

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

DECISION DATE: February 11, 2014
PROJECT ANALYST: Gloria C. Hale
TEAM LEADER: Lisa Pittman

PROJECT I.D. NUMBER: Q-10226-13 / Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center/ Add two new licensed gastrointestinal endoscopy procedure rooms / Pitt 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 applicant, Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center (Vidant), proposes to develop two licensed GI endoscopy rooms on the campus of Vidant located in Greenville, Pitt County. One will be located in a decommissioned operating room in Vidant's main operating suite. The other will be located at the medical center's Children's Hospital in its pediatric bronchoscopy room. Neither of these proposed GI endoscopy rooms would require new construction or renovation. The total projected cost for the proposed project is \$538,600.

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- (2) Repealed effective July 1, 1987.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

Vidant is an existing, licensed and accredited acute care hospital located in Greenville, Pitt County that provides GI endoscopy services in its two licensed GI endoscopy procedure rooms. Vidant proposes to develop two additional licensed GI endoscopy rooms on the campus of Vidant for a facility total of four GI endoscopy procedure rooms. One of the two proposed GI endoscopy procedure rooms is an existing licensed endoscopy room which will be acquired from Moye Medical Center, LLC d/b/a East Carolina Endoscopy Center. Moye Medical Center, LLC d/b/a East Carolina Endoscopy Center is a 50/50 joint venture between Vidant and East Carolina University. This GI endoscopy procedure room will be dedicated to two specialty endoscopy procedures, namely endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS). The second proposed GI endoscopy procedure room will be new to the service area and dedicated to pediatric patients.

Population to be Served

In Section III.7, page 44, the applicant provides the historical patient origin for Vidant’s GI endoscopy services for FFY 2013. In Section III.6, page 43, the applicant provides its projected patient origin for GI endoscopy services for the first two full years of operation following project completion, FFY 2015 and FFY 2016. This information is summarized in the table below:

Vidant Medical Center’s Historical and Projected Patient Origin

	HISTORICAL	PROJECT YEAR ONE	PROJECT YEAR TWO
COUNTY	FFY2013	FFY2015	FFY2016
Pitt	33.1%	33.1%	33.1%
Beaufort	5.9%	5.9%	5.9%
Lenoir	5.7%	5.7%	5.7%
Edgecombe	5.6%	5.6%	5.6%
Wayne	5.3%	5.3%	5.3%
Other Eastern NC Counties	41.1%	41.1%	41.1%
Outside Eastern NC	3.2%	3.2%	3.2%
Total	100.0%	100.0%	100.0%

The applicant states, “VMC (Vidant) assumes future patient origin will approximate current (FY13 actual patient origin.” The applicant adequately identifies the population it proposes to serve.

Demonstration of Need

The applicant states, in Section III.1, page 36, that it has experienced significant growth in GI endoscopy procedure volume over the past few years in 'traditional' GI endoscopy procedures at 3%, specialty GI endoscopy procedures at 27%, and in pediatric GI endoscopy procedures at 87%. The applicant projects its GI endoscopy procedures will increase by 12% overall from FY 2014 through FY 2017. The applicant states, on page 36, "*Inpatient, specialty, and pediatric GI endoscopy procedures take significantly longer to perform due to patient complexity, procedure complexity, and the need for deeper sedation and anesthesiology.*" According to the 2013 SMFP, Vidant had 5,020 endoscopy cases and performed 5,608 endoscopy procedures from October 1, 2010 to September 30, 2011. The performance standard for GI endoscopy services is 1,500 GI endoscopy procedures per GI endoscopy room. Therefore, Vidant GI endoscopy services were operating at 186% of capacity in FFY 2011 [(5,608 endoscopy procedures/2 endoscopy rooms)/1,500 = 1.86 or 186%]. In addition, the 2014 SMFP shows that Vidant's endoscopy procedures increased to 6,042 in FFY 2012 or more than double capacity.

The applicant states, in Section III, page 37, that in order to meet demand, Vidant would need to:

"further extend normal operating hours into the evenings and weekends to meet projected demand. The additional staff needed to support expanded operating hours significantly increases operational expenses. In addition, the operational challenges of managing split shifts and maintaining adequate support in other ancillary and support areas do not promote efficient facility operation."

Benefits of the development of two additional GI endoscopy procedure rooms, as stated by the applicant in Section III, pages 38-39, include: patient/physician satisfaction, patient placement, physician recruitment, increased education, research and clinical trial capacity, and quality improvement. Patients will benefit from not having late afternoon time slots that result in being discharged after dark or held overnight to accommodate recovery time, or having to fast for an extended time period. Physician satisfaction will be increased since office time will not be negatively impacted and they will have timely access to endoscopy procedure rooms. In addition, Vidant will be able to place the two proposed GI endoscopy procedure rooms in existing space "*that would be better suited from a clinical and quality perspective for specific/non-traditional GI endoscopy patients.*" One of the GI endoscopy procedure rooms, to be used for specialty GI endoscopy procedures, will be located in one of the hospital's two decommissioned operating rooms in its main operating suite. The room will be large enough to accommodate specialty GI equipment, and will be able to utilize existing portable fluoroscopy equipment and radiology staff. The proximity of the anesthesiology staff in the operative suite is also a benefit since the advanced anesthesiology and/or sedation needed for more complex, specialty GI endoscopy procedures will be supported. In

addition, the applicant states that the additional two proposed GI endoscopy procedure rooms will allow for growth and development of Vidant’s pediatric gastroenterology program and the expansion of the GI Fellowship program. Adequate capacity is needed to ensure provider access to these rooms. Furthermore, the additional GI endoscopy procedure rooms will provide adequate capacity for research, education and clinical trial space that Vidant needs as a tertiary, academic medical center. Lastly, the applicant states that the additional GI endoscopy procedure rooms will allow for new and innovative techniques in GI endoscopy procedures that will ultimately impact the quality of Vidant’s endoscopy services.

Utilization

The applicant provides Vidant’s historical utilization for GI endoscopy procedures for FFYs 2010 – 2013, its interim year of FFY 2014, and for the first three full fiscal years after project completion, FFYs 2015 – 2017, in Section IV, page 49, summarized below:

Vidant Medical Center’s Historical and Projected Endoscopy Procedures

	FFY 2010	FFY 2011	FFY 2012	FFY 2013	Interim Year FFY 2014	Project Year 1 FFY 2015	Project Year 2 FFY 2016	Project Year 3 FFY 2017
Pediatric GI endoscopy procedures	226	205	196	423	529	582	611	617
Specialty GI endoscopy procedures	472	508	642	602	632	664	697	732
Adult non- specialty GI endoscopy procedures	5,531	5,672	5,681	5,697	5,816	5,937	6,061	6,188
Total GI endoscopy procedures	6,229	6,385	6,519	6,722	6,976	7,182	7,369	7,536
# of GI rooms	2	2	2	2	2	4	4	4
Average procedures per GI room	3,115	3,193	3,260	3,361	3,488	1,796	1,842	1,884

The applicant provides its assumptions and methodology used to project utilization in Section III, page 36-38, and in Section IV, pages 48-49. In Section III, page 36, the applicant states, “*Inpatient, specialty and pediatric procedures take significantly longer to perform due to patient complexity, procedure complexity, and the need for deeper sedation and anesthesiology.*” The applicant, on page 37, presents Vidant’s historical GI endoscopy procedure capacity for FFY 2013 based on how much time there is available

each week to perform GI endoscopy procedures and how long, on average, each type of GI endoscopy procedure takes, as illustrated below:

Type of GI procedure	Hours per week	# of GI rooms	Maximum available procedure minutes/year	Average procedure time in minutes	FFY 2013 procedure volume	Total minutes	Percent capacity
Traditional Adult				45	5,697	256,365	
Specialty				120	602	72,240	
Pediatric				65	423	27,495	
TOTAL	52.5	2	315,000 [327,600]		6,722	356,100	113.0% [108.7%]

In Section III, page 36, the applicant further explains its methodology to project utilization as follows:

“Over the last four years, VMC (Vidant) has experienced a significant (8%) increase in GI endoscopy procedure volume in its two (2) existing licensed GI endo rooms (2.6% per year). While some of the growth can be attributable to the 3% growth in ‘traditional’ GI endoscopy procedures (mostly upper GIs and colonoscopy), most of the growth has come from the growth (27%) in more specialty GI endoscopy procedures (mostly ERCP and EUS) and the growth (87%) in pediatric GI endoscopy procedures (mostly due to the development of the Children’s Hospital and pediatric GI physician recruitment). In addition, VMC has also experienced a 4% increase in adult inpatient procedures. Future volume projection presented n [sic] Section IV of this application conservatively estimates VMC will experience a 12% increase in GI endoscopy procedures through FY 17.”

In addition, in Section IV, page 48, the applicant states, “VMC believes the projections are conservative based on 1) even with the significant projected growth in pediatric volumes, the overall growth rate is only slightly higher than historical experience (2.9% projected vs. 2.6% historical)” Appendix K contains information from Sg2, a healthcare intelligence firm, which forecasts an increase in GI endoscopy utilization over the next 10 years.

In summary, the applicant 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 Vidant. 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, page 45, the applicant describes two alternatives considered, as follows:

- 1) Maintain the Status Quo – the applicant concluded that maintaining the status quo was not a viable solution because it would not ensure sufficient access to GI endoscopy services, would not contain costs and increase efficiency, and would not improve patient, staff and physician satisfaction. As discussed in Section III, page 37, in order to meet demand Vidant would need to extend normal operating hours into evenings and weekends which would not only increase operational costs, but would also pose operational challenges and negatively affect both patient and physician satisfaction.
- 2) Develop a Freestanding Facility – the applicant stated that it considered building a separate, freestanding facility to house the two proposed GI endoscopy rooms, however it determined that this was not the least costly alternative. Ancillary and support services, and staffing would need to be duplicated and this would necessarily increase operational costs. Therefore, this was not the least costly or most effective alternative.

The applicant states in Section III, page 45, that its proposal to develop two GI endoscopy rooms is the least costly alternative to address Vidant’s needs. Not only would the demand for additional GI endoscopy capacity be met, but costs would be contained since no new construction would be needed, existing staff and ancillary and support services would be used, and patient and physician satisfaction would be improved. See Criterion (3) for discussion on the need for and effectiveness of the proposed project which is incorporated hereby as if set forth fully herein.

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

- 1. Pitt County Memorial Hospital, Inc. d/b/a Vidant 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, Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center shall material comply with the last made representation.

- 2. Pitt County Memorial Hospital, Inc. d/b/a Vidant 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 and that would otherwise require a certificate of need.**
 - 3. Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center shall develop no more than two gastrointestinal endoscopy rooms and shall be licensed for a total of no more than four gastrointestinal endoscopy rooms at Vidant Medical Center following project completion.**
 - 4. Pitt County Memorial Hospital, Inc. d/b/a Vidant 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.

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In Section VIII.3, page 74, the applicant projects the total capital cost for the project will be \$538,600, which includes \$446,600 for equipment purchases and \$92,000 for the purchase of an existing, unused GI endoscopy room at East Carolina Endoscopy Center (ECEC). A copy of the ECEC Board of Managers Meeting Minutes of October 8, 2013, indicating the approval of the purchase of ECEC's existing, unused GI endoscopy room, is included in Exhibit C. The applicant states, on page 73, that the "FMV" (fair market value) "of the ECEC endoscopy room was determined by an outside and independent valuation firm." On page 75, the applicant states the capital cost will be financed through Vidant's accumulated reserves. In Section IX, page 79, the applicant states there will be no start up or initial operating expenses since it is an existing facility.

Appendix S contains a letter, dated November 13, 2013, from the Chief Financial Officer of Vidant Health, confirming the availability of funding for the proposed project. The letter states, in part,

"VH and VMC will allocate \$538,600 in accumulated reserves to the development of two (2) new GI endoscopy rooms."

The applicant provides Vidant Health's most recent audited financial statements. As stated in the Independent Auditor's Report in Appendix T, page 2, Vidant Health is a health care delivery system which includes Vidant Medical Center as its "anchor", a teaching and

tertiary care hospital. As of September 30, 2012, Vidant Health had \$17,319,000 in cash and cash equivalents, \$434,431,000 in total net assets (total assets less total liabilities), and \$984,633,000 in total assets. The applicant projects Vidant's GI Endoscopy Services revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

Vidant GI Endoscopy Services	Project Year 1 FFY 2015	Project Year 2 FFY 2016	Project Year 3 FFY 2017
Projected # of Procedures	7,182	7,369	7,536
Projected Average Charge	\$2,569	\$2,646	\$2,725
Gross Patient Revenue	\$18,450,558	\$19,498,890	\$20,539,007
Deductions from Gross Patient Revenue	\$13,294,298	\$14,049,659	\$14,799,101
Net Patient Revenue	\$5,156,260	\$5,449,231	\$5,739,906
Total Expenses	\$4,190,227	\$4,880,112	\$5,604,565
Net Income	\$966,033	\$569,119	\$135,341

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 facility's projected average reimbursement for the ten most commonly performed GI endoscopy procedures for the first three project years, as provided on page 26 of the application and shown below:

CODE	PROCEDURE	FFY 2015	FFY 2016	FFY 2017
7500001	UGI endo dx w/ or w/o spec col	\$577	\$595	\$613
7500006	UGI endo w/bx single or multi	\$788	\$811	\$836
7500003	Colonoscopy	\$735	\$757	\$780
7500007	Colonoscopy w/bx single or multi	\$914	\$941	\$969
7500046	Esoph w/endo us fna/biopsy	\$1,038	\$1,069	\$1,101
7500017	UGI endo w/control of bleeding	\$605	\$623	\$642
7500021	ERCP w/sphincterotomy	\$955	\$983	\$1,013
7500010	Colonscpsy w/rem snare	\$978	\$1,007	\$1,037
7500022	ERCP w/stone removal	\$981	\$1,010	\$1,041
7500002	Sigmdscopy flx dx w/ or w/o spc	\$235	\$242	\$250

In Section II, page 26, the applicant states the services and supplies included in the charges are for the procedure and include anesthesiology. However, the charges do not include "billable medical supplies and other drugs (mostly IVs) or physician fees." The applicant provides the projected average facility charge per procedure for the ten most commonly performed GI endoscopy procedures on page 25. The assumptions used by the applicant in preparation of the pro formas, including projected utilization, are reasonable, credible and supported. See the pro formas 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 applicant adequately states 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.

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The applicant, Vidant Medical Center, operates the only acute care hospital in Pitt County. The hospital currently provides inpatient and outpatient GI endoscopy services in its two licensed GI endoscopy procedure rooms. In this application, the applicant proposes to develop two GI endoscopy rooms on the campus of Vidant Medical Center. There are six providers of GI endoscopy services in Pitt County and 22 in other eastern counties listed as being in the applicant's service area, as stated in Section III.9(a), page 46. The table below lists all of these providers, the number of licensed GI endoscopy rooms for each, and the number of GI procedures performed in each during FFY2012 as reported by the applicant on page 46. The table below also illustrates the FFY2012 utilization at all 28 facilities.

HOSPITAL BASED	COUNTY	# OF GI ROOMS	TOTAL # OF GI PROCEDURES PERFORMED	# OF GI PROCEDURES PER GI ROOM
Vidant Beaufort Hospital	Beaufort	1	1,869	1,869
Carteret General Hospital	Carteret	2	1,199	600
CarolinaEast Medical Center	Craven	2	2,188	1,094
Vidant Edgecombe Hospital	Edgecombe	2	172	86
Halifax Regional Medical Center	Halifax	1	1,306	1,306
Lenoir Memorial Hospital	Lenoir	2	2,092	1,046
Martin General Hospital	Martin	1	366	366
Nash General Hospital	Nash	4	5,555	1,389
Onslow Memorial Hospital	Onslow	3	3,675	1,225
Vidant Medical Center	Pitt	2	6,042	3,021
Wayne Memorial Hospital	Wayne	2	3,242	1,621
Wilson Medical Center	Wilson	5	3,430	686
Subtotal		27	31,136	
# of Procedures/ 1,500	24.3			
# of Procedures/ # of Rooms	1,153.2			
% of Regulatory Performance Std.	76.9%			
FREESTANDING, NON-HOSPITAL BASED				
CCHC Endoscopy Center	Craven	3	5,799	1,933
The Surgical Center of Morehead City	Carteret	1	1,596	1,596
CarolinaEast Internal Medicine	Craven	3	3,770	1,257
Vidant Endoscopy Center	Edgecombe	1	826	826
Kinston Medical Specialists	Lenoir	2	1,885	943
Park Endoscopy	Lenoir	2	1,941	971

Center				
Boice-Willis Clinic Endoscopy Center	Nash	2	3,593	1,797
East Carolina Gastroenterology Endoscopy Center	Onslow	1	2,517	2,517
Atlantic Gastroenterology Endoscopy Center	Pitt	2	3,567	1,784
Carolina Digestive Diseases	Pitt	2	3,951	1,976
East Carolina Endoscopy Center	Pitt	3	1,980	660
Gastroenterology East	Pitt	3	4,268	1,423
Quadrangle Endoscopy Center	Pitt	6	6,212	1,035
Goldsboro Endoscopy Center	Wayne	4	3,468	867
CGS Endoscopy Center	Wilson	2	1,478	739
Wilson Digestive Diseases Center	Wilson	2	4,062	2,031
Subtotal		39	50,913	
# of Procedures / 1,500	33.9			
# of Procedures / # of Rooms	1,305.5			
% of Regulatory Performance Std.	87.0%			
TOTALS				
# of GI Endoscopy Rooms/ Procedures		66	82,049	
# of Procedures / 1,500	54.7			
# of Procedures / # of Rooms	1,243.2			
% of Regulatory Performance Std.	82.9%			

As illustrated in the above table, nine other GI endoscopy facilities in Vidant's service area have exceeded 1,500 procedures per GI endoscopy room in FFY 2012. In addition, two of the five GI endoscopy facilities in Pitt County, Vidant's primary service area, have also exceeded 1,500 GI endoscopy procedures per GI endoscopy room in FFY 2012. Moreover, one of the five is nearing the performance standard of 1,500 procedures per GI endoscopy room at 1,423 procedures. These three facilities are freestanding GI endoscopy facilities. However, Vidant has projected a need for two additional GI endoscopy rooms to perform specialty GI endoscopy procedures and pediatric GI endoscopy procedures, each of which

typically take more time to perform than traditional GI endoscopy procedures and will be performed in an inpatient setting. In addition, based on the minimum performance standard promulgated in 10A NCAC 14C .3903(b), the facility is currently operating at 3,021 procedures per room, well above the standard of 1,500 procedures, per room, as required by this rule.

In summary, the applicant adequately demonstrates 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 discussion regarding the need to add two GI endoscopy rooms to Vidant. 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 Sections VII.1, 2, and 3, pages 66-68, and in supplemental information, the applicant provides the current and proposed staffing for its GI endoscopy services for the second full fiscal year. The applicant states in supplemental information, *“The additional staff identified in Question VII.3(a) represents the additional staff needed for 1 new endo room. Therefore the staffing tables reflect the needed staff for 2 new endo rooms.”* Vidant currently employs 23.2 full-time equivalent (FTE) employees to staff its GI endoscopy services. An additional 14.2 FTEs will be needed for the two new GI endoscopy rooms. Vidant’s current and projected staffing for its proposed GI endoscopy services are illustrated in the table below:

**Vidant GI Endoscopy Services
 Current and Proposed Staffing**

	FFY 2013 FTEs	FTEs TO BE ADDED	FFY 2016 FTEs
Manager	1.0	0	1.0
Assistant Manager	1.0	0	1.0
Secretary	0.9	0.2	1.1
Registered Nurses	14.3	8.0	22.3
GI Technician	5.0	4.0	9.0
GI Assistant	1.0	2.0	3.0
Totals	23.2	14.2	37.4

In Section VII.9(a), page 72, the applicant states that Dr. Hossan Kandil currently serves as the Medical Director of Vidant’s GI endoscopy program. The applicant states he will continue to provide medical oversight for the program following the completion of the proposed project. Dr. Kandil’s curriculum vitae is provided in Appendix O and an update is provided in supplemental information from Dr. Kandil, dated January 29, 2014. In addition, in Section VII.9(a), page 72, the applicant states that Vidant’s Director of Pediatric Services,

Dr. Ronald Perkin, will provide medical oversight for the proposed dedicated pediatric endoscopy room. The applicant provides a copy of his curriculum vitae in Appendix O.

In Section VII.7(a), pages 70-71, the applicant describes the strategies it employs to recruit and retain new employees and states, *“These strategies have proven to be highly successful...VMC does not anticipate any issues hiring the employees needed to staff the proposed project.”*

The applicant adequately documents the availability of sufficient health manpower and management personnel to staff the proposed two new GI endoscopy rooms at Vidant. 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

Vidant is an existing hospital and provider of GI endoscopy services. Therefore, it currently provides all of the ancillary and support services necessary to provide these services. In Section II.2(a), page 13, it provides a list of ancillary and support services, including, but not limited to, the following:

- *“Operative services (pre/post-op and operating room services)*
- *Anesthesiology services*
- *Pathology services*
- *Pharmacy services*
- *Inpatient care services*
- *Respiratory therapy services*
- *Emergency services*
- *Radiology services (MRI, X-ray, CT, NucMed, ultrasound, etc.)*
- *Other diagnostic services (EKG, ECHO, etc.)”*

Furthermore, the applicant states that it will continue to provide all of these services and support functions to all of its patients. Appendix D contains a copy of Vidant’s written policies and procedures for patient referral, transfer, follow-up, and blood transfusion policies.

In Sections V.2-V.6, pages 53–57, the applicant describes how Vidant’s health care services are coordinated with the existing health care system through transfer agreements with all acute care hospitals in the region, military hospitals, and nursing homes. Appendix M contains a listing of facilities Vidant has transfer agreements with. Vidant has many relationships with academic and private physicians throughout the region and receives many patient referrals from physicians in outlying offices, clinics and hospitals. In addition, it has maintained relationships with local and regional providers including the Department of

Social Services and the Department of Health, and seeks to build mutual support with regional hospitals. Moreover, the applicant provides letters of support from physicians in Appendix N.

The applicant adequately demonstrates the availability of the necessary ancillary and support services and that the proposed services will 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 applicant proposes to develop two GI endoscopy rooms at Vidant. One of the rooms will be located in a decommissioned operating room in the hospital's main operating suite. The other will be located in an existing pediatric bronchoscopy room in the Children's Hospital. No new construction or renovation will be required to make the GI endoscopy rooms operational. In Section VIII, page 74, the applicant projects the total capital cost for the two

GI endoscopy rooms will be \$538,600, of which \$446,600 will be used to purchase equipment and \$92,000 will be used to purchase the GI endoscopy room from Moye Medical Endoscopy Center, LLC d/b/a East Carolina Endoscopy Center. 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 Sections VI.12 and VI.13, page 64, the applicant provides the payer mix during the last full fiscal year, FFY 2013 (10/1/2012-09/30/2013), for the entire hospital and for its GI endoscopy services, illustrated in the table below:

Payer Mix FFY 2013
Current Patient Days / Procedures as a Percent of Total Utilization

Payer	Entire Hospital	GI Endoscopy Procedures Only
Commercial Insurance	1.3%	23.9%*
Medicaid	27.7%	13.9%
Medicare / Medicare Managed Care	45.3%	51.0%
Managed Care	16.7%	
Self Pay/ Indigent/Charity	4.2%	8.3%
Other (CHAMPUS/ Workman's Comp)	4.8%	2.9%
Total	100.0%	100.0%

*Inclusive of Commercial Insurance and Managed Care as stated in supplemental information

In Section VI.2, page 59, the applicant states:

“Part A.1. of VMC’s Policy on Patient Rights expressly states, ‘Persons seeking health care at the hospital have a right to treatments that are available and medically indicated, regardless of race, color, creed, age, sex, national origin, religion, disability status, sexual preference, or sources of payment for care.’ All inpatient and outpatient services are, and would continue to be, provided in accordance with this policy.”

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 Pitt County and statewide.

	Total # of Medicaid Eligibles as % of Total Population	Total # of Medicaid Eligibles Less than Age 21 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)
Pitt County	16.3%	10.9%	6.7%	21.3%
Statewide	16.5%	11.3%	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. A portion of Vidant's GI endoscopy services patients are children, however those under the age of 21 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 payer 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 Vidant. 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

In Section VI.11, page 63, the applicant states it has provided its required amount of uncompensated care in regard to the Hill-Burton regulations. However, it states it provides access to care for all those in need and further states on page 63, *“In fact, over the last five fiscal years, VMC has provided almost \$410.3 million in charity care services.”*

In Section VI.10(a), page 97, the applicant states that there have been no civil rights equal access complaints received against Vidant or any facilities or services owned by its parent company in the state within 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, page 65, the applicant provides the projected payer mix for the second full fiscal year (FFY 2016) of operations for GI endoscopy procedures, as illustrated in the table below.

SECOND FULL PROJECT FISCAL YEAR (FFY 2016) PROJECTED GI ENDOSCOPY PROCEDURES	
Payer	Percent of Total GI Endoscopy Procedures
Self Pay/Charity	8.3%
Medicare	51.0%
Medicaid	13.9%
Commercial Insurance	23.9%
Other	2.9%
Total	100.0%

In Section VI.6, page 61, the applicant states, *“It is VMC’s position to treat all patients regardless of their ability to pay. Thus, endoscopy patients will not be limited in access to the services because of an inability to pay.”* The applicant provides a copy of Vidant’s credit collection policies in Appendix P. Additionally, the applicant states on page 61 that Vidant provided over \$100 million or 9.7% of its Net Revenue in charity care in FFY2012.

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Therefore, 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

In Sections VI.5, page 61, and VI.9(a), page 62, the applicant states that patients are referred to Vidant's GI endoscopy services by physicians practicing at the hospital who diagnose and deem them appropriate for endoscopy procedures. In addition, in Section VI.9(b), page 62, the applicant states that local and regional physician practices refer patients to the facility, and that the health department refers indigent patients. These patients are referred to physicians who perform the GI endoscopy procedures at Vidant. Letters of support from physicians are included in Appendix N.

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

- (14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Section V.1(a), page 51, the applicant states that since Vidant is a leading training facility for medical, nursing and allied health students in eastern NC, it maintains many agreements with educational institutions, including, but not limited to, Brody School of Medicine at East Carolina University, East Carolina University School of Nursing, Pitt Community College, Barton College of Nursing, and East Carolina University School of Social Work. A list of training programs that Vidant currently has contracts with is provided in Appendix L.

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 applicant currently provides GI endoscopy services to patients in its proposed service area. In Section V.7, pages 57-58, the applicant discusses how the proposed project will foster competition by promoting cost effectiveness, quality, and access to services in the proposed service area. It will do this by “*promoting high quality, delivering cost effective services, and providing enhanced access to GI endoscopy services.*” 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 applicant adequately demonstrates 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 applicant adequately demonstrates the need to add two GI endoscopy rooms to Vidant. 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 applicant adequately demonstrates 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 applicant adequately demonstrates the cost effectiveness of its proposal.
- 2) The applicant adequately documents that it has and will continue to provide quality care. As stated in Section V, page 57, the proposed two new, licensed GI endoscopy rooms will be integrated into Vidant’s comprehensive quality assurance program that ensures a high standard of care. See also Sections II, pages 15-18, III, pages 39-40, and Appendix E of the application.
- 3) 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 II, page 15, and 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.

Therefore, 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

Vidant is accredited by The Joint Commission and certified for Medicare and Medicaid participation. According to the files in the Acute and Home Care Licensure and Certification Section, 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 Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center 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 Section III.6, page 43, the applicant identifies its proposed primary service area as Pitt County, consisting of 33.1% of its patient origin. Other counties included in its service area include: Beaufort, Lenoir, Edgecombe, Wayne, Wilson, Martin, Onslow, Craven, Bertie, Halifax, Nash, Greene, Carteret, Duplin, Hertford, Washington, Chowan and Northampton. These counties are projected to make up 60.2% of its service area, while all other eastern North Carolina counties and counties outside eastern North Carolina are projected to make up 6.8% of its patient origin.

.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, page 20, the applicant states that it currently has two licensed GI endoscopy rooms and in this application proposes to develop two additional licensed GI endoscopy rooms.

(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.

- C- The applicant states, in Section II, page 21, that it has a 50% membership interest in Moye Medical Endoscopy Center, LLC d/b/a East Carolina Endoscopy Center (ECEC). ECEC has three licensed GI endoscopy rooms.

(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 supplemental information, the applicant provides the number of GI endoscopy procedures performed in the last 12 months, FFY 2013, identified by ICD-9 PX code, in the applicant's existing two GI endoscopy rooms. The applicant performed 105 distinct types of GI endoscopy procedures.

(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 supplemental information, the applicant provides the number of GI endoscopy procedures, identified by ICD-9 PX code, projected to be performed in each of the first three operating years of the project.

(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, page 22, the applicant states it does not currently perform non-GI endoscopy procedures in its licensed GI endoscopy rooms.

(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, page 22, the applicant states that pediatric bronchoscopy procedures will continue to be performed in the room that it proposes to become one of the two new licensed GI endoscopy rooms, to be located in Vidant's Children's Hospital. The table below identifies the number of

pediatric bronchoscopy procedures projected to be performed in this room in each of the first three operating years of the project:

Procedure	FY2015	FY2016	FY2017
Pediatric Bronchoscopy	179	183	190

(G) the number of patients served in the licensed or non-licensed GI endoscopy rooms in the last 12 months.

- C- In Section II, page 23, the applicant states that 4,815 patients were served at Vidant in its two licensed GI endoscopy rooms in the last 12 months, FFY 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, page 23, the applicant projects to serve 5,130 patients in Operating Year 1, 5,263 patients in Operating Year 2, and 5,383 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, page 23, the applicant states that Vidant has the following existing or approved ORs: 3 dedicated IP ORs, 26 shared ORs, and 4 dedicated C-Section ORs for a total of 33 operating rooms.

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

- C- In Section II, page 24, the applicant provides the number of procedures by type performed in Vidant's operating rooms in the last 12 months. The applicant reports a total of 21,682 procedures were performed in FFY 2013 in its 33 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, page 24, the applicant provides the projected number of procedures by type to be performed in Vidant's operating rooms in each of the first three operating years of the project.

.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, page 25, the applicant states it provides inpatient and outpatient GI endoscopy care to patients during the hours of 6:30am to 5:00pm, Monday-Friday. In addition, the applicant states that Vidant “accommodates emergency, unscheduled, and after hours patients 24/7 through the use of on-call staffing.”

.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, page 25, the applicant provides its average facility charge for each of the 10 most commonly performed GI endoscopy procedures in the facility during the last 12 months, FFY 2013, as illustrated in the table below:

Description	Average Charge
UGI endo dx w/ or w/o spec col	\$1,717
UGI endo w/bx single or multi	\$2,342
Colonoscopy	\$2,186
Colonoscopy w/bx single or multi	\$2,717
Esoph w/endo us fna/biopsy	\$3,086
UGI endo w/control of bleeding	\$1,798
ERCP w/sphincterotomy	\$2,839
Colonscpy w/rem snare	\$2,907
ERCP w/stone removal	\$2,917
Sigmdscopy flx dx w/ or w/o spc	\$700

.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, page 25, the applicant provides the type and average facility charges it projects during the first three operating years for the ten procedures projected to be performed most often at Vidant. Vidant 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, page 26, the applicant states, *“The average charges listed above are just for the procedure (including necessary anesthesiology or sedation). Nothing else is included in these charges.”*

.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, page 26, the applicant describes which services will not be included in the facility’s charges. Those services include: billable medical supplies and other drugs (mostly IVs) or physician fees.

.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, page 26, the applicant provides the average reimbursement received for each of the 10 most commonly performed procedures during the preceding 12 months, FFY 2013, as illustrated below:

Description	Average Reimbursement
UGI endo dx w/ or w/o spec col	\$544
UGI endo w/bx single or multi	\$742
Colonoscopy	\$693
Colonoscopy w/bx single or multi	\$861
Esoph w/endo us fna/biopsy	\$978
UGI endo w/control of bleeding	\$570
ERCP w/sphincterotomy	\$900
Colonscpy w/rem snare	\$922
ERCP w/stone removal	\$925
Sigmdscopy flx dx w/ or w/o spc	\$222

.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, page 27, the applicant provides 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 applicant is an existing provider 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 applicant is an existing provider 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 applicant is an existing provider of GI endoscopy services.

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

-NA- The applicant is an existing provider 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 applicant is an existing provider 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 applicant is an existing provider 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, page 28, the applicant states that Vidant provides endoscopies Monday – Friday, excluding holidays, and after hours 24/7 to accommodate emergency or unscheduled patients.

.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 IV, page 49, the applicant projects to perform 7,369 GI endoscopy procedures during Operating Year 2, FFY 2016, which is an average of 1,842 procedures per room (7,369 procedures / 4 procedure rooms = 1,842.3 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 IV, page 49, the applicant indicates it will provide upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures at Vidant.

.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*

(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 it performs all of its GI endoscopy procedures in Vidant's existing, licensed GI endoscopy rooms.

.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 Sections III, page 36, and IV, pages 48-49, the applicant provides 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- The applicant states, in Section II, page 29, it has a laboratory department at Vidant that provides pathology services and is available for all services Vidant provides, including GI endoscopy 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- Appendix F contains a copy of the GI endoscopy policies and procedures regarding sedation and anesthesiology.

.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- Appendix G contains a copy of Vidant'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.

-NA- The proposed facility for the GI endoscopy rooms is the same as the hospital, Vidant Medical Center.

(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 two new licensed GI endoscopy rooms will be located at Vidant, which is a tertiary hospital.

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

-NA- The proposed two new licensed GI endoscopy rooms will be located at Vidant, 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 VII.6, page 70, the applicant provides a table identifying the number of staff FTE's to be utilized in each of the areas as follows: 3.00 FTEs for administration; and 34.3 FTEs assigned to the GI lab which includes pre-operative, post-operative, and operating rooms. In addition, in supplemental information, the applicant states, *“Pre-operative, post-operative, equipment cleaning, safety, and maintenance services are provided by other departments of the hospital that support more than just GI services. It is not possible to split out and allocate a percentage of this staff solely to the GI lab. The services are already in place, are fully staffed, and are able to support the addition of 2 new GI labs without the need to hire more FTEs.”*
- .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 supplemental information, the applicant provides a listing of 50 physicians by specialty and board certification status who currently use the GI endoscopy service at the facility and who are projected to continue using the facility.
- .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 Appendix I for a copy of the criteria Vidant uses in extending privileges to medical staff who 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- Vidant 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- Vidant is accredited by The Joint Commission.