ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

DECISION DATE: September 25, 2013
PROJECT ANALYST: Bernetta Thorne-Williams
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: H-10138-13 / FirstHealth Moore Regional Hospital and FirstHealth of the Carolinas, Inc. / Develop a second GI Endoscopy room in the existing GI Suite / Moore 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

The applicants, FirstHealth Moore Regional Hospital (FMRH) and its parent company, FirstHealth of the Carolinas, Inc. (FirstHealth) propose to develop a second GI endoscopy room on the campus of FirstHealth Moore Regional Hospital in Pinehurst, in More County. As part of a 2005 CON application, FMRH closed two GI rooms in its existing GI suite and converted them to two hybrid ORs in the Reid Heart Hospital (see Project I.D. # H-7427-05). Therefore, the proposed second GI endoscopy room exists, although its medical gas hookups were disconnected and would require no renovations or equipment purchase to make the room operational again. The total projected cost for the proposed project is $40,000 with no start-up or initial operating cost.

As the total projected capital cost for the proposal is less than two million dollars, Policy GEN-4: Energy Efficiency and Sustainability for Health Service Facilities on page 43 in the 2013 State Medical Facilities Plan (SMFP) is not applicable to this review. Furthermore, there are no other policies or need determinations in the 2013 SMFP 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(2) Repealed effective July 1, 1987.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

The applicants, FirstHealth Moore Regional Hospital (FMRH) and FirstHealth of the Carolinas, Inc. (FirstHealth) propose to develop a second GI endoscopy room on the campus of FirstHealth Moore Regional Hospital. First Health Moore Regional Hospital is a 320 licensed acute care bed hospital (total licensed beds is 395 which includes 25 inpatient rehabilitation beds, 14 substance abuse / chemical dependency beds, and 36 in-patient psychiatric beds) that currently provides GI endoscopy services. As part of a 2005 CON application, FMRH closed two GI rooms in its existing GI suite and converted them to two hybrid ORs in the Reid Heart Hospital (see Project I.D. # H-7427-05). When the two GI rooms were closed, their medical gas hookups were disconnected, however, the connections still exist. Therefore, the proposed second GI endoscopy room still exists and would require no renovations or equipment purchase to make the GI endoscopy room operational. FMRH is located at 155 Memorial Drive, in Pinehurst, in Moore County.

Population to be Served

In Sections III.6 and III.7, pages 65-66, the applicants provide the projected patient origin, by percentages for the first two years of operation following completion of the project (FY2015 and FY2016) and the current percentage of patient origin for GI cases at FMRH, as illustrated in the table below:

COUNTY	FY2013 YTD	FY2015	FY2016
Moore	50.8%	50.8%	50.8%
Hoke	9.2%	9.2%	9.2%
Robeson	8.5%	8.5%	8.5%
Montgomery	8.4%	8.4%	8.4%
Scotland	6.2%	6.2%	6.2%
Lee	5.2%	5.2%	5.2%
Other*	11.6%	11.6%	11.6%
Total	100.0%	100.0%	100.0%

*Other includes North Carolina counties (Harnett, Cumberland, Chatham, Randolph, and Anson) and other states.

The applicants state, *"FMRH assumes that patient origin will remain consistent with historical patient origin for GI cases."* In Section VI.1-2, page 90, the applicants state how the residents of the service area will have access to the proposed services, including those residents that are low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups. The applicants state:

"FMRH participates in the Medicaid program and otherwise provides care to low income individuals. Medicaid patients represented 8.2 percent of FMRH GI cases during FY2012. Furthermore, FirstHealth provided over $37.4 million of charity care in FY2012."

The applicants adequately identified the population they propose to serve.

Demonstration of Need

In Section I.13(d), page 15, the applicants state that FMRH is a tertiary care referral center for the service area which supports 1.2 million residents and 12 primary care hospitals in the 15-county service area that comprises central North Carolina. In Section III.1, pages 50-52, the applicants describe the need for a second licensed GI endoscopy procedure room at FirstHealth Moore Regional Hospital. The applicants state on page 50 that three factors are driving the need for a second GI procedure room at FMRH: (1) physician issues, (2) service area population growth trends, and (3) GI relationship to older population. Each factor governing the need for a second GI endoscopy procedure room is discussed below.

Physician Issues

In Section III.1, page 51, the applicants state that as part of its 2005 application, (see Project I.D # H-7427-05), it closed two GI rooms and converted them to two hybrid ORs. The applicants based their decision to close the two GI rooms on the following, as stated on page 51:

"FMRH is planning for a decrease in GI endoscopy cases treated at FMRH due to the expected increase of both physician office-based and licensed GI endoscopy rooms. …"

The applicants go on to state on page 51 that their original analysis of a decrease in GI cases and an increase of GI rooms in Moore County was correct, as illustrated in the table below.

	2005	2006	2007	2008	2009	2010	2011	2012	2013*
FMRH Licensed GI Rooms	3	3	3	3	3	3	1	1	2
Total GI Cases	5,514	4,874	4,763	3,859	3,820	3,701	2,940	3,164	2,857
Cases per Room	1,838	1,625	1,588	1,286	1,273	1,234	2,940	3,164	2,857
PMC GI Rooms**		2	2	2	5	5	5	5	
OP GI Cases		5,878	5,750	3,772	8,323	7,834	8,170	8,001	
Cases per Room		2,939	2,875	1,886	1,665	1,567	1,634	1,600	
Total # of Licensed GI Rooms in Moore County	3	5	5	5	8	8	6	6	
Total County Cases	5,514	10,752	10,513	7,631	12,143	11,535	11,110	11,165	
Total County Cases per Room***	1,838	2,150	2,103	1,526	1,518	1,442	1,852	1,861	

Note: All GI cases performed in either a GI room or in an OR are represented in the table.
*Annualized 2013 volumes do not include Richmond County cases.
**Pinehurst Medical Clinic Endoscopy Center
***Totals rounded

As illustrated in the table above, in 2005 Pinehurst Medical Clinic Endoscopy Center, a freestanding outpatient GI endoscopy facility, opened and began providing GI services. In 2006 FMRH experienced a shift in patient utilization of 640 cases[1] [5,514 total cases 2005 – 4,874 total cases in 2006 = 640]. The majority of this shift occurred with patients that had the option of receiving their GI endoscopy procedures on an outpatient basis. The applicants state on page 52, that despite the decrease in GI cases since 2005, there were nearly 3,000 cases at FMRH annually from FY2011-2013. As a result of the number of cases, FMRH has utilized a shared OR full-time to meet the existing case volume. As illustrated in the table above, the applicants project an annualized GI case load of 2,857 cases in FY2013 which excludes volumes from Richmond County. The applicants further state that since 2005, FMRH has performed over 4,000 GI procedures per year using both its dedicated GI procedure room and the shared ORs, which has resulted in over 2,000 procedures per room or 33.0% utilization over the state-defined capacity for a single GI endoscopy room, which is 1,500 procedures per room.

Additionally, in Section III.1, page 52, the applicants state that another concern for the physicians is that patients treated in the shared ORs are prepped and recovered in the Reid Heart Hospital because of its proximity to the main OR and to the Reid Heart Hospital hybrid OR. This process requires the removal of the GI staff from the GI Suite thereby decreasing

[1] 2006 and 2007 License Renewal Applications for FirstHealth of the Carolinas, Inc and 2006 and 2007 License Renewal Application for Pinehurst Medical Clinic Endoscopy Center

the efficiency of the service. The applicants also state that having one shared OR always set-up for GI procedures does not allow surgeons to block off early times to utilize the main OR.

Service Area Population Growth Trends

In Section III.1, page 53, the applicants state:

> *"From 2010 to 2013, the population of Moore County grew by 3.8 percent. Based on NCOSBM projections, Moore County's population is projected to grow by an additional 4.7 percent from 2013 to 2017. In particular:*
>
> - *The 45-64 population grew by 0.3 percent from 2010 to 2013, representing 26.4 percent of Moore County's population. NCOSBM projects that the 45-64 population will only slightly increase from 2013 to 2017.*
>
> - *The elderly population (65+ years old) grew by 11.2 percent from 2010 to 2013, to represent 24.3 percent of Moore County's total population. NCOSBM projects that the elderly population will be the fastest growing population, increasing by 10.2 percent from 2013 to 2017."*

On page 53, the applicants provide a projected population growth table which illustrates that the total population (for all age groups) for Moore County in 2010 was 88,550; in 2013 was 91,879; and the projected population for 2017 is 96,206. This results in a growth rate from 2010-2013 of 3.8% and a projected growth rate from 2013 to 2017 of 4.7%, with the most significant growth in the 65+ age group with a growth rate of 11.2% from 2010-2013 and a projected growth rate of 10.2% from 2013-2017.
The applicants state on pages 65-66, that its historical and projected patient origin is made up of 50.8% of Moore County residents. The applicants further state that the remaining 49.2 of its patient origin comprises of residents from Hoke, Robeson, Montgomery, Scotland, Lee and other counties. In Section III.1, page 54, the applicants provide the overall demographics, by age cohorts, for FMRH service area. The applicants state the six-county (including Moore County) service area grew by 2.3% from 2010-2013. The applicants state based on the projections from NCOSBM, that the proposed service area is projected to grow by 3.2% from 2013-2017. In Section III.1, page 54, the applicants state:

> *"In particular:*
>
> - *The 45-64 population grew by 0.2 percent from 2010 to 2013, representing 25.3 percent of the service area's population. NCOSBM projects that the 45-64 population will slightly increase from 2013 to 2017.*
>
> - *The elderly population (65+ years old) grew by 11.8 percent from 2010 to 2013, to represent 15.6 percent of the service area's total population. NCOSBM projects that the elderly population will be the fastest growing population, increasing by 12.3 percent from 2013-2017."*

On page 54, the applicants provide a projected population growth table which illustrates that the total population (for all age groups) for the six-county proposed service area in 2010 was 392,608; in 2013 was 401,491; and the projected population for 2017 is 414,169. This results in a percent growth rate from 2010-2013 of 2.3% and a projected growth rate from 2013 to 2017 of 3.2% with the most significant growth in the 65+ age group with a growth rate of 11.8% from 2010-2013 and a projected growth rate of 12.3% from 2013-2017.

GI Relationship to Older Populations

In Section III.1, pages 55-57, the applicants describe the need for GI services as it relates to an older and aging population. The applicants supply information from, ***A Review of the Literature (Part 1): Bashir S. Roy P; Vol 5, No.2 (2008-05 -2008-06)*** which states:

> *Upper GI bleed is more common in men than women (ratio 3:2) and the frequency increases with age – a 20-30 fold increase has been witnessed from the 3rd to the 9th decade. The elderly, thus, appear to be at particular risk, with persons above 60 years accounting for more than 40% of cases."*

Additional information on the importance of accessible GI services for an older and aging population is taken from ***The Better of Living & Living Health: Kyle J. Norton, May 2013*** which states:

> *"The prevalence of upper gastrointestinal diseases is increasing in subjects aged 65 years and over. Pathophysiological changes in esophageal functions that occur with aging, may at least in part, be responsible for the high prevalence of:*
>
> 1. *Gastro-esophageal reflux disease in old age.*
> 2. *The incidence of gastric and duodenal ulcers and their bleeding complications is increasing in old-aged populations worldwide.*
> 3. *H. pylori infection in elderly patients with H. plori-associated peptic ulcer disease and severe chronic gastritis.*
> 4. *Almost 40% of gastric ulcer and 25% of duodenal ulcer in the elderly patients are associated with the use of NSAID and/or aspirin."*

The articles cited above, go on to discuss symptoms, risk factors and diagnosis for the diseases that most commonly occur within an aging population and the use of GI endoscopy services.

Utilization

In Section IV.I, page 70, the applicants provide their historical and projected utilization for GI endoscopy procedures at FirstHealth Moore Regional Hospital, as illustrated in the table below.

*FirstHealth Moore Regional Hospital*GI Cases and GI Procedures (10-01 to 09-30)*

	Historical	***Interim/Partial***	***Years 1 - 3***

			Years				
	FY2011	*FY2012*	*FY2013*	*FY2014*	*FY2015*	*FY2016*	*FY2017*
IP GI Cases	*1,601*	*1,710*	*1,425*	*1,432*	*1,439*	*1,446*	*1,454*
OP GI Cases	*1,339*	*1,454*	*1,432*	*1,439*	*1,446*	*1,454*	*1,461*
Total GI Cases	*2,940*	*3,164*	*2,857*	*2,871*	*2,886*	*2,900*	*2,915*
Total GI Procedures	***3,822***	***4,398***	***4,114***	***4,135***	***4,155***	***4,176***	***4,197***

Source: 2012 and 2013 License Renewal Applications; Need Methodology
**Historical GI volumes include Richmond County GI cases, but Inerim/Partial Years and Years 1-3 do not include Richmond County GI cases.*

In Section IV.I, page 71, the applicants provide their methodology and assumptions, as follows:

"A simple need methodology to project future GI cases at FMRH was used for several reasons. Theses reasons include:

- *Although GI case volumes have decreased from 2005, FMRH's GI case volume averages 2,987 cases from 2011 to 2013.*
- *FMRH is a tertiary hospital and the only hospital in Moore County where inpatient GI cases can be treated.*
- *The introduction of esophageal ultrasound at FMRH has increased the volume of GI procedures at FMRH.*

Step 1

In FY2013, FMRH is projected to have annualized GI case load of 2,857 cases; this volume does not include any GI cases from Richmond County.

Step 2

Although total GI cases increased by 7.6 percent from 2011 to 2012 (3,164 case [sic] *- 2,940 cases* [= 224]*) / 2,940 cases x 100 = 7.6%]; FMRH projects GI cases to increase by 0.5 percent per year, which results in a 2.0 percent increase from 2013 through 2017. FMRH increases GI cases by 0.5 percent annually to conservatively account for population growth and medical staff growth. This 4-year GI case growth of 2.0 percent is almost 75 percent less than one year (2011-2012) GI case growth experienced at FMRH.*

Step 3

FMRH used the average number of GI procedures per GI case from FY2013 YTD [3,992 procedures / 2,780 cases = 1.44 procedures per case; this calculation excludes procedures and cases originating from Richmond County patients] to project the number of GI procedures to be performed from 2013 through 2017.

Step 4

FMRH multiplied the total projected GI cases by the FY2013 YTD IP and OP GI case rates to project the number of IP and OP GI endoscope cases per year.

- *IP GI cases = (1,425 cases / 2,857 cases) x 100 = 49.9%*
- *OP GI cases = (1,432 cases* / 2,857 cases) *x 100 = 50.1%"*

As discussed above, the applicants had 1,710 inpatient and 1,454 outpatient GI endoscopy cases in FY2012 for a total of 3,164 cases (3,822 GI procedures). The applicants then project to perform 4,155 GI endoscopy procedures during Operating Year 1, which is an average of 2,078 procedures per room (4,155 procedures / 2 procedure rooms = 2,077.5 procedures per room); 4,176 in Operating Year 2, which is an average of 2,088 procedures per room (4,176 procedures / 2 procedure rooms = 2,088 procedures per room); and 4,197, which is an average of 2,098 procedures per room (4,197 procedures / 2 procedure rooms = 2,098.5 procedures per room). Thus, the applicants adequately demonstrate that the two GI endoscopy procedure rooms at FMRH will exceed the performance standard of at least 1,500 GI endoscopy procedures per room as required in 10A NCAC 14C .3903(b).

Although, the applicants do not propose to add operating rooms, in Section IV.I, pages 72-76, the applicants provide their methodology for projected OR utilization to demonstrate why it is not feasible to continue to perform GI endoscopy procedures in the shared ORs. The applicants provide their methodology and assumptions for weighted inpatient and outpatient surgical procedures which is based on the projected population growth, historical trends and the transfer of two ORs from FMRH to FirstHealth Hoke Community Hospital (FHCH). See Project I.D. # H-8843-12 for discussion on the relocation of the operating rooms. The applicants' conclusion of its four step methodology for its surgical case projections for FY2011 – FY2017, as reported on page 76 of the application, is summarized in the table below.

FMRH Surgical Case Projections FY2011 – FY2017

	2012*	***2013****	***2014***	***2015***	***2016***	***2017***
Previous Year IP Surgical Cases			*5,409*	*5,229*	*5,160*	*5,088*
Annual FMRH Increase			*0.95%*	*0.94%*	*0.93%*	*0.91%*
Projected IP Surgical Cases			*5,460*	*5,279*	*5,208*	*5,134*
FHCH IP Surgical Cases Incremental "shift" from FMRH			*231*	*119*	*120*	*0*
Total FMRH IP Surgical Cases	***5,204***	***5,409***	***5,229***	***5,160***	***5,088***	***5,134***
Previous Year OP Surgical Cases			*4,750*	*4,206*	*4,129*	*4,049*
Annual FMRH Increase			*0.96%*	*0.95%*	*0.94%*	*0.91%*
Projected OP Surgical Cases before each "shift"			*4,796*	*4,246*	*4,167*	*4,086*
FHCH OP Surgical Cases Incremental "shift" from FMRH before FHCH "Shift"			*590*	*117*	*118*	*0*
Total FMRH OP Surgical Cases	***4,414***	***4,750***	***4,206***	***4,129***	***4,049***	***4,086***
Total FMRH Surgical Cases	***9,879***	***10,159***	***9,435***	***9,288***	***9,137***	***9,220***

**Actual surgical cases*
*** Annualized surgical cases*

As illustrated in the table above, the applicants project to perform 9,220 combined inpatient and outpatient surgical cases or 65.7% utilization in the third year of operations (FY2017) for the proposed project [(5,134 IP cases x 3 hours = 15,402) + (4,086 OP cases x 1.5 hours = 6,129); 15,402+6,129 = 21,531 hours; (2,340 hours x 14 operating rooms = 32,760); 21,531 / 32,760 = 0.657 x 100 = 65.7%. The applicants state on page 76, that this utilization rate indicates that shifting of some surgical volume to FHCH will have little effect on the utilization rate of the ORs at FMRH. Thus, the applicants adequately demonstrate the need for a second licensed GI endoscopy room at FMRH.

Access

In Section VI.2, pages 90-91, FMRH describes how underserved persons will continue to have access to services, stating, *"The FirstHealth Non-Discrimination Policy guarantees equal access to hospital services for members of all racial, ethnic and religious minority groups."*

In summary, the applicants adequately identified the population to be served, demonstrated the need the population has for the project and the extent to which all residents of the area, in particular underserved groups are likely to have access to the services provided at FMRH. Therefore, the application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income

persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

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

CA

In Section III.8, pages 66-68, the applicants describe the alternatives considered, which include:

1) Maintain the Status Quo – the applicants concluded that maintaining the status quo was not a viable option because it required the use of two shared ORs with one of the ORs always set-up to perform GI endoscopy procedures. This option is inefficient and limits the availability of the ORs for early surgical start times.

2) Convert an Existing OR – the applicants concluded that this was not a viable option due to the projected utilization of the existing ORs. The applicants project to provide 9,061 surgical cases for a utilization of 62.9 percent in the third year of operation for the proposed project.

3) Develop an Off-campus Medical Office Building to Provide GI Services – the applicants concluded that developing an off-campus medical office building to provide GI endoscopy services was not a cost affective alternative.

4) Engage in a Joint Venture – the applicants concluded that a joint venture was impractical because the project is an internal issue. Thus, FMRH needs to ensure that it has accessible space to perform GI endoscopy procedures within its current GI suite.

5) Add a Second GI Room – the applicants concluded that the addition of a second GI endoscopy procedure room was FMRH's best option given the fact that the GI endoscopy room already exists and would require no renovations or equipment purchase to make the room operational. Thus, the applicants concluded that developing the project as proposed was its most effective and least costly alternative.

Furthermore, the application is conforming to all other applicable statutory and regulatory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative.

The applicants adequately demonstrate that the proposed alternative is the most effective or least costly alternative to meet the need to improve GI endoscopy services at FMRH. Consequently, the application is conforming to this criterion and approved subject to the following conditions:

1. **FirstHealth Moore Regional Hospital and FirstHealth of the Carolinas, Inc. shall materially comply with all representations made in the certificate of need application.**

2. **FirstHealth Moore Regional Hospital and FirstHealth of the Carolinas, Inc. shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VIII of the application and that would otherwise require a certificate of need.**

3. **FirstHealth Moore Regional Hospital and FirstHealth of the Carolinas, Inc. shall develop no more than one gastrointestinal endoscopy room and shall be licensed for a total of no more than two gastrointestinal endoscopy rooms at FirstHealth Moore Regional Hospital following project completion.**

4. **FirstHealth Moore Regional Hospital and FirstHealth of the Carolinas, Inc. 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

On page 19 the applicants state the second GI endoscopy room already exists and needs only reconnection of medical gas and minor paint and finishes to make it functional. In Section VIII.1, page 115, the applicants project that the total capital cost will be $40,000 which includes $10,000 for construction costs and $30,000 for administrative/legal/ consultant/permit/impact fees, etc. In Section IX.1, page 119, the applicants project there will be no start-up expenses or initial operating expenses associated with the proposed project. In Section VIII.3, page 116, the applicants state that the project will be funded by FirstHealth of the Carolinas' accumulated reserves. Exhibit 21 contains a letter dated June 5, 2013, from the Chief Financial Officer of FirstHealth of the Carolinas, Inc, which states:

"FirstHealth of the Carolinas, Inc. will provide $40,000 through Accumulated Reserves (Cash and cash equivalents) to fund the GI endoscopy room project at FirstHealth Moore Regional Hospital in Moore County."

Exhibit 22 contains the consolidated financial statements for FirstHealth of the Carolinas Inc. and Affiliates for the year ended September 30, 2012. As of September 30, 2012 FirstHealth of the Carolinas Inc. and Affiliates had $37,620,000 in Cash and Cash Equivalents,

$581,287,000 in Total Net assets (total assets less total liabilities), and $922,045,000 in Total Current Assets.

The applicants adequately demonstrated the availability of sufficient funds for the capital needs of the project.

Below is a table that shows the facility's projected average reimbursement for the 10 most commonly performed GI endoscopy procedures for the first three project years, as reported by the applicants in Section II.11, page 41.

CODE	PROCEDURE	FY 2015	FY 2016	FY 2017
45.16	EGD w/ Closed Biopsy	$1,546	$1,592	$1,640
45.13	SM Bowel Endoscopy Nec	$1,098	$1,131	$1,165
45.25	Close Large Bowel Biospy	$1,418	$1,461	$1,505
45.42	Endo Polpectomy Large Int	$1,062	$1,094	$1,127
45.23	Colonoscopy	$948	$977	$1,006
42.92	Esophageal Dilation	$1,202	$1,238	$1,275
88.74	DX Ultrasound-Digestive	$2,890	$2,977	$3,066
44.43	Endoscopy Control Gast Hem	$1,164	$1,199	$1,235
51.85	Endoscopy Sphincterotomy	$3,895	$4,011	$4,132
51.88	Endoscopy Remove Bile Stone	$3,882	$3,998	$4,118

On page 39, the applicants state the services and supplies included in the charges are for the following:

- Nursing and technical personnel
- Use of facility
- Drugs, biological, surgical dressings, supplies, splints, appliances, and equipment
- Diagnostic and therapeutic items
- Administrative, record keeping, and housekeeping
- Blood, blood plasma, platelets, etc.
- Materials for anesthesia/sedation
- Lab and diagnostic services required the day of the GI procedure

The applicants state on page 40 that anesthesiologist or physician fees and pathology charges will be billed separately.

Below is a table which illustrates projected revenues (charges) and operating expenses (costs) for the entire hospital and the GI endoscopy suite for each of the first three project years, as reported by the applicants in the pro forma section of the application.

	Entire Hospital			GI Endoscopy Suite		
	FY2015	FY2016	FY2017	FY2015	FY2016	FT2017
Total Revenues	$469,291,000	$477,017,000	$486,737,000	$3,515,429,000	$3,639,845,000	$3,768,291,000
Total Expenses	$452,735,000	$461,317,000	$469,852,000	$1,434,852,000	$1,474,769,000	$1,515,916,000
Net Income	**$16,556,000**	**$15,700,000**	**$16,885,000**	**$2,080,577,000**	**$2,165,076,000**	**$2,252,375,000**

As shown in the table above, the applicants project revenues will exceed expenses in each of the first three project years for the entire hospital and the GI endoscopy suite. The assumptions used by the applicants in preparation of the pro formas, including projected utilization, are reasonable, credible and supported. See the ProFormas tab of the application for the pro formas and assumptions. See Criterion (3) for discussion regarding projected utilization which is incorporated hereby as if set forth fully herein. The applicants adequately demonstrate that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

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

C

The applicants, FirstHealth Moore Regional Hospital and FirstHealth of the Carolinas, Inc operate the only acute care hospital in Moore County. The hospital currently provides inpatient and outpatient GI endoscopy services in its one licensed GI endoscopy procedure room and in shared ORs. In this application, the applicants propose to develop a second GI endoscopy room on the campus of FirstHealth Moore Regional Hospital. There is only one other provider of GI endoscopy services in Moore County and that is Pinehurst Medical Clinic Endoscopy Center. In the applicants' defined service area there are a total of seven providers of GI endoscopy services (including FMRH). The table below describes those facilities and the number of GI procedures performed in the last year (FY2012), as reported by the applicants on page 69.

NAME OF FACILITY	COUNTY	# OF GI ROOMS	# OF GI PROCEDURES PERFORMED	# OF PROCEDURES PER GI ROOM
Central Carolina Hospital	Lee	2	992	496
Mid Carolina Gastroenterology	Lee	2	3,241	1,620
Pinehurst Medical Clinic Endoscopy Center	Moore	5	10,605	2,122
FMRH	Moore	1	3,164	3,164
Southeastern Gastroenterology Center	Robeson	1	596	596
Southeastern Regional Medical Center	Robeson	5	3,768	754
Scotland Memorial Hospital	Scotland	2	1,791	896

Source: 2013 Hospital and ASC License Renewal Applications

The number of procedures per room was determined by dividing the number of rooms by the number of procedures performed [example: 10,605 procedures / 5 rooms =2,121.5 procedures per room. As illustrated in the above table, Mid-Carolina Gastroenterology (MCG) and Pinehurst Medical Clinic Endoscopy Center (PMCEC) each exceed 1,500 procedures per GI endoscopy room in FY2012. Pinehurst Medical Clinic Endoscopy Center, according to Google Maps, is 0.5 miles from FMRH. As an outpatient facility, PMCEC provides the residents of Moore and surrounding counties with a choice when considering having a GI endoscopy procedure that can be performed on an outpatient basis. Regarding utilization of the existing GI endoscopy room at FMRH, as illustrated in the table above, the applicants reported that 3,164 procedures were performed at the facility in FY2012. Based on the minimum performance standard promulgated in 10A NCAC 14C .3903(b), the facility is currently operating above the standard of 1,500 procedures, per room, as required by this rule. Additionally, in Section III, page 65, the applicants state, FMRH assumes that patient origin will remain consistent with historical patient origin for GI cases.

In summary, the applicants adequately demonstrate the need for its proposal and that the proposal would not result in the unnecessary duplication of existing or approved GI endoscopy rooms in licensed facilities in the proposed service area. See Criterion (3) for the discussion regarding the need to add a second GI endoscopy room to the existing GI suite at Firsthealth Moore Regional Hospital. Consequently, the application is conforming to this criterion.

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

C

In Section VII.1(a)(b), pages 102-103, the applicants provide the current and proposed staffing for its GI endoscopy services for the second full fiscal year. The applicants state that FMRH currently employees 10.0 full-time equivalent (FTE) to staff the GI suite. On page

104, the applicants state that there will be no new FTE positions as a result of the proposed second GI endoscopy room.
In Section VII.2, page 103, and in Section VII.6, page 105 the applicants provide tables to illustrate projected staffing for the proposed GI endoscopy services, as shown in the table below:

FMRH GI Services Proposed Staffing FY2016

	ADMINISTRATION	PRE-OPERATIVE	POST-OPERATIVE	OPERATING ROOM	OTHER	TOTAL
	Number of FTEs					
Supervising RN	0.95					0.95
Registered Nurses		1.86	1.86	2.00		5.72
Surgical Technicians				2.50	0.71	3.21
LPN		0.06	0.06			0.12
Totals	0.95	1.92	1.92	4.50	0.71	10.00

Exhibit 14 contains a letter from Eric R. Frizzell, M.D., in which he confirms his intent to serve as Medical Director of GI endoscopy services at FMRH. Exhibit 14 also contains a copy of Dr. Frizzell curriculum vitae which documents that he is board-certified in internal medicine. In Section VII.3(b), page 104, the applicants state, FMRH has had no difficulty in recruiting staff in the past. The applicants further state that the competitive pay and attractive benefits offered by FMRH attracts qualified staff.

The applicants adequately document the availability of sufficient health manpower and management personnel to staff the proposed second GI endoscopy room at FMRH. 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

FirstHealth Moore Regional Hospital is an existing hospital and provider of GI endoscopy services. Therefore, the necessary ancillary and support services are currently available. In Section II.2(b), page 24, the applicants provide a summary of the availability of the necessary ancillary and support services. Exhibit 5 contains a letter dated June 10, 2013 from the President/CEO of FirstHealth of the Carolinas affirming that the necessary ancillary and support services to provide GI endoscopy services are currently provided by FMRH. See Exhibit 6 for copies of the FMRH's referral, transfer, follow-up, and blood transfusion policies.

In Sections V.2-V.6, pages 78–84, the applicants describe FMRH coordination with existing health care providers, which includes the following:

- FirstHealth Montgomery Memorial Hospital
- FirstHealth Richmond Memorial Hospital
- Womack Army Medical Center
- Scotland Memorial Hospital
- UNC Hospitals

See Exhibit 13 for a list of facilities in which FMRH has transfer agreements. Exhibit 24 contains physician and community letters of support.

The applicants adequately demonstrated the availability of the necessary ancillary and support services and that the proposed services would be coordinated with the existing healthcare system. Therefore, the application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

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

NA

(11) Repealed effective July 1, 1987.

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

NA

The applicants propose to develop a second GI endoscopy room on the campus of FirstHealth Moore Regional Hospital. As part of a 2005 CON application, FMRH closed two GI rooms in its existing GI suite and converted them to two hybrid ORs in the Reid Heart Hospital (see Project I.D. # H-7427-05). When the two GI rooms were closed, their medical gas hookups were disconnected, however, the connections still exist. Therefore, the proposed second GI endoscopy room still exists and would require no renovations or construction costs to make the GI endoscopy room operational. On page 115, the applicants project the total capital cost for the second GI endoscopy room will be $40,000, $10,000 of which covers paint and finishes in the existing space. The remainder of the capital cost ($30,000) is for consultation fees. Therefore, this criterion is not applicable to this review.

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

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

C

In Section VI.12 and VI.13, pages 98-99, the applicants provide the payor mix during the last full fiscal year (10/1/2011-09/30/2012) for the entire hospital and its GI endoscopy services, as illustrated in the table below:

Payor Mix FFY 2012 Current Patient Days / Procedures as a Percent of Total Utilization			
	Entire Hospital	Inpatient GI	Outpatient GI
Self Pay/ Charity/Other	8.9%	6.0%	2.6%
Medicare / Medicare Managed Care	64.2%	68.5%	55.3%
Medicaid	8.1%	9.6%	6.8%
Commercial Insurance	1.3%	13.4%*	31.2%*
Managed Care	14.4%		
Other	3.1%	2.4%	4.1%
Total	**100.0%**	**100.0%**	**100.0%**

*Includes Managed Care/Commercial Insurance as reported on page 99 of the application.

In Section VI.2, page 90, the applicants state:

"FMRH participates in the Medicaid program and otherwise provides care to low income individuals. Medicaid patients represented 8.2 percent of FMRH GI cases during FY2012. Further, FirstHealth provided over $37.4 million of charity care in FY2012."

Further in Section VI.2, page 90, the applicants state:

"The FirstHealth Non-Discrimination Policy guarantees equal access to hospital services for members of all racial, ethnic and religious minority groups."

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 Moore County and statewide.

	Total # of Medicaid Eligibles as % of Total Population	**Total # of Medicaid Eligibles Age 21 and older as % of Total Population**	**% Uninsured CY 2009 (Estimate by Cecil G. Sheps Center)**
Moore	14%	5.7%	18.5%
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 at the same rate as the older segments of the population.

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 Office of State Budget & Management (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 applicants demonstrated that medically underserved populations currently have adequate access to the services offered at FirstHealth Moore Regional Hospital. Therefore, the application is conforming to this criterion.

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

C

Recipients of Hill-Burton funds were required to provide uncompensated care, community service and access by minorities and handicapped persons. In Section VI.11, page 97, the applicants state:

"In June 1995, FMRH fulfilled its Hill-Burton quota to provide uncompensated care, community service, and access to minorities and handicapped persons under Hill-Burton. …

Nonetheless, based on its mission, FMRH continues to provide uncompensated care …

… FirstHealth's community services include dental and medical care, screenings and immunizations, as well as transportation, childcare, safety seats and elderly emergency response systems. Target populations include the communities' most under-served residents. …"

In Section VI.10(a), page 97, the applicants state:

"No complaints have been filed against FirstHealth or FMRH 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

In Section VI.14(a), page 100, the applicants provide the projected payor mix for the second full fiscal year (FFY 2016) of operations for inpatient and outpatient GI services, as illustrated in the table below.

SECOND FULL PROJECT FISCAL YEAR PROJECTED PROCEDURES AS % OF TOTAL		
	IP GI	**OP GI**
Self Pay/Charity	6.0%	2.6%
Medicare/Medicare Managed Care	68.5%	55.3%
Medicaid	9.6%	6.8%
Managed Care/ Commercial Insurance	13.4%	31.2%
Other	2.4%	4.1%
Total	**100.0%**	**100.0%**

In Section VI.4, page 91, the applicants state that all persons have access to the services at FMRH regardless of their ability to pay. Exhibit 16 contains a copy of the FMRH Credit and Collection Policy. Additionally, the applicants state on page 95 that FRMH provided a total of $37.4 million or 7.8% of its Net Revenue for charity care in FY2012 and the hospital estimates that it will provide $501,080 or 4.25% of net revenue in FY2015 and $518,727 or 4.25% of next revenue in FY2016 for charity care.

The applicants demonstrated that medically underserved populations will have adequate access to the proposed services. Therefore, the application is conforming with this criterion.

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

C

In Section VI.9, page 96, the applicants state that as a regional, tertiary referral center, FMRH receives referrals from physicians throughout its primary and secondary service

area. The applicants also provide a list of the hospitals in which FMRH has transfer agreements on page 96.

The applicants adequately demonstrated it offers a range of means by which patients will have access to the proposed services. Therefore, the application is conforming 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

In Section V.1, page 77, the applicants state that they have over 80 agreements with health professional training programs. See Exhibit 12 for a list of those training programs. FMRH also provided a copy of its training agreement with Sandhills Community College as a sample of FMRH's training agreements.

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

The applicants currently provide GI endoscopy services to patients in its proposed service area. In Section V.7, pages 84-89, the applicants discuss how the proposed project will foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area. See Sections II, III, VI and VII of the application for additional discussion by the applicants about the impact of its proposal on cost effectiveness, quality and access to GI endoscopy services.

The applicants adequately demonstrate that its proposal would enhance competition by promoting cost effectiveness, quality and access to the proposed services based on the information in the application and the following analysis:

1) The applicants adequately demonstrate the need to add one GI endoscopy room to FMRH. Projected utilization of GI endoscopy services is based on reasonable, credible and supported assumptions. See Criterion (3) for discussion regarding historical and projected utilization which is incorporated hereby as if fully set forth herein. The applicants adequately demonstrate the financial feasibility of the proposal is based upon reasonable projections of costs and charges. See the Pro Formas and Criterion (5) for discussion regarding financial feasibility which is incorporated hereby as if fully set forth herein. Therefore, the applicants adequately demonstrated the cost effectiveness of its proposal.
2) The applicants have and will continue to provide adequate access to medically underserved groups, including self pay / charity care patients, Medicare beneficiaries and Medicaid recipients. See Section VI of the application and Criterion (13c) for discussion regarding projected access by these groups which is incorporated hereby as if fully set forth herein.
3) The applicants adequately document that it has and will continue to provide quality care. See Sections II and VII of the application.
4) The proposed project will have a positive impact on competition by providing patients with increased access to quality services. See Sections II and V of the application.

Therefore, the applicants adequately demonstrate that its proposal 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

FMRH is accredited by the Joint Commission and certified for Medicare and Medicaid participation. See Exhibit 7 for a copy of FirstHealth's accreditation and North Carolina license. According to the files in the Acute and Home Care Licensure and Certification Section, Division of Health Service Regulation, an unannounced onsite complaint investigation survey, focused full survey, and follow-up survey to the Conditions out of compliance and immediate jeopardy (IJ) identified during the 08/01/2013 survey was conducted on August 27 through August 29, 2013. Based on validation of the facility's plan of correction, the SA recommends the IJ be removed and the 23 day termination from the Medicare program be aborted effective 08/29/2013. The SA recommends the facility to be in compliance with 482.12 Governing Body, 482.13 Patients' Rights, 482.23 Nursing Services and 482.51 Surgical Services. No other deficiencies were cited. 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 FMRH and FirstHealth is conforming to all applicable Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900, which are discussed below.

.3902 INFORMATION REQUIRED OF APPLICANT

.3902(a)(1) *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 Sections II.11, page 32 and III.5, page 63, the applicants identify the service area as Hoke, Lee, Montgomery, Moore, Robeson, and Scotland counties. The applicants project in Section III.7, page 66 that 50.8% of patients will come from Moore County; 9.2% from Hoke County; 8.5% from Robeson County; 8.4% come from Montgomery County, 6.2% from Scotland County, 5.2% from Lee County, and the remaining 11.6% of patients will come from other counties in North Carolina and other states.

.3902(a)(2) *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- In Section II.11, page 32, FMRH states that it currently has one existing GI endoscopy room and in this application proposes to develop a second GI endoscopy room.

(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 FirstHealth nor FMRH operate a GI room in any other licensed health service facility located in the service area.

(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 33, the applicants provide the number of GI endoscopy procedures performed from May 2012 through April 2013 (2,966), identified by CPT code, in the applicant's existing GI endoscopy room.

(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 34, the applicants provide the number of GI endoscopy procedures, identified by CPT code, projected to be performed in each of the first three operating years of the project. The applicants project to perform 4,155 procedures in Operating Year 1 (FY2015); 4,176 in Operating Year 2 (FY2016); and 4,197 procedures in Operating Year 3 (FY2017).

(E) the number of procedures by type, other than GI endoscopy procedures, performed in the GI endoscopy rooms in the last 12 months.

-C- In Section II.11, page 35, the applicants state the following other procedures were performed at FMRH in the GI endoscopy room in the last 12 months (May 2012-April 2013):

Esophageal Manometry	51
Replace Gastrostomy Tube	36

(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.

-C- In Section II.11, page 35, the applicants state the following other procedures are projected to be performed in the GI endoscopy room in each of the first three operating years of the project.

Code/Description	***FY2015***	***FY2016***	***FY2017***
89.32 Esophageal Manometry	*52*	*52*	*53*
97.02 Replace Gastrostomy Tube	*36*	*36*	*37*

(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 36, the applicants state that 2,060 patients were served at FMRH in its licensed GI endoscopy room in the last 12 months (May 2012 and April 2013).

(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, page 36, the applicants state FMRH projects 2,886 patients in Operating Year 1, 2,900 patients in Operating Year 2, and 2,915 patients in Operating Year 3.

.3902(a)(3) *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 36, the applicants state that FMRH has the following existing or approved ORs: 2 IP ORs and 16 shared ORs for a total of 18 operating rooms. It should be noted that, FirstHealth was approved to relocate two operating rooms from FMRH to FHCH (FirstHealth Hoke Community Hospital). See Project I.D # N-8497-10 and Project I.D. # N-8843-12.

(B) the number of procedures by type performed in the operating rooms in the last 12 months; and

-C- In supplemental information, the applicants provide the number of procedures by type performed in FMRH operating rooms in the last 12 months. The applicants report a total of 11,537 procedures were performed from May 2012–April 2013 in its 18 operating rooms.

(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 Section II.11, page 38, the applicants project no GI endoscopy procedures will be performed in other operating rooms outside of the GI operating suite.

.3902(a)(4) *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 38, the applicants state as a regional hospital, FMRH will provide GI services 7:30AM-5:00PM, Monday-Friday, on call and after hours, as necessary, to accommodate the needs of the patients in the proposed service area.

.3902(a)(5) *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 38, the applicants provide the charge for each of the 10 GI endoscopy procedures most commonly performed in the facility during the last 12 months (May 2012-April 2013), as illustrated in the table below:

Code/Description	***Average Charge***
45.16 EGD WITH CLOSED BIOPSY	*$4,302*
45.13 SM BOWEL ENDOSCOPY NEC	*$3,167*
45.25 CLOS LARGE BOWEL BIOPSY	*$4,339*
45.42 ENDO POLPECTOMY LRGE INT	*$2,437*
45.23 COLONOSCOPY	*$2,038*
42.92 ESOPHAGEAL DILATION	*$3,255*
88.74 DX ULTRASOUND-DIGESTIVE	*$8,133*
44.43 ENDOSC CONTROL GAST HEM	*$3,565*
51.85 ENDOSC SPHINCTEROTOMY	*$9,646*
51.88 ENDOSC REMOVE BILE STONE	*$10,419*

.3902(a)(6) *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 39, the applicants provide the type and average facility charges by CPT code projected during the first three operating years for the ten procedures projected to be performed most often at FMRH. FMRH projects that the 10 most commonly performed procedures will remain the same.

.3902(a)(7) *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 39, the applicants state, *"Services and supplies included in the procedure charge are:*

- *Nursing and technical personnel*
- *Use of facility*

- *Drugs, biologicals, surgical dressings, supplies splints, appliances, and equipment*
- *Diagnostic and therapeutic items*
- *Administrative, record keeping, and housekeeping*
- *Blood, blood plasma, platelets, etc.*
- *Materials for anesthesia/sedation*
- *Lab and diagnostic services required the day of the GI procedure."*

.3902(a)(8) *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 40, the applicants describe which charges will not be included in the facility charges. Those charges include anesthesiologist and physician fees, pathology charges, durable medical equipment charges, ambulance services, and independent laboratory and diagnostic charges for services prior to the date of service.

.3902(a)(9) *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 10 GI endoscopy procedures most commonly performed in the facility during the preceding 12 months.*

-C- In Section II.11, page 40, the applicants provide the average reimbursement received per procedure for each of the 10 most commonly performed procedures during the preceding 12 months (May 2012-April 2013), as illustrated below.

Code/Description	***Average Reimbursement***
45.16 EGD WITH CLOSED BIOPSY	*$1,457*
45.13 SM BOWEL ENDOSCOPY NEC	*$1,035*
45.25 CLOS LARGE BOWEL BIOPSY	*$1,337*
45.42 ENDO POLPECTOMY LRGE INT	*$1,001*
45.23 COLONOSCOPY	*$894*
42.92 ESOPHAGEAL DILATION	*$1,133*
88.74 DX ULTRASOUND-DIGESTIVE	*$2,724*
44.43 ENDOSC CONTROL GAST HEM	*$1,097*
51.85 ENDOSC SPHINCTEROTOMY	*$3,671*
51.88 ENDOSC REMOVE BILE STONE	*$3,659*

.3902(a)(10) *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 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility.*

-C- In Section II.11, page 41, the applicants provide the average reimbursement projected to be received for the 10 GI endoscopy procedures which the applicant projects will be performed most frequently in the facility for the first three project years.

.3902(b) *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;

-NA- The applicants are existing providers of GI endoscopy services

(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;

-NA- The applicants are existing providers of GI endoscopy services

(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;

-NA- The applicants are existing providers of GI endoscopy services

(4) a written description of patient selection criteria including referral arrangements for high-risk patients;

-NA- The applicants are existing providers of GI endoscopy services

(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;

-NA- The applicants are existing providers of GI endoscopy services

(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- The applicants are existing providers of GI endoscopy services

.3903 PERFORMANCE STANDARDS

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

-C- In Section II.11, page 43, the applicants state that FMRH is available 365 days per year for emergency GI services.

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

-C- In Section II.11, page 43, the applicants state the number of projected GI procedures to be performed at FMRH. The applicants project to perform 4,155 GI endoscopy procedures during Operating Yr 1, which is an average of 2,078 procedures per room (4,155 procedures / 2 procedure rooms = 2,077.5 procedures per room); 4,176 in Operating Yr 2, which is an average of 2,088 procedures per room (4,176 procedures / 2 procedure rooms = 2,088 procedures per room); and 4,197 in Yr 3, which is an average of 2,098 procedures per room (4,197 procedures / 2 procedure rooms = 2,098.5 procedures per room). See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

.3903(c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall demonstrate that at least the following*

types of GI endoscopy procedures will be provided in the proposed facility or GI endoscopy room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.

-C- In Section II.11, page 34, the applicants demonstrate they will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at FMRH.

.3903(d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility, or a related entity to the applicant owns operating rooms located in the proposed service area, the applicant shall meet one of the following criteria: (1) if the applicant or a related entity performs GI endoscopy procedures in any of its surgical operating rooms in the proposed service area, reasonably project that during the second operating year of the project the average number of surgical and GI endoscopy cases per operating room, for each category of operating room in which these cases will be performed, shall be at least: 4.8 cases per day for each facility for the outpatient or ambulatory surgical operating rooms and 3.2 cases per day for each facility for the shared operating rooms; or*

-NA- The applicants state that currently GI endoscopy procedures are being performed in two shared operating rooms. With the development of the proposed project, the applicants state no GI endoscopy procedures will be performed in the ORs.

(2) demonstrate that GI endoscopy procedures were not performed in the applicant's or related entity's inpatient operating rooms, outpatient operating rooms, or shared operating rooms in the last 12 months and will not be performed in those rooms in the future.

-NA- The applicants state GI endoscopy procedures were performed in two shared operating rooms over the past 12 months. The applicants further state that no GI endoscopy procedures will be performed in the ORs in the future.

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

-C- In Section IV.1(d), pages 71-76, the applicants provide all assumptions and the methodology used to project GI endoscopy procedures. See Criterion (3) for discussion of projected utilization which is incorporated hereby as if set forth fully herein.

.3904 SUPPORT SERVICES

.3904(a) *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- See Exhibit 9 for a copy of agreement between FMRH and Pinehurst Pathology Center, Inc to provide pathology services.

.3904(b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall 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- In Exhibit 10 the applicants provide a copy of FMRH's conscious sedation policy.

.3904(c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall 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- In Exhibit 10 the applicants provide a copy of FMRH's policies and procedures for cleaning and monitoring the cleanliness of scopes, other equipment, and the procedure rooms between cases.

.3904(d) *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 5 for documentation that all physicians utilizing the proposed facility will have practice privileges at FMRH.

(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.

-NA- The proposed second GI endoscopy room will be located at FMRH which is a tertiary hospital. However, in Exhibit 13, the applicants provide a copy of a transfer agreement with UNC-North Carolina Memorial Hospital.

(3) documentation of a transfer agreement with a hospital in case of an emergency.

-NA- The proposed second GI endoscopy room will be located at FMRH which is a tertiary hospital

.3905 STAFFING AND STAFF TRAINING

.3905(a) *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 Section II.11, page 46, the applicants state the proposed second GI endoscopy room at FMRH will have sufficient staff in the areas identified in this rule. There will be 0.95 FTEs for administration; 1.92 FTEs assigned to pre-operative; 1.92 FTEs assigned to post-operative; 4.50 FTEs assigned to procedure rooms; and 0.71 FTEs assigned to other duties.

.3905(b) *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 46, the applicants states FMRH hospital currently has a board certified staff of seven general physicians and six gastroenterologists. The applicants project to have the same number of board certified physicians in 2016 (OP Yr 2 of the proposed project). See Exhibit 13 for an active list of physicians on staff at FMRH. Exhibit 14 contains a letter from Dr. Eric R. Frizzell, agreeing to serve as the Medical Director of GI Endoscopy Services at Firsthealth Moore Regional Hospital. Exhibit 14 also contains a brief resume for Dr. Frizzell.

.3905(c) *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- See Exhibit 11 for a copy of FMRH's Policy and Procedure manual which describes extending privileges to medical personnel that will provide services in the facility.

.3905(d) *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- FMRH is accredited by the Joint Commission.

.3906 FACILITY

.3906(a) *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.*

(b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in an existing licensed health service facility shall 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) *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- FMRH is accredited by the Joint Commission.