referral arrangements for high-risk patients; (5) the number of GI endoscopy procedures performed by the applicant in any other existing licensed health service facility in each of the last 12 months, by facility; (6) if the applicant proposes reducing the number of GI endoscopy procedures it performs in existing licensed facilities, the specific rationale for its change in practice pattern."*

-NA- NHBMC is an existing licensed acute care hospital, proposing to develop a second GI endoscopy procedure room.

.3903 PERFORMANCE STANDARDS

.3903(a) This rule states *"In providing projections for operating rooms, as required in this Rule, the operating rooms shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding 10 days for holidays."*

-C- The applicant states, *"In providing projections for operating rooms, as required in this Rule, the GI endoscopy procedures rooms at NHBMC shall be considered to be available for use 250 days per year, which is five days per week, 52 weeks per year, excluding ten days for holidays."*

.3903(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI endoscopy procedures only per GI endoscopy room in each licensed facility the applicant or a related entity owns in the proposed service area, during the second year of operation following completion of the project."*

-C- In Section III.1, page 56, and Section IV.1, page 67, the applicant projects performing 3,031 GI endoscopy procedures during Year 2, which is an average of 1,515 procedures per room (3,031 procedures / 2 procedure rooms = 1,515.5 procedures per room). See Criterion (3) for a detailed analysis of the applicant's projected utilization which is hereby incorporated as if fully set forth herein.

.3903(c) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures."*

-C- In Section II.11, page 31 and in NHBMC President's letter in Exhibit 4, the applicant states it will continue to provide upper endoscopy, esophagoscopy and colonoscopy procedures at NHBMC.

.3903(d)(1) This rule states *"If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health*

service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms."

-C- The applicant states NHBMC does not have a related entity in the proposed NHBMC GI Endoscopy service area of Brunswick County. The applicant further states NHBMC will not perform GI endoscopy procedures in any of its inpatient operating rooms, outpatient operating rooms or shared operating rooms.

.3903(d)(2) This rule states *"If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: … (2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future."*

-C- The applicant states NHBMC does not have a related entity in the proposed NHBMC GI Endoscopy service area of Brunswick County. The applicant further states GI endoscopy procedures were not performed in NHBMC's inpatient operating rooms, outpatient operating rooms or shared operating rooms in the last 12 months, and will not be performed in those rooms in the future. See NHBMC President's letter in Exhibit 4.

.3903(e) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop an additional GI endoscopy room in an existing licensed health service facility shall describe all assumptions and the methodology used for each projection in this Rule."*

-C- The applicant provides the assumptions and methodology used to project GI endoscopy procedures in Section III.1, pages 39-56 and Exhibit 3, Tables 1-13. See Criterion (3) for a detailed analysis of the applicant's projected utilization which is hereby incorporated as if fully set forth herein.

.3904 SUPPORT SERVICES

.3904(a) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of an agreement between the applicant and a pathologist for provision of pathology services."*

-C- In Exhibit 4, page 0421, the applicant documents that it has an agreement with Wilmington Pathology Laboratory, Inc. for pathology services.

.3904(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the guidelines it shall follow in the administration of conscious sedation or any type of anesthetic to be used, including procedures for tracking and responding to adverse reactions and unexpected outcomes."*

-C- See Exhibit 4, beginning on page 0375, for NHBMC's conscious sedation policies, identified as Pre-Anesthetic Patient Evaluation and Moderate Sedation & Analgesia Management by Non-Anesthesiologists – Adults & Pediatrics.

.3904(c) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide a copy of the policies and procedures it shall utilize for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases."*

-C- See Exhibit 4, beginning on page 0401, for copies of NHBMC's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure room between cases.

.3904(d)(1) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide: (1) evidence that physicians utilizing the proposed facility will have practice privileges at an existing hospital in the county in which the proposed facility will be located or in a contiguous county."*

-C- See Exhibit 4, page 0346, for a letter from NHBMC President providing evidence that physicians utilizing the existing licensed GI endoscopy procedure room and the proposed second GI endoscopy procedure room have and will continue to have practice privileges at NHBMC or in a contiguous county.

.3904(d)(2) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide: … (2) documentation of an agreement to transfer and accept referrals of GI endoscopy patients from a hospital where physicians utilizing the facility have practice privileges."*

-C- See Exhibit 4, page 0346 for a letter from the President of NHBMC stating that NHBMC will accept referrals of GI endoscopy patients from other hospitals where the physicians who practice in the NHBMC GI Endoscopy Suite have privileges. Also see Exhibit 15 for copies of transfer agreements with other area hospitals, including New Hanover Regional Medical Center.

.3904(d)(3) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide: … (3) documentation of a transfer agreement with a hospital in case of an emergency."*

-C- See Exhibit 15 for documentation of transfer agreements with other hospitals, including New Hanover Regional Medical Center, to transfer patients in case of an emergency that requires health care services not available at NHBMC.

.3905 STAFFING AND STAFF TRAINING

.3905(a) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of staff to be utilized in the following areas: (1) administration; (2) pre-operative; (3) post-operative; (4) procedure rooms; (5) equipment cleaning, safety, and maintenance; and (6) other."*

-C- In response to this rule, in Section II.11, page 35, the applicant states:

> *"Please see Exhibit 13 for NHBMC GI Endoscopy Department job descriptions and see also the applicant's table in response* [sic] *Question VII.7, which identifies the number of staff to be utilized in the areas identified in subsection (1)-(6) in Project Years 1 and 2, respectively."*

The following table illustrates the projected staffing at NHBMC by functional area, as reported by the applicant in Section VII.7, page 105.

FUNCTIONAL AREA	TYPE	# OF FTE POSITIONS
Administration	Manager Surgical Services	0.25
Pre-operative	RNs	0.5
Post-operative	RNs	0.5
GI endoscopy procedure rooms	RNs Endoscopy Surgical Technicians	2.0 2.0
Equipment cleaning, safety & maintenance [(1)]		
Other	Total	1.25
	Manager Surgical Services	0.25
	Endoscopy Surgical Technicians	0.8
	Data Specialist	0.2

[(1)] The table in Section VII.7, page 105, does not have a column labeled "Equipment cleaning, safety and maintenance." The applicant includes the 0.8 FTE surgical technician position in the Other category. A review of the job description for the endoscopy technician position provided in Exhibit 13 documents that the endoscopy surgical technician is responsible for equipment cleaning, safety and maintenance.

.3905(b) This rule states *"The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall identify the number of physicians by specialty and board certification status that currently utilize the facility and that are projected to utilize the facility."*

-C- In Section II.11, page 26, the applicant refers to responses to Questions V.3(b), VII.8(a) and VII.9 for information identifying the number of physicians by specialty and board certification status utilizing NHBMC's existing and proposed GI endoscopy procedure rooms. The response to V.3(b) describes the credentialing process, identifies the physician support letters and identifies the Medical Director for NHBMC's GI endoscopy services.

In Section VII.8(a), page 107, the applicant states that two board-certified physicians on staff at NHBMC, one gastroenterologist and one general surgeon, currently perform cases in the GI endoscopy procedure room at NHBMC. In addition, as of February 2013, two additional gastroenterologists from Wilmington Gastroenterology Associates (WGA) began performing cases at NHBMC. See Exhibit 5 for letters from each of the four physicians above stating they are board-certified and medical staff member at NHBMC. The applicant says that three to five more WGA gastroenterologists may seek privileges at NHBMC, stating, *"Thus, shortly after the opening of the second GI Endoscopy Room at NHBMC, 4 or more endoscopists could be practicing there."* See Exhibit 5 for additional physician support letters.

Section VII.9 lists Dr. Richard Scallion as Chief of Surgical Services for NHBMC. Exhibit 4 contains a letter from Dr. Scallion confirming his capacity as Medical Director for Surgical Services at NHBMC, including oversight for the GI Endoscopy program.

.3905(c) This rule states *"The applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall provide the criteria to be used by the facility in extending privileges to medical personnel that will provide services in the facility."*

-C- In Section II.11, page 108, the applicant states that NHBMC uses a unified medical staff credentialing process, so that NHBMC follows the same criteria in extending privileges to medical staff as those used at other Novant Health facilities. See Exhibit 4 for the Medical Staff Bylaws and Rules and Regulations. Exhibit 4 also contains a letter from the Chief of the Medical Staff at NHBMC explaining the NHBMC credentialing process.

.3905(d) This rule states *"If the facility is not accredited by The Joint Commission on Accreditation of Healthcare Organizations, The Accreditation Association for Ambulatory Health Care, or The American Association for Accreditation of Ambulatory Surgical Facilities at the time the application is submitted, the applicant shall demonstrate that each of the following staff requirements will be met in the facility: (1) a Medical director who is a board certified gastroenterologist, colorectal surgeon or general surgeon, is licensed to practice medicine in North Carolina and is directly involved in the routine direction and management of the facility; (2)all physicians performing GI endoscopy procedures in the facility shall be board eligible or board certified gastroenterologists by American Board of Internal Medicine, colorectal surgeons by American Board of Colon and Rectal Surgery or general surgeons by American Board of Surgery; (3) all physicians with privileges to practice in the facility will be active members in good standing at a general acute care hospital within the proposed service area; (4) at least one registered nurse shall be employed per procedure room; (5) additional staff or patient care technicians shall be employed to provide assistance in procedure rooms, as needed; and, (6) a least one health care professional who is present during the period the procedure is performed and during postoperative recovery shall be ACLS certified; and, at least one other health care professional who is present in the facility shall be BCLS certified."*

-NA- NHBMC and its GI endoscopy program are accredited by the The Joint Commission. See Exhibit 17.

.3906 FACILITY

.3906(a) This rule states *"An applicant proposing to establish a licensed ambulatory surgical facility that will be physically located in a physician's office or within a general acute care hospital shall demonstrate reporting and accounting mechanisms exist that confirm the licensed ambulatory surgery facility is a separately identifiable entity physically and administratively, and is financially independent and distinct from other operations of the facility in which it is located."*

-NA- NHBMC is not proposing to establish a licensed ambulatory surgical facility.

.3906(b) This rule states *"An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall commit to obtain accreditation and to submit documentation of accreditation of the facility by The Accreditation Association for Ambulatory Health Care, The Joint Commission on Accreditation of Healthcare Organizations, or The American Association for Accreditation of Ambulatory Surgical Facilities within one year of completion of the proposed project."*

-C- See Exhibit 17 for a copy of NHBMC's accreditation certificate from The Joint Commission on Accreditation of Healthcare Organizations (TJC). The applicant states that the expanded NHBMC GI endoscopy program will also be accredited by TJC.

.3906(c) This rule states *"If the facility is not accredited at the time the application is submitted, an applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall: (1) document that the physical environment of the facility conforms to the requirements of federal, state, and local regulatory bodies. (2) provide a floor plan of the proposed facility identifying the following areas: (A) receiving/registering area; (B) waiting area; (C) pre-operative area; (D) procedure room by type; and (E) recovery area. (3) demonstrate that the procedure room suite is separate and physically segregated from the general office area; and, (4) document that the applicant owns or otherwise has control of the site on which the proposed facility or GI endoscopy rooms will be located."*

-NA- NHBMC is an existing facility. NHBMC and its GI endoscopy program were TJC accredited at the time of application submission. See Exhibit 17.