ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

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

Decision Date: March 16, 2016
Findings Date: March 16, 2016

Project Analyst: Tanya S. Rupp
Team Leader: Fatimah Wilson

Project ID #: Q-11115-15
Facility: Vidant Medical Center
FID #: 933410
County: Pitt
Applicant(s): Pitt County Memorial Hospital, Inc.
Project: Acquire and relocate one existing GI endoscopy procedure room from East Carolina Endoscopy Center to the main OR suite in the hospital for performance of complex GI procedures

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Agency 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 (VMC) proposes to acquire and relocate one existing gastrointestinal (GI) endoscopy procedure room from Moye Medical Endoscopy Center, LLC d/b/a East Carolina Endoscopy Center (ECEC) to a decommissioned operating room in the main operating room (OR) suite on the VMC campus, and to dedicate the relocated GI endoscopy room to performing complex GI endoscopy procedures. Upon project completion, VMC will be licensed for five GI endoscopy procedure rooms at the main hospital campus, and ECEC will be licensed for one GI endoscopy room.

Need Determination

The proposed project does not involve the addition of any new health service facility beds, services, or equipment for which there is a need determination in the 2015 State Medical Facilities Plan (2015 SMFP).

Policies

In addition, there are no policies in the 2015 SMFP that are applicable to this review.

Conclusion

In summary, there are no need determinations or policies in the 2015 SMFP that are applicable to this review. Therefore, this criterion is not applicable.

(2) Repealed effective July 1, 1987.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 applicant proposes to acquire and relocate one existing GI procedure room from ECEC to a decommissioned operating room in the main OR suite on the VMC campus, and to dedicate the relocated GI endoscopy room to performing complex GI endoscopy procedures. Upon project completion, VMC will be licensed for five GI endoscopy procedure rooms at the main hospital campus and ECEC will be licensed for one GI endoscopy room.

In Section III.1, page 22, the applicant states that VMC owns 100% membership interest in ECEC. ECES is currently licensed for two GI endoscopy rooms. In Section III.1, page 22, the applicant also states the two GI endoscopy rooms at ECEC are currently underutilized; therefore, the applicant proposes to relocate one of the rooms to existing space in the main OR suite in the hospital.

Population to be Served

The 2015 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. In Section III.5, page 29, the applicant defines its primary service area as Pitt and Greene counties, and its secondary service area as *"any other county that represents 2.0% or greater of VMC's patient origin."* Facilities may also serve residents of counties not included in their service area.

In Sections III.6 and III.7, pages 29 - 30, the applicant provides both current and projected patient origin for GI endoscopy services at VMC, as illustrated in the following table:

COUNTY	HISTORICAL PATIENT ORIGIN, FY 2015		PROJECTED PATIENT ORIGIN, FY 2019	
	# Patients	% of Total	# Patients	% of Total
Pitt	1,812	33.0%	2,014	33.0%
Greene	173	3.1%	192	3.1%
Beaufort	348	6.3%	387	6.3%
Edgecombe	282	5.1%	313	5.1%
Lenoir	272	4.9%	302	4.9%
Onslow	230	4.2%	256	4.2%
Wayne	220	4.0%	244	4.0%
Martin	219	4.0%	243	4.0%
Craven	218	4.0%	242	4.0%
Wilson	217	3.9%	241	3.9%
Nash	191	3.5%	212	3.5%
Halifax	153	2.8%	170	2.8%
Bertie	152	2.8%	169	2.8%
Carteret	133	2.4%	148	2.4%
Washington	120	2.2%	133	2.2%
Hertford	112	2.0%	124	2.0%
Other*	645	11.0%	717	11.0%
Total	**5,497**	**100.0%**	**6,109**	**100.0%**

Totals may not foot due to rounding.
*Other includes any other county in North Carolina that represents 2% or greater of VMC's patient volume. In Appendix F the applicant includes a detailed map depicting patient origin.

On page 29, the applicant states future patient origin will approximate current actual patient origin. The applicant adequately identifies the population proposed to be served.

Analysis of Need

In Section II.1, pages 9 – 10 and Section III.1, pages 20 – 21, the applicant states that in 2014 it developed a dedicated endoscopic retrograde cholangiopancreatography (ECRP) / endoscopic ultrasound (EUS) endoscopy procedure room and a dedicated pediatric GI endoscopy procedure room at VMC. The applicant states ECRP and EUS are complex procedures which take two to three times longer than a routine GI endoscopy procedure due to patient comorbidities, complication risks, procedure complexity, deeper sedation and equipment needs. Prior to the development of the two dedicated GI endoscopy procedure rooms at VCM, the applicant performed these procedures in operating rooms as surgical procedures, which was more costly to the patients. The time the procedures took, according to the applicant, limited the number of procedures VMC could perform. The applicant extended operating hours into evenings and weekends to accommodate patient demand but the extended hours adversely affected both staff and patients.

In Section III, page 20, the applicant states that since the development of the two dedicated GI endoscopy procedure rooms at VMC, the volume of ECRP and EUS procedures performed has

more than doubled from 969 procedures in FY 2013 to 1,945 procedures in FY 2015. In Section III.1, page 20, the applicant projects that the four existing GI endoscopy procedure rooms at VMC will operate at 100% capacity in FY 2016, prior to the relocation of one room from ECEC. It is unfeasible, according to the applicant, to maintain 100% capacity without sacrificing quality of services to patients and jeopardizing staff morale.

In addition, the existing GI endoscopy procedure rooms at ECEC are currently underutilized, according to the applicant on page 22. The applicant states that ECEC's current volume of 1,800 procedures per year in FY 2015 is insufficient to support two GI endoscopy procedure rooms and in fact, one room is not utilized. The applicant states that it is therefore reasonable to relocate one room to the hospital where it will not only be adequately utilized, but will ease existing complex GI endoscopy procedure capacity constraints at the hospital.

In Section III.1, pages 20 – 24, the applicant states the following factors support the need to relocate the existing GI endoscopy procedure room from ECEC to VMC:

- Patient/physician satisfaction
- Patient placement
- Physician recruitment
- Increased education, research and clinical trial capacity
- Improve quality

Patient/physician satisfaction

In Section III.1, page 23, the applicant states existing capacity constraints negatively impacts both physicians and patients. Longer procedure times often result in patients staying until after dark or sometimes overnight, which results in additional cost. An additional GI endoscopy procedure room dedicated to the longer procedures will address patient and physician demands without extending normal operating hours or requiring patients to stay overnight.

Patient Placement

In Section III.1, page 23, the applicant states it will develop the relocated GI endoscopy procedure room in a decommissioned operating room currently located in the operative suite in the hospital. Since the applicant proposes to dedicate the GI endoscopy procedure room to more complex procedures involving higher risk patients, it is optimal to relocate the proposed room to the operative suite where existing equipment, staff, and services are already in place. The types of procedures typically performed require heavier sedation and the anesthesiology staff will also be located within the suite. As a result, quality and outcomes for patients will be positively impacted.

Physician Recruitment

In Section III.1, page 24, the applicant states the existing GI program at VMC began as a fellowship program years ago and the program continues to successfully recruit new gastroenterologists. The applicant states VMC has one gastroenterologist on staff who is trained

to perform ERCP and EUS procedures, and it is recruiting another specialist. The applicant further states that volume and capacity constraints limit the future development of the fellowship program and thus inhibit the program's ability to attract and recruit additional gastroenterologists. The addition of the GI endoscopy procedure room as proposed in this application will allow for program development and physician recruitment.

Increased Research, Education and Clinical Trials Capacity

In Section III.1, page 24, the applicant states that as a tertiary academic medical center, VMC is dedicated to clinical research and clinical trials and training. The addition of a GI endoscopy procedure room dedicated to ERCP and EUS procedures will ensure adequate capacity to *"meet and expand the need to support education, research and clinical trial initiatives."*

Improved Quality

In Section III.1, page 24, the applicant states it has a comprehensive quality assurance program currently in place that provides a structure for quickly implementing new standards of quality and care. Furthermore, the applicant states the additional GI endoscopy capacity at VMC as proposed in this application will inevitably have a positive effect on the quality of services provided, because *"the combination of a strong, comprehensive quality program and additional capacity allows VMC to safely implement new and innovative techniques that will ultimately improve upon the quality of endoscopy services."*

Projected Utilization

In Section IV.1, pages 33 – 35, the applicant provides historical utilization of the four existing GI endoscopy procedure rooms at VMC, and projects utilization following the relocation of the GI endoscopy procedure room. The applicant's assumptions, on pages 33 – 34, are:

- For purposes of projecting utilization and capacity, the applicant distinguishes between routine and complex GI endoscopy procedures based on the time it takes to perform each procedure.
- Complex procedures such as ERCP and EUS are projected based on 150 minutes per procedure; and routine procedures are based on 45 minutes per procedure.
- In FY 2012, the applicant began to perform routine GI endoscopy procedures in the outpatient setting of ECEC rather than the hospital where costs to the patient are higher.
- In FY 2014 a certificate of need was awarded (Project Q-10226-13) to convert a decommissioned operating room to a dedicated ERCP/EUS GI endoscopy procedure room at VMC. As a result, the volume of complex GI endoscopy procedures performed at VMC has more than doubled.
- The applicant assumes that the relocated GI endoscopy procedure room proposed in this application will also replace a decommissioned operating room at VMC and will also be dedicated to performing complex GI endoscopy procedures.
- Since the applicant proposes to perform complex GI endoscopy procedures in the room to be relocated, it assumes utilization at VMC will initially increase *"as pent up demand is met,"* but thereafter will grow at a rate closer to projected population growth in

eastern North Carolina, which the applicant states is approximately 1%. The applicant likewise projects a 1% per year decline in routine GI endoscopy procedures at VMC through FY 2020.

- The applicant calculates percent of capacity based on total procedure minutes (45 minutes for routine procedures and 150 minutes for complex procedures) and total minutes available (52.5 operating hours per week x 60 minutes per hour x 50 weeks per year x the number of GI endoscopy procedure rooms available).

The following table illustrates historical and projected utilization of the GI endoscopy procedure rooms at VMC through the third project year, FY 2020:

Procedure Type	Historical			Projected				
	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
Routine								
Number of Procedures	6,007	5,940	5,919	5,860	5,801	5,743	5,686	5,629
Minutes/Procedure	45	45	45	45	45	45	45	45
Total Procedure Minutes	270,315	267,300	266,355	263,700	261,045	258,435	255,870	253,305
Complex								
Number of Procedures	969	1,433	1,945	2,431	2,796	2,936	3,053	3,145
Minutes/Procedure	150	150	150	150	150	150	150	150
Total Procedure Minutes	145,350	214,950	291,750	364,650	419,400	440,400	457,950	471,750
Total Facility								
Number of Procedures	6,976	7,373	7,864	8,291	8,597	8,679	8,739	8,774
Total Procedure Minutes	415,665	482,250	558,105	628,379	680,445	698,804	713,834	725,015
Total Available Minutes*	315,000	630,000	630,000	630,000	787,500	787,500	787,500	787,500
Number of Rooms	2	4	4	4	5	5	5	5
% Capacity	132%	76.5%	88.6%	99.7%	86.4%	88.7%	90.6%	92.1%

*Total available minutes explained in assumptions (52.2 hours per week x 60 minutes per hour x 50 weeks per year = 157,500; x number of GI rooms)

In Section XII, page 80, the applicant projects operation and certification of the 5th GI endoscopy procedure room to be in January 2017; therefore, the first year of operation will be FY 2018. The applicant adequately demonstrates that it will perform between 88% and 92% of its own defined capacity, based on the number of routine and complex GI endoscopy procedures it projects to perform in each of the project years following the relocation of the GI endoscopy procedure room from ECEC to VMC.

Furthermore, the applicant adequately demonstrates that it will perform 8,739 total GI endoscopy procedures in five GI endoscopy rooms in the second operating year, FY 2019, which is an average of 1,747 procedures per room [8,739 procedures / 5 rooms = 1,747 procedures per room]. Thus, the applicant reasonably demonstrates that it will perform at least 1,500 GI endoscopy procedures per room in the second year of operation as required by G.S. 131E-182(a) and 10A NCAC 14C .3903(b).

Access

In Section VI.2, pages 44, the applicant states:

"VMC has traditionally provided services to a variety of patient populations. In FY 15, the distribution of patients treated at VMC receiving endoscopy services was as follows:

	MEDICALLY UNDERSERVED	*SENIORS*	*WOMEN*	*MINORITY*
GI Endoscopy	*21.0%*	*43.2%*	*54.6%*	*42.0%*

…

VMC, as it has in the past, would continue to provide services to all patients, from all races, regardless of sex, age, handicapped status, socioeconomic status, or ability to pay for services."

In Section VI.13, page 49, the applicant states that Medicare comprised 47.6% of VMC's historical payor mix and Medicaid comprised 13.9% of its historical payor mix for GI endoscopy services in FY 2015. In Section VI.14, page 50, the applicant projects the same payor mix for GI endoscopy services in FY 2019. In Section III.6, page 29, the applicant states projected payor mix is based on historical utilization at VMC.

The applicant describes its charity and financial payment policies on pages 45 - 47. The applicant projects, in Section VI.8, page 47, that VMC will provide $283,480 (3.7% of net revenue) in charity care to GI endoscopy patients in its second year of operation.

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

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

C

The applicant proposes to acquire and relocate one existing GI endoscopy procedure room from ECEC to a decommissioned operating room in the main OR suite on the VMC campus, and to dedicate the relocated room to performing complex GI endoscopy procedures in the main OR suite. Upon project completion, VMC will be licensed for five GI endoscopy procedure rooms at the main hospital campus, two of which will be dedicated to performing ERCP and EUS procedures; and ECEC will be licensed for one GI endoscopy room.

In Section III.1, page 22, the applicant states that VMC owns 100% membership interest in ECEC, which is currently licensed for two GI endoscopy rooms. In Section III.1, page 22, the

applicant states one of the existing GI endoscopy rooms at ECEC is not utilized at all; therefore, the applicant proposes to relocate one room to existing space in the OR suite in the hospital. The relocated GI endoscopy procedure room would ease capacity constraints at VMC and allow the remaining GI endoscopy procedure room at ECEC to continue to be utilized for routine GI endoscopy procedures. The total number of GI endoscopy procedure rooms in the county would not change as a result of this proposal.

Table 6F: Endoscopy Room Inventory on page 99 in the 2016 SMFP consists of data submitted by facilities on their 2015 License Renewal Applications (LRAs). According to that table, ECEC performed a total of 2,228 total procedures in FY 2014. In Section III.1, page 20, the applicant states that the utilization of the two rooms decreased in FY 2015 to 1,800 total procedures since the complex GI endoscopy procedures shifted to the hospital. The *Performance Standards* in 10A NCAC 14C .3903(b) requires an applicant to reasonably project to perform an average of *"at least 1,500 GI endoscopy procedures only per GI endoscopy room, in each licensed facility that the applicant or a related entity owns in the propose service area, during the second year of operation following completion of the proposed project."* Although the Administrative Rules do not apply to this review, the performance standards are a guide for minimum utilization. In FY 2014, the applicant performed 2,228 GI endoscopy procedures in two rooms at ECEC, which is a utilization of 74% [2,228 / 2 rooms = 1,114 procedures per room; 1,114 / 1,500 = 0.743]. In FY 2015, the applicant performed 1,800 GI endoscopy procedures in two rooms at ECEC, which is a utilization of 60% [1,800 / 2 rooms = 900 procedures per room. 900 / 1,500 = 0.60].

On page 34, the applicant assumes 45 minutes per routine GI endoscopy procedure. The applicant further assumes total procedure minutes available are 52.5 hours per week x 60 minutes per hour x 50 weeks per year x the number of GI endoscopy rooms, which is 157,500 procedure minutes per room [52.5 x 60 = 3,150; 3,150 x 50 = 157,500 procedure minutes per room]. In FY 2014, there was a total of 2,228 routine GI endoscopy procedures performed in two rooms at ECEC, which is 1,114 procedures per room, or 32% of capacity [1,114 procedures x 45 minutes per procedure = 50,130; 50,130 / 157,500 = 0.318]. Similarly, in FY 2015, there was a total of 1,800 routine GI endoscopy procedures performed in two rooms, which is 900 procedures per room, or 26% of capacity [900 procedures x 45 minutes per procedure = 40,500; 40,500 / 157,500 = 0.257]. Therefore, the one GI endoscopy procedure room that will remain at ECEC will continue to adequately serve the patients needing routine GI endoscopy procedures.

In summary, the applicant adequately demonstrates that the needs of the population presently served at ECEC will continue to be adequately met following the relocation of one of the existing GI endoscopy procedure rooms to VMC. Therefore, the application is conforming to this criterion.

(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 30 – 31, the applicant discusses the alternatives considered prior to submitting this application, which include:

- Maintain the Status Quo - the applicant states that this option ignores the need for the additional GI endoscopy procedure room at VMC, since the utilization has been in excess of its stated capacity for two years. In addition, the applicant states maintaining the status quo would not allow VMC to ensure sufficient access to meet demand for services, and would inhibit the hospital's ability to improve patient, staff and physician satisfaction. Furthermore, the two rooms that would remain at ECEC would continue to be underutilized.
- Relocate the GI Endoscopy Procedure Room to VMC's Main GI Suite – The applicant states this is not a viable option, although there is a decommissioned GI endoscopy procedure room in the existing GI suite, because the current size of those rooms is insufficient to enable the performance of complex GI endoscopy procedures as proposed in this application. The existing rooms are too small to accommodate the GI and imaging equipment needed, and are too remote from the main operating room to safely administer general anesthesia/sedation for the complex patient population to be served.

After considering the above alternatives, the applicant states that it believes developing the new GI endoscopy procedure room by relocating a licensed but not operational room to the operative suite at VMC is the most effective alternative to meet the needs of the patient population in the area.

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

In summary, the applicant adequately demonstrates that this proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **Pitt County Memorial Hospital, d/b/a Vidant Medical Center shall materially comply with all representations made in the certificate of need application and in the supplemental information received. In those instances where representations conflict, Pitt County Memorial Hospital, d/b/a Vidant Medical Center shall materially comply with the last made representation.**

2. **Pitt County Memorial Hospital, 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, d/b/a Vidant Medical Center shall relocate no more than one additional gastrointestinal endoscopy room and shall be licensed**

for a total of no more than five gastrointestinal endoscopy rooms at Vidant Medical Center following project completion.

4. **Pitt County Memorial Hospital, d/b/a Vidant Medical Center shall take the necessary steps to delicense one gastrointestinal endoscopy procedure room at East Carolina Endoscopy Center, for a total of no more than one gastrointestinal endoscopy procedure room upon project completion.**

5. **Pitt County Memorial Hospital, d/b/a Vidant Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and 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

The applicant proposes to relocate an existing licensed GI endoscopy procedure room from ECEC to decommissioned operating room space in VMC. The applicant states the relocated room will be dedicated to performing complex GI endoscopy procedures.

Capital and Working Capital Costs

In Section VIII.1, page 58, the applicant projects the total capital cost for the project will be $1,282,981, which includes $242,595 in renovation costs and $1,040,386 in equipment costs. In Section IX, page 63, the applicant states there will be no start-up costs or working capital costs associated with the project, since there are no new services proposed with this project.

Availability of Funds

In Section VIII.3, page 59, the applicant states the capital costs will be financed through the accumulated reserves of VMC. In Appendix P the applicant provides a *Certificate of Financial Commitment* signed by the Chief Financial Officer of VMC which confirms the availability of sufficient funds for the project, and commits those funds to the development of the project. In Appendix Q the applicant provides copies of Vidant Health's audited financial statements for fiscal years 2013 and 2014, which show $135,886,000 in cash and cash equivalents and $1,013,618,000 in net assets (total assets less total liabilities) as of September 30, 2014.

Financial Feasibility

In Section X, page 72, the applicant provides pro forma financial statements for the first three years of the project. The applicant projects that VMC's GI endoscopy services revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the following table:

VMC GI ENDOSCOPY PROCEDURES	OPERATING YEAR 1 FY 2018	OPERATING YEAR 2 FY 2019	OPERATING YEAR 3 FY 2020
Projected # Procedures	8,679	8,739	8,774
Projected Average Charge per Procedure	$ 2,934	$ 3,022	$ 3,113
Gross Patient Revenue	$25,465,158	$26,410,435	$27,310,879
Deductions from Gross Patient Revenue	$18,077,758	$18,748,811	$19,388,037
Net Patient Revenue	$ 7,387,401	$ 7,661,624	$ 7,922,841
Total Expenses	$ 6,840,067	$ 7,043,930	$ 7,243,988
Net Income	$ 547,334	$ 617,694	$ 678,853

In Section X, page 68, the applicant states net revenue is based on FY 2015 actual reimbursement for GI endoscopy services provided at VCM.

The applicant adequately demonstrates that the projected revenues and operating costs are based on reasonable and adequately supported assumptions, including projected utilization. See Section X of the application, pages 66 - 68, for the assumptions regarding revenues and expenses. The discussion regarding analysis of need and projected utilization found in Criterion (3) is incorporated herein by reference.

In summary, the applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project and adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of operating costs and revenues. 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 applicant proposes to acquire and relocate one existing GI procedure room from ECEC to a decommissioned operating room in the main OR suite on the VMC campus, and to dedicate the relocated GI endoscopy room to the performance of complex GI endoscopy procedures. Upon project completion, VMC will be licensed for five GI endoscopy procedure rooms at the main hospital campus and ECEC will be licensed for one GI endoscopy room.

In Section III.1, page 22, the applicant states the two GI endoscopy rooms at ECEC are underutilized; in fact, the applicant states one room was not being utilized at the end of CY 2015. Therefore, the applicant proposes to relocate one of those rooms to existing space in the OR suite in the hospital. Both facilities are on the hospital campus, less than ¼ mile apart. The total number of GI endoscopy procedure rooms in Pitt County would not change as a result of the proposed project.

The 2015 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients. In Section III.5, page 29, the

applicant defines its primary service area as Pitt and Greene counties, and its secondary service area as *"any other county that represents 2.0% or greater of VMC's patient origin."* Facilities may also serve residents of counties not included in their service area.

There are six providers of GI endoscopy services in Pitt County and none in Greene County, which together comprise the applicant's primary service area, as stated in Section III.6, page 29.

In Section III.9, the applicant provides a table that lists existing GI endoscopy facilities in the applicant's defined service area, the number of licensed GI endoscopy rooms for each, and the number of GI procedures performed in each during FY 2014. The applicant states on page 31 that the data is derived from the draft 2016 SMFP. The analyst separated the data into hospital based and free standing GI endoscopy centers or ambulatory surgical facilities, and calculated utilization.

Vidant Medical Center Service Area GI Endoscopy Utilization
Hospital-Based GI Endoscopy Procedure Rooms, FY 2014

FACILITY	COUNTY	# GI ENDOSCOPY ROOMS	# PROCEDURES	PROCEDURES PER ROOM	% UTILIZATION*
Hospital Based GI endoscopy rooms					
Vidant Beaufort Hospital	Beaufort	1	2,451	2,451	163%
Carteret General Hospital	Carteret	2	710	355	24%
Vidant Chowan Hospital	Chowan	1	269	269	18%
Carolina East Medical Center	Craven	2	2,122	1,061	71%
The Outer Banks Hospital	Dare	2	377	188	13%
Vidant Edgecombe Hospital	Edgecombe	2	54	27	2%
Halifax Regional Medical Center	Halifax	1	477	477	32%
Vidant Roanoke-Chowan Hospital	Hertford	1	1,009	1,009	67%
Lenoir Memorial Hospital	Lenoir	2	887	443	30%
Martin General Hospital	Martin	1	346	346	23%
Nash General Hospital	Nash	4	5,448	1,362	91%
Onslow Memorial Hospital	Onslow	3	2,777	926	62%
Sentara Albermarle Medical Center	Pasquotank	3	2,510	836	56%
Vidant Medical Center	Pitt	3	6,814	2,271	151%
Wayne Memorial Hospital	Wayne	2	3,596	1,798	120%
Wilson Medical Center	Wilson	5	2,769	554	37%
Total Hospital Based GI Endoscopy Rooms		**35**	**32,616**	**931**	**62%**

***Utilization based on 10A NCAC 14C .3902, which requires 1,500 procedures per day per room**

Vidant Medical Center Service Area GI Endoscopy Utilization
Free-Standing GI Endoscopy Procedure Rooms, FY 2014

Facility	County	# GI Endoscopy Rooms	# Procedures	Procedures per Room	% Utilization*
Free-Standing (Non-hospital based) GI endoscopy rooms					
The Surgical Center of Morehead City	Carteret	1	1,538	1,538	102%
Carolina East Internal Medicine	Craven	3	3,613	1,204	80%
CCHC Endoscopy Center	Craven	3	6,114	2,038	136%
Vidant Endoscopy Center	Edgecombe	1	723	723	48%
Halifax Gastroenterology, P.C.	Halifax	2	1,959	980	65%
Kinston Medical Specialists Endoscopy Center	Lenoir	2	1,845	922	62%
Park Endoscopy Center	Lenoir	2	1,633	816	54%
Boice-Willis Clinic Endoscopy Center	Nash	2	5,696	2,848	190%
East Carolina Gastroenterology Endoscopy Ctr	Onslow	1	2,552	2,552	170%
Atlantic Gastroenterology Endoscopy Center	Pitt	2	3,298	1,649	109%
Carolina Digestive Diseases	Pitt	2	3,983	1,991	133%
East Carolina Endoscopy Center	Pitt	3	2,228	743	50%
Gastroenterology East	Pitt	3	4,850	1,616	107%
Quadrangle Endoscopy Center	Pitt	6	6,536	1,089	73%
Goldsboro Endoscopy Center	Wayne	4	3,565	891	59%
CGS Endoscopy Center	Wilson	2	1,807	904	60%
Wilson Digestive Diseases Center	Wilson	2	3,281	1,641	109%
Total Free-Standing GI Endoscopy Rooms		**41**	**55,211**	**1,347**	**90%**

***Utilization based on 10A NCAC 14C .3902, which requires 1,500 procedures per day per room**

The tables show that VMC's utilization has historically been among the highest among the hospital-based GI endoscopy providers. Furthermore, the applicant's proposal to dedicate the proposed relocated GI endoscopy room to perform complex GI endoscopy procedures will allow the applicants to offer those specialized GI endoscopy services more cost-effectively and safely to those patients needing those services.

The applicants adequately demonstrate that developing the proposed GI endoscopy room in a decommissioned OR in the hospital by relocating one underutilized GI endoscopy procedure room from ECEC would not result in an unnecessary duplication of existing or approved health service capabilities or facilities.

Therefore, the application is conforming to this criterion.

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

C

In Section VII.2, page 52, the applicant projects staffing in full time equivalents (FTE) positions during the second full fiscal year, as illustrated in the table below:

EMPLOYEE CATEGORY	# FTEs
Manager	1.0
Assistant Manager	1.0
GI Endoscopy Technicians	7.2
RN	18.8
GI Assistant	0.9
Secretary/Registrar	1.0
Total	29.9

In Section VII.9, page 56, the applicant states that Dr. Glenn Harvin is the current medical director of GI endoscopy services at VMC, and has agreed to continue to serve in that capacity following the relocation of the GI endoscopy room.

The applicant adequately documents the availability of sufficient resources, including health manpower and management personnel, for the project as proposed. Therefore, the application is conforming to this criterion.

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

C

The applicant states all of the necessary ancillary and support services are currently available at VMC and identifies those services in Section II.2, page 13. The applicant discusses coordination with the existing health care system in Sections V.2 - V.6, pages 38 - 42. The applicant provides supporting documentation of coordination and support from hospital and area physicians in Appendices H and J. The applicant adequately demonstrates it will continue to provide or make arrangements for the necessary ancillary and support services and the proposed services will be coordinated with the existing health care 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

(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 49, the applicant provides the payor mix during FY 2015 for VMC for the entire hospital and GI endoscopy services, as illustrated in the tables below.

VMC Entire Hospital Payor Mix, FY 2015

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	10.2%
Managed Care	23.5%
Medicaid	26.2%
Medicare	36.2%
Other	3.9%
Total	**100.0%**

VMC GI Endoscopy Payor Mix, FY 2015

PAYOR	PROCEDURES AS % OF TOTAL
Self Pay/Indigent	7.1%
Managed Care	27.0%
Medicaid	13.9%
Medicare	47.6%
Other	4.3%
Total	**100.0%**

Totals may not foot due to rounding.

Appendix M contains a copy of VMC's Admissions Policy, which contains policies pertaining to non-discrimination and provision of services to underserved populations. In Section VI.8, pages 46 - 47, the applicant provides additional discussion of VMC's charity care, financial payment policies and handicap access.

The United States Census Bureau[1] provides demographic data for North Carolina and all counties in North Carolina. The following table contains relevant demographic statistics for the applicant's service area.

Percent of Population						
County	**% 65+**	**% Female**	**% Caucasian**	**% Persons in Poverty**	**% < Age 65 with a Disability**	**% < Age 65 without Health Insurance**
Pitt	11%	53%	56%	23%	8%	18%
Greene	15%	46%	48%	28%	15%	22%
Statewide	15%	51%	64%	17%	10%	15%

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, women or handicapped persons who utilize health services.

The applicant demonstrates that it currently provides adequate access to medically underserved populations. Therefore, the application is conforming to this criterion.

The applicant demonstrates that medically underserved populations currently have adequate access to the applicant's existing services offered at VMC. 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;

[1] http://www.census.gov/quickfacts/table

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 48, the applicant states:

> *"VMC is bound by the Civil Rights Act, Hill-Burton Community Services obligation as well as its admissions policy to provide equal access to care without discrimination and without regard to race, color, creed, national origin, or source of payment. VMC has fulfilled its required volume of uncompensated care services in compliance with Hill-Burton regulations. However, there exists into perpetuity the Hill-Burton requirement that VMC provide access to all those in need. … over the last five fiscal years, VMC has provided over half a billion dollars in charity care services."*

The applicant states it will continue to provide care to all persons, including low income, racial and ethnic minorities, women, handicapped persons, elderly and other underserved populations. In Section VI.10, page 48, the applicant states that no civil rights complaints were filed against VMC in the last five years. Therefore, 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 50, the applicant projects payor mix during the second year of operation following project completion, which is shown in the following table.

VMC Endoscopy Services, LLC FY 2019

Payor	Procedures as % of Total
Self Pay/Indigent	7.1%
Managed Care	27.0%
Medicaid	13.9%
Medicare	47.6%
Other	4.3%
Total	**100.0%**

As shown above, the applicant projects that 61.5% of all GI endoscopy procedures projected to be performed will be provided to recipients of Medicare/Medicaid. In Section IV.14, page 50, the applicant states it assumes the projected payor mix will approximate the historical payor mix.

The applicant demonstrates that medically underserved populations will continue to have adequate access to the GI endoscopy services offered at VMC. 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 Section VI.9, page 47, the applicant describes the range of means by which a person will have access to VMC's endoscopy services. The applicant adequately demonstrates that the facility will offer 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.

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See Section V.1, pages 36 - 37 and referenced exhibits for documentation that VMC accommodates the clinical needs of health professional training programs in the area and that it will continue to do so. The information provided is reasonable and 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.

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The applicant proposes to acquire and relocate one existing gastrointestinal endoscopy (GI) procedure room from ECES to a decommissioned operating room in the main OR suite on the VMC campus, and to dedicate the relocated GI endoscopy room to performing complex GI endoscopy procedures. Upon project completion, VMC will be licensed for five GI endoscopy rooms at the main hospital campus, and ECEC will be licensed for one GI endoscopy room.

The 2015 SMFP does not define the service area for GI endoscopy procedure rooms. The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms, promulgated in 10A NCAC 14C .3901(6) does define the service area as the geographical area, as defined by the applicant using county lines, from which the applicant projects to serve patients.

There are currently three hospital-based and 16 non-hospital based licensed GI endoscopy procedure rooms in Pitt County, six of which are licensed as part of VMC. This application proposes to relocate one existing GI endoscopy room from ECEC to unutilized space in a decommissioned operating room in the main OR suite at VMC, and dedicate the room to performing complex GI endoscopy procedures. The total complement of GI endoscopy rooms in the county will not change following completion of this project. The applicant adequately demonstrates that utilization of the five GI endoscopy procedure rooms at VMC is projected to be in excess of 100% by the second project year.

In Section V.7, pages 42 - 43, the applicant discusses how any enhanced competition will have a positive impact on the cost-effectiveness, quality and access to the proposed services.

See also Sections II, III, V, VI and VII in which the applicant discusses the impact of the project on cost-effectiveness, quality and access.

The information provided by the applicant in those sections is reasonable and adequately demonstrates that any enhanced competition in the service area includes a positive impact on the cost-effectiveness, quality and access to GI endoscopy services. This determination is based on the information in the application and the following analysis:

- The applicant adequately demonstrates the need for its proposal and that it is a cost-effective alternative. The discussions regarding analysis of need and alternatives found in Criteria (3) and (4), respectively, are incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide quality services. The discussion regarding quality found in Criterion (20) is incorporated herein by reference.
- The applicant adequately demonstrates that it will continue to provide adequate access to medically underserved populations. The discussion regarding access found in Criteria (3), (3a) and (13) are incorporated herein by reference.

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

In Section I.13, page 6 - 7, the applicant provides a list of other health care facilities it currently owns, lease or manages in North Carolina. According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, during the 18 months immediately preceding the submittal of this application through the date of the decision, no facilities were found to be out of compliance with one or more Medicare conditions of participation. At this time, all of the facilities are in compliance with all Medicare conditions of participation. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section and considering the quality of care provided at both facilities, the

applicant provided sufficient evidence that quality care has been provided in the past. 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.

NA

The Criteria and Standards for Gastrointestinal Endoscopy Procedure Rooms in Licensed Health Service Facilities as promulgated in 10A NCAC 14C .3900 are not applicable to this review, because the applicant is not proposing to establish a new licensed ambulatory surgical facility for performance of GI endoscopy procedures or develop a GI endoscopy room in a licensed health service facility. The applicant proposes to relocate one existing licensed GI endoscopy procedure room from ECEC to the main hospital OR suite.