

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

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

Decision Date: November 27, 2018
Findings Date: November 27, 2018

Project Analyst: Jane Rhoe-Jones
Team Leader: Gloria C. Hale

Project ID #: Q-11562-18
Facility: Vidant Medical Center
FID #: 933410
County: Pitt
Applicant: Pitt County Memorial Hospital, Inc.
Project: Develop one new Gastrointestinal Endoscopy Procedure Room for a total of five at the medical center

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

N.C. Gen. Stat. 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 develop a new gastrointestinal endoscopy (GI-Endo) procedure room for a total of five upon completion of this project at VMC located at 2100 Stantonsburg Road, Greenville, Pitt County. In addition to the four GI-Endo procedure rooms at VMC, the applicant also operates two GI-Endo procedure rooms at the Moye Medical Endoscopy Center, LLC d/b/a East Carolina Endoscopy Center (ECEC) in which the applicant owns 100% membership interest and is also located in Pitt County.

Need Determination and Policies

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 2018 State Medical Facilities Plan (SMFP). Therefore, no need determination is applicable to this review nor any policy. Thus, this criterion is not applicable to this review.

Conclusion

The applicant does not propose to:

- develop any beds or services for which there is a need determination in the 2018 SMFP
- acquire any medical equipment for which there is a need determination in the 2018 SMFP
- offer a new institutional health service for which there are any policies in the 2018 SMFP

Therefore, Criterion (1) is not applicable to this review.

- (2) Repealed effective July 1, 1987.
- (3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant, VMC, proposes to develop a new GI-Endo procedure room at the medical center for a total of five at VMC upon completion of this project.

Patient Origin

The 2018 SMFP does not define the service area for GI-Endo 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.”*

Vidant Medical Center GI Endoscopy

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VMC GI ENDO Patient Origin				
County	Current 10/1/2016		Third Full FY of Operation following Project Completion (10/01/2022-09/30/2023)	
	Patients	% of Total	Patients	% of Total
Pitt	1,691	37%	2,233	37%
Beaufort	276	6%	364	6%
Lenoir	243	5%	321	5%
Martin	209	5%	276	5%
Wayne	204	4%	269	4%
Craven	202	4%	267	4%
Wilson	201	4%	265	4%
Edgecombe	197	4%	260	4%
Greene	177	4%	234	4%
Nash	110	2%	145	2%
Bertie	109	2%	144	2%
Halifax	108	2%	143	2%
Onslow	101	2%	133	2%
Hertford	101	2%	133	2%
Duplin	100	2%	132	2%
All other <2% of total	579	13%	764	13%
TOTAL	4,608	100.0%	6,083	100.0%

Source: Section C.2 and C.3, pages 18 and 19.

In Section C.3, page 20, the applicant provides the assumptions and methodology used to project its patient origin. The applicant’s assumptions are reasonable and adequately supported.

Analysis of Need

In Section C.4, pages 20-24, the applicant explains why it believes the population projected to utilize the proposed services needs the proposed services. On pages 20-24, the applicant states:

- The opening of the dedicated endoscopic retrograde cholangiopancreatography (ERCP)/endoscopic ultrasound (EUS) procedure room in FY14 has increased the ability of VMC to perform these complex procedures. The volume of complex GI-Endo procedures at VMC has more than doubled – from 969 in FY13 to 1,732 in FY18 (annualized) and has led to significant capacity constraints of its existing GI-Endo procedure rooms. (Pages 20-21)
- Complex procedures such as ERCP/EUS take much longer to perform due to patient comorbidities and complication risks, procedure complexity requires complex equipment, deeper sedation and anesthesiology, higher costs to patients and payor sources, and limits the number of procedures VMC can perform which lead to inefficiencies and inconvenience for patients such as extended hours. (Page 20)

- The ERCP/EUS procedure room has increased VMC’s capacity to accommodate patients requiring these complex procedures. (Page 20)
- Due to the growth in the number of GI-Endo procedures, the four GI-Endo rooms are experiencing capacity constraints that limit the number of procedures that can be performed; which negatively impacts patients if they have to wait to have a procedure. However, due to increased utilization and complex procedures, the applicant projects that VMC’s capacity will decrease over the next few years until the new GI Endo room is developed and operational. (Page 21)

The information is reasonable and adequately supported for the following reasons:

- Increased patient/physician satisfaction
- Creates space to more effectively and efficiently treat high risk patients
- Improved physician recruitment
- Increased capacity for education, research and clinical trials
- Improved quality

In Section Q, Form C, page 75, the applicant provides historical and projected utilization as illustrated in the following table.

VMC Historical and Projected Utilization FY2016-FY2023								
	FY2016	FY2017	FY2018	FY2019	FY2020	FY2021	FY2022	FY2023
# GI-Endo Rooms	4	4	4	4	5	5	5	5
Total Procedures	6,945	5,949	7,459	7,884	8,199	8,445	8,614	8,700

In Section Q, pages 74-75, the applicant provides the assumptions and methodology used to project utilization, which are summarized below.

- FY23 is based on the assumption FY2018 projects future distribution
- FY18 represents annualized data from 10/1/2017 - 6/30/2018
- The projected time per procedure is based actual historical time per procedure
- Complex procedures are included as they impact time and resources expended
- VMC assumes the growth rate for routine endoscopy procedures will approximate population growth rate at 1.0% per year
- VMC assumes the growth rate for complex endoscopic procedures will decrease proportionately to population growth which is almost 1.0% per year
- VMC’s new gastroenterologist will positively impact growth in the number of procedures

Projected utilization is reasonable and adequately supported because the percentage growth in the number of GI-Endo procedures is based on the percentage of population growth which is more conservative than recent historical growth.

Access

In Section C.8, page 27, the applicant states that it has an obligation as a non-profit entity to accept all patients that need medically necessary treatment. The applicant further states that no patient is denied access to care because of low income, racial or ethnic minority status, women, handicap, elderly or other classifications as underserved groups. In Section L.3, page 63, the applicant projects the following payor mix during the second full fiscal year of operation following completion of the project, as illustrated in the following table.

VMC Projected Payor Mix 10/1/2021-09/30/2022	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	5.4%
Charity Care*	0.0%
Medicare	56.1%
Medicaid	10.7%
Insurance**	25.4%
Workers Compensation	0.0%
TRICARE	1.7%
Other	0.8%
Total	100.0%

Source: Section L, page 63. *The applicant states that charity care patients are included in self-pay (majority) as well as other payor groups where patients may not be able to meet their financial obligation for the bill. ** Including any managed care plans.

The projected payor mix is reasonable and adequately supported.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately identifies the population to be served.
- The applicant adequately explains why the population to be served needs the services proposed in this application.
- Projected utilization is reasonable and adequately supported.
- The applicant projects the extent to which all residents, including underserved groups, will have access to the proposed services (payor mix) and adequately supports its assumptions.

- (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

The applicant does not propose to reduce, relocate or eliminate a service. Therefore, Criterion (3a) is not applicable to this review.

- (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

The applicant, VMC, proposes to develop a new GI-Endo procedure room at the medical center for a total of five at VMC upon completion of this project.

In Section E, pages 37-38, the applicant describes the alternatives it considered and explains why each alternative is either more costly or less effective than the alternative proposed in this application to meet the need. The alternatives considered were:

- Maintain the Status Quo – The applicant states that by not expanding services, it could not ensure adequate access to meet current and projected need, operate cost effectively or efficiently, and enhance patient, staff and physician satisfaction.
- Extend Hours – The applicant states that this is not the most cost-effective alternative. Expanding hours would result in additional staffing requirements which means increased operational expenses, diminished patient satisfaction, plus lowered staff and physician morale. Higher operating costs could also result in losing market share if their pricing is no longer competitive.
- Shift Patients to ECEC or Another Provider - The applicant states that this alternative is not medically feasible due to the comorbidity status of many of VMC's patients. Patients with co-morbidity prevents them from being treated in outpatient-based provider offices. This is especially problematic when a higher level of sedation/anesthesia is necessary and may not be known until the patient is underway with the procedure. Thus, advanced medical care, staff and monitoring become necessary.

On page 38, the applicant states that its proposal is the most effective alternative because it is the alternative determined to be the least costly while allowing greater access to meet the needs of patients, staff and physicians. This alternative is stated by the applicant to contain costs, increase efficiency while expanding services and improving patient, staff and physician satisfaction.

The applicant provides supporting documentation in Exhibit O.

The applicant adequately demonstrates that the alternative proposed in this application is the most effective alternative to meet the need for the following reasons:

- It will increase overall patient access
- It will ensure the level of care necessary for high-risk patients
- It will contain costs vs. the other alternatives
- The application is conforming to all statutory and regulatory review criteria.
- The applicant provides credible information to explain why it believes the proposed project is the most effective alternative.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above. Therefore, the application is 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.**
- 2. Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center shall develop one new gastrointestinal endoscopy procedure room for a total of five at the medical center.**
- 3. Upon completion of the project, Vidant Medical Center shall be licensed for no more than five gastrointestinal endoscopy procedure rooms.**
- 4. 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 expenditures in Section Q of the application and that would otherwise require a certificate of need.**
- 5. For the first three years of operation following completion of the project, Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center shall not increase**

charges more than 5% of the charges projected in Section Q of the application without first obtaining a determination from the Healthcare Planning and Certificate of Need Section that the proposed increase is in material compliance with the representations in the certificate of need application.

- 6. The procedure room shall not be used for procedures that should be performed only in a gastrointestinal endoscopy procedure room based on current standards of practice.**
 - 7. Procedures performed in the procedure room shall not be reported for billing purposes as having been performed in a gastrointestinal endoscopy room and shall not be reported on the facility's license renewal application as procedures performed in a gastrointestinal endoscopy room.**
 - 8. No later than three months after the last day of each of the first three full years of operation following initiation of the services authorized by this certificate of need, Pitt County Memorial Hospital, Inc. d/b/a Vidant Medical Center shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payor mix for the services authorized in this certificate of need.**
 - b. Utilization of the services authorized in this certificate of need.**
 - c. Revenues and operating costs for the services authorized in this certificate of need.**
 - d. Average gross revenue per unit of service.**
 - e. Average net revenue per unit of service.**
 - f. Average operating cost per unit of service.****
 - 9. 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 Agency 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, VMC, proposes to develop a new GI-Endo procedure room at the medical center for a total of five at VMC upon completion of this project.

In Section Q, page 76, the applicant projects the total capital cost of the project as shown in the table below.

Vidant Medical Center GI Endoscopy

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VIDANT MEDICAL CENTER Projected Capital Cost	
Construction	\$544,000
Architect/Engineering	\$100,000
Medical Equipment	\$524,500
Furniture	\$65,000
Information Systems & Security	\$56,000
Total	\$1,289,500

In Section Q, page 76, the applicant provides the assumptions used to project the capital cost.

In Section F, page 41, the applicant projects no start-up costs and no initial operating expenses because the proposed project is not a new service or facility.

Availability of Funds

In Exhibit G, the applicant states that the capital cost will be funded as shown below in the table.

Type	VIDANT MEDICAL CENTER	Total
Loans		
Accumulated reserves or OE*	\$1,289,500	\$1,289,500
Bonds		
Other (Specify)		
Total Financing	\$1,289,500	\$1,289,500

* OE = Owner's Equity

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Section Q, Form F.3, pages 86 and 87, the applicant projects that revenues will exceed operating expenses in the first three operating years of the project, as shown below in the table.

VIDANT MEDICAL CENTER*			
GI-Endo Procedure Rooms			
	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
Total Procedures*	8,445	8,614	8,700
Total Gross Revenues (Charges)	\$37,687,593	\$39,017,965	\$39,999,267
Total Net Revenue	\$11,381,111	\$11,782,864	\$12,079,203
Average Net Revenue per Procedure	\$3,394	\$3,453	\$3,505
Total Operating Expenses (Costs)	\$10,083,029	\$10,415,878	\$10,694,670
Average Operating Expense per Procedure	\$908	\$922	\$937
Net Income	\$1,298,083	\$1,366,987	\$1,384,533

*The table includes the number of GI-Endo procedures, revenues and operating expenses for 5 GI-Endoscopy rooms at VMC only. (See Section Q, Form F.3. and page 74.)

The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs and charges. See Section Q of the application for the assumptions used regarding costs and charges. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the following reasons:

- The applicant adequately demonstrates that the capital and working capital costs are based on reasonable and adequately supported assumptions.
- The applicant adequately demonstrates availability of sufficient funds for the capital and working capital needs of the proposal.
- The applicant adequately demonstrates sufficient funds for the operating needs of the proposal and that the financial feasibility of the proposal is based upon reasonable projections of costs and charges.

- (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, VMC, proposes to develop a new GI-Endo procedure room at the medical center for a total of five at VMC upon completion of this project.

The 2018 SMFP does not define the service area for GI-Endo procedure rooms, however the applicant defines its primary service area as Pitt and Greene counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 47, the applicant identifies the existing and approved GI-Endo services in its primary service area and the number of GI-Endo procedures performed during FY2017, as depicted in the following table.

Vidant Medical Center GI Endoscopy

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VMC Service Area GI-Endo Providers*					
County	Provider	Rooms	Cases	Procedures	Procedures per Room
Pitt	VMC	4	4,867	6,034	1,508.5
	ECEC	2	2,166	2,627	1,313.5
	Atlantic Gastroenterology Endoscopy Center	2	3,410	3,538	1,769
	Carolina Digestive Diseases	2	3,932	4,024	2,012
	Carolinas Endoscopy Center	3	7,776	7,776	2,592
	Quadrangle Endoscopy Center	6	6,503	7,247	1,207.8
Total	6	19	28,654	31,246	1,644.5

*Case & Procedure Data for 10/01/2016-09/30/2017 reported on Hospital & Ambulatory License Renewal Applications.

As illustrated in the table above, four of the six GI-Endo facilities in Pitt County, have exceeded 1,500 procedures per GI-Endo procedure room in FY2017. Greene County, the only other county that VMC considers as being in its primary service area does not have any facilities that provide licensed GI-Endo services.

In Section G, page 48, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI Endo services in VMC’s primary and secondary 15 county service area; with 12 counties providing GI Endo services. The applicant states:

“... the proposed project is not designed to address the inadequacy or inability of existing providers. The proposed project is intended to increase capacity, access, and quality of the services provided by VMC and to address current and future demand.”

The applicant adequately demonstrates that the proposal would not result in an unnecessary duplication of existing or approved services in the service area because the applicant adequately demonstrates that the proposed GI Endo procedure room is needed in addition to the existing or approved GI Endo services in VMC’s service area.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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 Q, Form H, page 94, the applicant provides current and projected staffing for the proposed services as illustrated in the following table.

VMC Current & Projected Staffing FTEs				
Position	Current	Projected		
	FFY2017	1st Full Fiscal Year	2nd Full Fiscal Year	3rd Full Fiscal Year
RN	19.7	22.7	22.7	22.7
GI Lab Manager	1.0	1.0	1.0	1.0
GI Lab Nurse Manager	1.2	1.2	1.2	1.2
Endo Equipment Tech	5.3	5.3	5.3	5.3
GI Tech	2.9	3.9	3.9	3.9
Total	30.1	34.1	34.1	34.1

Source: Form H in Section Q of the application. FTE = full time equivalent employee. FFY = Federal Fiscal Year.

The assumptions and methodology used to project staffing are provided in Section Q. Adequate costs for the health manpower and management positions proposed by the applicant are budgeted in Form F, page 94, which is found in Section Q. In Section H, pages 49-51, the applicant describes the methods used to recruit or fill new positions and its existing training and continuing education programs. In Section H, page 51, the applicant identifies the current medical director, and confirms his commitment to continue to serve in this role. In Section H, page 51, the applicant describes its physician recruitment plans. In Exhibit J, the applicant provides supporting documentation.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion for the above stated reasons.

- (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

In Section I, page 53, the applicant states that the following ancillary and support services are necessary for the proposed services:

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

On page 53, the applicant adequately explains how ancillary and support services are made available.

In Section I, page 54, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibits I and J.

The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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

The applicant does not project to provide the proposed services to a substantial number of persons residing in Health Service Areas (HSAs) that are not adjacent to the HSA in which the services will be offered. Furthermore, the applicant does not project to provide the proposed services to a substantial number of persons residing in other states that are not adjacent to the North Carolina county in which the services will be offered. Therefore, Criterion (9) is not applicable to this review.

- (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

The applicant is not an HMO. Therefore, Criterion (10) is not applicable to this review.

- (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.

C

In Section K, page 56, the applicant states that the project involves renovating 500 square feet of existing space. Line drawings are provided in Exhibit C.

On page 56, the applicant adequately explains how the cost, design and means of construction represent the most reasonable alternative for the proposal and provides supporting documentation in Exhibit C., Site and Floor Plans. The applicant states,

“The location identified in the main GI endoscopy suite has been identified as the most reasonable alternative for the proposed project. This option allows VMC to expand capacity while taking advantage of a location that is already under renovation (no new costly construction needed) and the co-location of GI services allows for economies of scale related to shared resources.”

On page 57, the applicant adequately explains why the proposal will not unduly increase the costs to the applicant of providing the proposed services or the costs and charges to the public for the proposed services; since the applicant is utilizing space created by another project. In Section C. 1, pages 14-17, the applicant provides detailed information regarding the project already underway which allows for the renovation for the proposed GI-Endo procedure room in this project.

On page 57, the applicant identifies any applicable energy saving features that will be incorporated into the construction plans.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the application is conforming to this criterion.

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

C

In Section L, page 62, the applicant provides the historical payor mix during 10/01/2016 – 09/30/2017 for the proposed services the last full fiscal year, as shown below in the table.

Vidant Medical Center GI Endoscopy

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VMC GI/Endoscopy Payor Mix 10/01/2016 – 09/30/2017	
Payor Category	GI-Endo Services as Percent of Total
Self-Pay	5.5%
Charity Care*	0.0%
Medicare	52.5%
Medicaid	12.6%
Insurance**	26.4%
Workers Compensation	0.0%
TRICARE	2.0%
Other	1.0%
Total	100.0%

Source: Section L, page 62. * The applicant states that charity care Patients are included in self pay (majority) as well as other payor Groups where patients may not be able to meet their financial obligation for the bill. ** Including any managed care plans.

In Section L, page 61, the applicant provides the following comparison.

VMC Medically Underserved Populations as Percentage of Total Population in the Service Area		
	Percentage of Total Patients Served by the Facility or Campus during the Last Full FY	Percentage of the Population of the Service Area
Female	56.2%	50.6%
Male	43.8%	49.4%
Unknown	n/a	n/a
64 and Younger	58.2%	83.6%
65 and Older	41.8%	16.4%
American Indian	0.3%	0.6%
Asian (inc Hawaiian or Pacific Islander)	0.2%	1.6%
Black or African-American	39.1%	31.9%
White or Caucasian	56.5%	59.1%
Other Race (inc Hispanic)	3.6%	6.8%
Declined / Unavailable	0.3%	n/a

Inc = includes.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately documents 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. 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

Regarding any obligation to provide uncompensated care, community service or access by minorities and persons with disabilities, in Section L, page 62, the applicant states,

“VMC is obligated to provide care, regardless of race, color, creed, age, sex, national origin, religion, disability status, sexual preference, ability to pay for care. ... VMC will continue to adhere to this policy at the completion of the project.”

In Section L, page 63, the applicant states that during the last five years no patient civil rights access complaints have been filed against the facility or any similar facilities owned by the applicant or a related entity and located in North Carolina.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L, page 63, the applicant projects the following payor mix for the proposed services at VMC only during the second full fiscal year of operation following completion of the project, as shown below in the table.

VMC Projected Payor Mix 10/1/2021-09/30/2022	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	5.4%
Charity Care*	0.0%
Medicare	56.1%
Medicaid	10.7%
Insurance**	25.4%
Workers Compensation	0.0%
TRICARE	1.7%
Other	0.8%
Total	100.0%

Source: Section L, page 63. *The applicant states that charity care patients are included in self pay (majority) as well as other payor Groups where patients may not be able to meet their financial obligation for the bill. **Including any managed care plans.

As shown in the table above, during the second full fiscal year of operation, the applicant projects that 5.4% of total services will be provided to self-pay patients, 56.1% to Medicare patients and 10.7% to Medicaid patients.

On page 63, the applicant provides the assumptions and methodology used to project payor mix during the second full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported because the applicant assumes the proposed project will not have a significant impact on payor mix, thus the projected payor mix will closely resemble the existing payor mix.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 L.B, page 64, the applicant adequately describes the range of means by which patients will have access to the proposed services.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that 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 M, pages 65-66, the applicant describes the extent to which health professional training programs in the area have access to the facility for training purposes and provides supporting documentation in Exhibit M.

The Agency reviewed the:

- Application
- Exhibits to the application

Based on that review, the Agency concludes that the applicant adequately demonstrates that the proposed services will accommodate the clinical needs of area health professional training programs, and therefore, the application is conforming to 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, VMC, proposes to develop a new GI-Endo procedure room at the medical center for a total of five at VMC upon completion of this project.

The 2018 SMFP does not define the service area for GI-Endo procedure rooms, however the applicant defines its primary service area as Pitt and Greene counties. Facilities may also serve residents of counties not included in their service area.

In Section G.1, page 47, the applicant identifies the existing and approved GI-Endo services in its primary service area and the number of GI-Endo procedures performed during FY2017, as depicted in the following table.

VMC Service Area GI-Endo Providers*					
County	Provider	Rooms	Cases	Procedures	Procedures per Room
Pitt	VMC	4	4,867	6,034	1,508.5
	ECEC	2	2,166	2,627	1,313.5
	Atlantic Gastroenterology Endoscopy Center	2	3,410	3,538	1,769
	Carolina Digestive Diseases	2	3,932	4,024	2,012
	Carolinas Endoscopy Center	3	7,776	7,776	2,592
	Quadrangle Endoscopy Center	6	6,503	7,247	1,207.8
Total	6	19	28,654	31,246	1,644.5

*Case & Procedure Data for 10/01/2016-09/30/2017 reported on Hospital & Ambulatory License Renewal Applications.

As illustrated in the table above, four of the six GI-Endo facilities in Pitt County, have exceeded 1,500 procedures per GI-Endo procedure room in FY2017. Greene County, the only other county that VMC considers as being in its primary service area does not have any facilities that provide licensed GI-Endo services.

In Section N, page 67-68, the applicant describes the expected effects of the proposed services on competition in the service area and discusses how any enhanced competition in the service area will promote the cost-effectiveness, quality and access to the proposed services. On pages 67-68, the applicant states:

“The proposed project will foster competition by promoting high quality, delivering cost effective services, and providing enhanced access to GI-Endo services. ...”

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates:

- The cost-effectiveness of the proposal (see Sections F and Q of the application and any exhibits)
- Quality services will be provided (see Section O of the application and any exhibits)
- Access will be provided to underserved groups (see Section L of the application and any exhibits)

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information which was publicly available during the review and used by the Agency (if applicable)

Based on that review, the Agency concludes that the application is conforming to this criterion for the reasons stated above.

- (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 O, page 71, the applicant identifies the GI-Endo facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of seven of this type of facility located in North Carolina.

In Section O, pages 71-71, the applicant states that, during the 18 months immediately preceding the submittal of the application, incidents related to quality of care occurred in none of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all seven 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.

C

The proposal 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. The specific criteria are discussed below.

.3903 PERFORMANCE STANDARDS

- (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.*
- NA- The applicant does not propose to develop operating rooms. Therefore, this Rule is not applicable to this review.
- (b) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall reasonably project to perform an average of at least 1,500 GI-Endo procedures only per GI-Endo 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 C, page 29, the applicant states that it projects to perform an average of 1,614 GI-Endo procedures in each licensed facility that the applicant or a related entity owns in the proposed service area during the second year of operation following completion of the project.
- (c) *An applicant proposing to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo room in an existing licensed health service facility shall demonstrate that at least the following types of GI-Endo procedures will be provided in the proposed facility or GI-Endo room: upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures.*
- C- In Section Q, Form C, page 75, the applicant states that upper endoscopy procedures, esophagoscopy procedures, and colonoscopy procedures have historically and will continue to be provided at VMC.
- (d) *If an applicant, which proposes to establish a new licensed ambulatory surgical facility for performance of GI-Endo procedures or develop a GI-Endo 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-Endo 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-Endo 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-Endo 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- In Section C, page 30, the applicant states that neither it nor any related entities perform GI-Endo procedures in licensed operating rooms.

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

- C- In Section Q, pages 74-76, the applicant provides the assumptions and methodology used to project GI-Endo procedures at the proposed facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.