

ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS

C = Conforming

CA = Conditional

NC = Nonconforming

NA = Not Applicable

Decision Date: November 22, 2022

Findings Date: November 22, 2022

Project Analyst: Donna Donihi

Team Leader: Mike McKillip

Project ID #: Q-12251-22

Facility: Vidant Medical Center

FID #: 933410

County: Pitt

Applicant(s): Pitt County Memorial Hospital, Inc.

Project: Develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion

REVIEW CRITERIA

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

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

NA

Pitt County Memorial Hospital, Inc. (hereinafter referred to as “Vidant Medical Center” (VMC) or “the applicant”) proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

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 2022 State Medical Facilities Plan (SMFP). Therefore, no need determinations are applicable to this review.

Policies

There are no policies in the 2022 SMFP which are applicable to this project.

Conclusion

The Agency reviewed the:

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

Based on that review, the Agency concludes that 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- (2) Repealed effective July 1, 1987.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 low-income persons, racial and ethnic minorities, women, ... persons [with disabilities], the elderly, and other underserved groups are likely to have access to the services proposed.

C

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

Patient Origin

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 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), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.* In Section C, page 35, the applicant projects that 35% of its patients will originate from Pitt County. Thus, the primary service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

The following tables illustrate historical and projected patient origin.

County	Vidant Medical Center Historical Patient Origin for GI Endoscopy	
	Last Full FY 10/01/2020-09/30/2021	
	Patients	% of Total
Pitt	3,063	35.0%
Beaufort	548	6.3%
Lenoir	511	5.8%
Wayne	501	5.7%
Wilson	437	5.0%
Craven	401	4.6%
Edgecombe	381	4.4%
Martin	313	3.6%
Halifax	250	2.9%
Onslow	236	2.7%
Greene	228	2.6%
Nash	227	2.6%
Bertie	220	2.5%
Duplin	204	2.3%
Hertford	181	2.1%
Carteret	165	1.9%
Washington	125	1.4%
Northampton	104	1.2%
All Other	653	7.5%
Total	8,748	100.0%

Source: Section C, page 35

Vidant Medical Center (Proposed) GI Endoscopy Projected Patient Origin						
County	1st Full FY		2nd Full FY		3rd Full FY	
	10/01/2023 to 09/30/2024		10/0/2024 to 09/30/2025		10/01/2025 to 09/30/2026	
	Patients	% of Total	Patients	% of Total	Patients	% of Total
Pitt	3,467	35.0%	3,537	35.0%	3,572	35.0%
Beaufort	620	6.3%	633	6.3%	639	6.3%
Lenoir	578	5.8%	590	5.8%	596	5.8%
Wayne	567	5.7%	578	5.7%	584	5.7%
Wilson	495	5.0%	505	5.0%	510	5.0%
Craven	454	4.6%	463	4.6%	468	4.6%
Edgecombe	431	4.4%	440	4.4%	444	4.4%
Martin	354	3.6%	361	3.6%	365	3.6%
Halifax	283	2.9%	289	2.9%	292	2.9%
Onslow	267	2.7%	272	2.7%	275	2.7%
Greene	258	2.6%	263	2.6%	266	2.6%
Nash	257	2.6%	262	2.6%	265	2.6%
Bertie	249	2.5%	254	2.5%	257	2.5%
Duplin	231	2.3%	236	2.3%	238	2.3%
Hertford	205	2.1%	209	2.1%	211	2.1%
Carteret	187	1.9%	191	1.9%	192	1.9%
Washington	141	1.4%	144	1.4%	146	1.4%
Northampton	118	1.2%	120	1.2%	121	1.2%
All Other	739	7.5%	754	7.5%	761	7.5%
Total	9,902	100.0%	10,100	100%	10,201	100.0%

Source: Section C, page 36-37

In Section C, page 37, the applicant refers to Section Q for the assumptions and methodology used to project its patient origin. Based on the percentage of total patients by county, as stated in the table above, the projected patient origin is based on the assumption that the GI endoscopy patient origin will approximate the last full fiscal year 2021. The applicants' assumptions are reasonable and adequately supported.

Analysis of Need

In Section C, pages 39-44, the applicant explains why it believes the population projected to utilize the proposed services, needs the proposed services, as summarized below.

Population

The applicant states: “VMC is one of the main providers of GI endoscopy services for the Pitt County service area, as well as a major provider for much of the ENC region. VMC currently has 5 GI endoscopy procedure rooms, which are currently operating at 126% capacity. In Section C.4, page 39, the applicant states the proposed project will address the need to:

- *“Address VMC’s Historical and Projected GI Endoscopy Growth & Capacity Constraints.*
- *Maintain Adequate Capacity to Meet the Needs of the Medically Underserved*
- *Maintain Adequate Capacity to Meet the Need for Complex Care*
- *Maintain Capacity to Meet the Need for Complex Care*
- *Maintain Capacity to Continue to be a Regional Resource to Serve All ENC*
- *Increase Patient and Physician Satisfaction*
- *Maintain Adequate Capacity for Education and Research”*

The information is reasonable and adequately supported based on the following:

- Projected population growth in service area.
- The historical growth in GI endoscopy procedures performed at VMC.
- The growing trend in the GI endoscopy industry.

Projected Utilization

In Section Q, Form C.3, the applicant provides historical and projected utilization, as illustrated in the following tables.

Vivant Medical Center (VMC) Historical and Interim OR and GI Endoscopy Utilization						
	Last Full Fiscal Year	Interim Full Fiscal Year 1	Interim Full Fiscal Year 2	1st Full Year	2nd Full Year	3rd Full Year
GI Endoscopy	10/01/2020- 09/30/2021	10/01/2021- 09/30/2022	10/01/2022- 09/30/2023	10/01/2023 09/30/2024	10/01/2024 9/30/2025	10/01/2025 9/30/2026
# of Rooms	5	5	5	6	6	6
# Inpatient GI Endoscopy Procedures	2,612	2,835	2,884	2,974	3,030	3,060
# Outpatient GI Endoscopy Procedures	6,136	6,623	6,730	6,932	7,070	7,141
Total GI Endoscopy Procedures	8,748	9,458	9,614	9,902	10,100	10,201
Average # of Procedures per Room	1,750	1,892	1,923	1,650	1,683	1,700

In Section Q, Form C.3 a & b, page 107 the applicant provides the assumptions and methodology used to project utilization, which is summarized below.

Step 1: Identify the number of procedures performed at the existing facility from CY2018 through CY2022.

Procedures at VMC from 2018-2022

	CY2018	CY2019	CY2020	CY2021	CY2022
Procedures	7,621	8,601	7,894	8,748	9,458

Source Figure C.4.1

Procedures per patient (PX/): For VMC, the PX/PT was assumed to be the average of FY18-YTD FY22 actual ratios. For ECEC, from FY20-FY22 the average PX/PT has been steady at 1.0. VMC assumed this ratio for future years. To be conservative, VMC assumes the future distribution will be reflective for FY21 and YTD FY22

Step 2: Annualize CY2022 based on procedures performed for the first three months of (Analyst calculations in brackets) Source; Section Q, page, 108

$(2,187 \text{ procedures} / 3 \text{ months}) \times 12 \text{ months} = 8748 \text{ procedures}$

Step 3: Calculate the 4-Year CAGR for CY2018 through CY2022

$CAGR = (CY2022 / CY2018) \times (1 / \# \text{ of years}) - 1 \times 100$
 $CAGR = (9,458 / 7,621) \times (1 / 4) - 1 \times 100$
 $CAGR = 5.55\%$

Step 4: Calculate 50% of the 4-Year CAGR calculated in Step 3

$5.55\% \times 50.0\% = 2.77\%$

Step 5: Project utilization for CY2023 through CY2026 using the 4-Year CAGR of 5.5%.

Vidant Medical Center Historical Utilization					
	CY2018	CY2019	CY2020	CY2021	Annualized CY2022
Procedures	7,621	6,493	6,069	6,979	7,651
4-Year CAGR					5.55%

Vidant Medical Center (Proposed) Projected Utilization				
	CY2023	CY2024	CY2025	CY2026
Procedures	9,614	9,902	10,100	10,201
50% of 4-Year CAGR				2.77%

Projected utilization is reasonable and adequately supported based on the following:

- Projected utilization is based on the most recent GI endoscopy procedure data annualized.
- The applicant’s projected growth rate in GI endoscopy procedures is supported by the historical four-year average growth rate.
- The applicant demonstrates that the projected utilization exceeds the required 1,500 procedures per GI endoscopy room.

Access to Medically Underserved Groups

In Section C, page 49, the applicant states:

“As with all existing GI endoscopy rooms at VMC, all persons identified above will have access to the proposed new room. As a not-for-profit corporation, VH, and all its subsidiaries, including VMC, have an obligation to provide medically necessary treatment and quality health care services to ALL persons seeking care. VMC recognizes that it serves a diverse population that includes persons of different races, religions, national origin, sexual orientation, gender identities, genders, education levels, citizenship status, English language proficiency, age, disability status, and sources of payment for care (including lack of medical insurance) ...”

The applicant provides the estimated percentage for each medically underserved group proposed to be served during the third full fiscal year, as shown in the following table.

Medically Underserved Groups	Percentage of Total Patients
Low-income persons	N/A
Racial and ethnic minorities	43.5%
Women	55.4%
Persons with Disabilities	N/A
Persons 65 and older	44.0%
Medicare beneficiaries	50.4%
Medicaid recipients	11.9%

Source: Section C, page 49

The applicant adequately describes the extent to which all residents of the service area, including underserved groups, are likely to have access to 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 all the reasons described above.

- (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, ... persons [with disabilities], and other underserved groups and the elderly to obtain needed health care.

NA

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

The applicant does not propose to a reduce, eliminate, or relocate any services. Therefore Criteria (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 proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

In Section E, pages 59-60, 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 Status Quo - The applicant states, “*VMC considered continuing current operations. This option was not considered to be a viable solution. Maintaining the status quo would not allow VMC to ensure sufficient access to meet current and projected demand, contain costs and increase efficiency, expand services, and improve patient, staff, and physician satisfaction. Consequently, this option was rejected.*”

Extending Hours - The applicant states “*VMC has contemplated further extending normal operating hours into the evenings and weekends to meet the current and projected demand. While this initiative may temporarily address the capacity issues, it is not the most cost-effective solution. The additional staff needed to manage the GI endoscopy rooms beyond normal operating hours on evenings and weekends is cost prohibitive and negatively impacts staff morale, not mention patient and physician satisfaction. The additional staff needed to support expanded hours significantly increases operational expenses. VMC cannot afford to carry these additional costs long term and keep charges as low as possible and competitive in the market. Consequently, this option was rejected.*”

Shift Patients to ECEC or Another Private Provider – The applicant states, “*VMC contemplated moving some volume to ECEC or another local provider to gain additional capacity at the hospital. However, this option was determined too not be medically feasible. Many of the patients VMC provides GI endoscopy service to can't be treated in outpatient based ambulatory provider offices. This is especially true with complex procedures where the higher level of sedation and/or anesthesia is traditionally used. But it is also true for even what is traditionally classified as routine GI endoscopy procedures. Many of VMC's "routine" patients have several complicating comorbidity and risk factors that make it impossible to provide even routine services in an ambulatory setting. The need to have advanced medical care, staff, and monitoring on site for the patients "just in case" is a necessity. Consequently, this option was rejected.*”

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

- The applicant’s proposal will provide a more cost-effective and efficient setting for GI endoscopy services.
- The applicant provides reasonable information to explain why it believes the proposed project is the most effective alternative.
- The application is conforming to all other statutory and regulatory review criteria. Therefore, the application can be approved.

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. (hereinafter certificate holder) shall materially comply with all representations made in the certificate of need application.**
- 2. The certificate holder shall develop no more than one additional GI endoscopy room for a total of no more than 6 GI endoscopy rooms at Vidant Medical Center.**

3. Upon completion of the project, Vidant Medical Center, shall be licensed for no more than six GI endoscopy rooms.
4. Progress Reports:
 - a. Pursuant to G.S. 131E-189(a), the certificate holder shall submit periodic reports on the progress being made to develop the project consistent with the timetable and representations made in the application on the Progress Report form provided by the Healthcare Planning and Certificate of Need Section. The form is available online at: <https://info.ncdhhs.gov/dhsr/coneed/progressreport.html>.
 - b. The certificate holder shall complete all sections of the Progress Report form.
 - c. The certificate holder shall describe in detail all steps taken to develop the project since the last progress report and should include documentation to substantiate each step taken as available.
 - d. The first progress report shall be due on April 1, 2023.
5. The certificate holder shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Sections F and Q of the application and that would otherwise require a certificate of need.
6. For the first three years of operation following completion of the project, the certificate holder 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.
7. 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, the certificate holder shall submit, on the form provided by the Healthcare Planning and Certificate of Need Section, an annual report containing the:
 - a. Payors 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.

8. The certificate holder 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 proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

Capital and Working Capital Costs

In Section Q, Form F.1a, the applicant projects the total capital cost of the project, as shown in the table below.

Vidant Medical Center Capital Costs	
Medical Equipment	\$659,650
Non-Medical Equipment	\$5,000
Total	\$664,650

In Section Q, the applicant provides the assumptions used to project the capital cost. The applicant adequately demonstrates that the projected capital cost is based on reasonable and adequately supported assumptions that are based on the vendor's estimated costs for construction and equipment. The applicant provides supporting documentation in Exhibit F.1.

In Section F, page 63, the applicant states:

“The proposed project is not for a new service or facility. The proposed project is for the expansion of an existing service. Form F.2b shows the proposed project with the additional GI endoscopy procedure room has a positive net income in the first year of operation. Therefore, no start-up costs, initial operating costs, nor working capital is needed.”

Availability of Funds

In Section F, page 61, the applicant states that the capital cost will be funded, as shown in the table below.

Sources of Capital Cost Financing

Type	VMC	Total
Accumulated reserves or OE *	\$664,650	\$664,650
Total Financing	\$664,650	\$664,650

* OE = Owner's Equity

Exhibit F.2 contains a letter dated August 8, 2022, from the Chief financial Officer of Vidant Health, stating VH will commit accumulated reserves to fund the proposed addition of the GI endoscopy procedure room at VMC. The applicant adequately demonstrates the availability of sufficient funds for the capital needs of the project.

Financial Feasibility

The applicant provided pro forma financial statements for the first three full fiscal years of operation following completion of the project. In Form F.2b, the applicant projects that revenues will exceed operating expenses in the first three full fiscal years following completion of the project, as shown in the table below.

Vidant Medical Center	1 st FFY 10/01/2023- 09/30/2024	2 nd FFY 10/01/2024- 09/30/2025	3 rd FFY 10/01/2025 09/30/2026
Total Procedures	9,614	9,902	10,100
Total Gross Revenues (Charges)	\$53,732,284	\$56,177,103	\$57,589,957
Total Net Revenue	\$16,173,417	\$16,909,308	\$17,334,577
Average Net Revenue per Treatment	\$4,088	\$4,150	\$4,154
Total Operating Expenses (Costs)	\$14,427,818	\$15,081,984	\$15,633,044
Average Operating Expense per Treatment	\$5,426	\$5,562	\$5,645
Net Income	\$1,745,599	\$1,827,324	\$1,701,533

The assumptions used by the applicant in preparation of the pro forma financial statements are provided in Section Q. The applicant adequately demonstrates that the financial feasibility of the proposal is reasonable and adequately supported based on the following:

- The applicant provides reasonable assumptions in determining revenue and operating expenses in preparation of Form F.2, F.3 and F.4.
- Projected utilization is based on reasonable and adequately supported assumptions. See the discussion regarding projected utilization in Criterion (3) which 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 costs are based on reasonable and adequately supported assumptions for all the reasons described above.
 - The applicant adequately demonstrates availability of sufficient funds for the capital needs of the proposal for all the reasons described above.
 - 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 revenues and operating expenses for all the reasons described above.
- (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 develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 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), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Pitt County. In Section C, page 35, the applicant projects that 35% of its patients will originate from Pitt County. Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP shows there are 19 existing GI endoscopy rooms in six facilities in Pitt County, as shown below.

Pitt County GI Endoscopy Services – FY2021 Data			
Existing Facilities	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Atlantic Gastroenterology Endoscopy Center	2	3,269	3,418
Carolina Digestive Disease	2	3,333	3,504
Carolina Endoscopy Center	3	7,831	7,831
East Carolina Endoscopy Center	2	1,884	2,150
Quadrangle Endoscopy Center	6	3,701	4,256
Vidant Medical Center	4	5,491	7,962

Source: Table 6F: Endoscopy Room Inventory (page 93 of the 2022 SMFP)

In Section G, page 69, the applicant explains why it believes its proposal would not result in the unnecessary duplication of existing or approved GI endoscopy services in Pitt County. The applicant states:

“NCGS 131E-183(b) indicates that VMC, as an academic medical center teaching hospital, is not required 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.”

The applicant indicates per statute NCGS 131E-183 that they do not need to provide proof of existing or approved services in the service area, because the applicant is a teaching hospital.

The applicant adequately demonstrates that the proposed additional GI endoscopy room is needed in addition to the existing or approved GI endoscopy rooms.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 all the reasons described above.

- (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.

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

In Section Q, Form H, the applicant provides current and projected full-time equivalent (FTE) staffing for the proposed services, as illustrated in the following table.

Position	Current FTE Staff	Projected FTE Staff
	Fiscal Year (CY as of 5/31/2022)	3rd Full Fiscal Year (CY 2025)
Manager	1.0	1.0
Assistant Nurse Manager	1.0	1.0
Unit Secretary	1.0	1.0
Rn Endo Clinic Coordinator	1.0	1.0
Registered Nurse	20.5	23.5
Lead Endoscopy Reprocessing Tech	1.0	1.0
Endoscopy Supply Chain Tec	2.0	3.0
Endoscopy Reprocessing Tech	1.0	1.0
Endoscopy Technologist	2.5	2.5
Surgical Technologist	0.5	0.5
TOTAL	31.5	35.5

The assumptions and methodology used to project staffing are provided in Section Q. There are adequate operating expenses for the health manpower and management positions proposed by the applicant are budgeted in F.3b. In Section H, pages 71-73, the applicant describes the methods to be used to recruit or fill new positions and its existing training and continuing education programs.

The applicant adequately demonstrates the availability of sufficient health manpower and management personnel to provide the proposed services based on the following:

- The applicant will offer competitive salaries/benefits and recruit staff through traditional methods, including a partnership with local colleges to hire new graduates.
- All VMC employees are provided orientation specific to their positions and ongoing education.

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 all the reasons described above.

- (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 proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

Ancillary and Support Services

In Section I, page 74, the applicant identifies the necessary ancillary and support services for the proposed services. On page 76, the applicant explains how each ancillary and support service is or will be made available and provides supporting documentation in Exhibit 12. The applicant adequately demonstrates that the necessary ancillary and support services will be made available.

Coordination

In Section I, pages 75-76, the applicant describes its existing and proposed relationships with other local health care and social service providers and provides supporting documentation in Exhibit 12. The applicant adequately demonstrates that the proposed services will be coordinated with the existing health care system based on the applicant's established relationships with local health care and social service providers in the service area.

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 all the reasons described above.

- (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's 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.

NA

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

In Section K, page 78, the applicant states that the project involves converting an existing bronchoscopy room located in the hospital's GI suite into the new GI endoscopy room.

The applicant does not propose any construction or renovations. Therefore, Criterion (12) is not applicable to this review.

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

identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

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

C

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

In Section L, page 82, the applicant provides the historical payor mix during the last full FY before submission of the application for the proposed services, as shown in the table below.

Vidant Medical Center Historical Payor Mix 10/01/2020-09/30/2021	
Payor Category	GI Endo Services as Percent of Total
Self-Pay	8.9%
Medicare*	35.8%
Medicaid*	23.9%
Insurance*	27.1%
Workers Compensation	0.6%
TRICARE	1.3%
Other	2.4%
Total	100.0%

*Including any managed care plans.

In Section L, page 83, the applicant provides the following comparison.

Vidant Medical Center Last Full FY	Percentage of Total Patients Served	Percentage of the Population of the Service Area
Female	51.6%	50.6%
Male	48.4%	49.4%
64 and Younger	92.3%	81.9%
65 and Older	7.7%	18.1%
American Indian	0.3%	0.9%
Asian	0.5%	1.4%
Black or African American	39.9%	30.6%
Native Hawaiian or Pacific Islander	Included in Other	0.2%
White or Caucasian	52.2%	64.5%
Other Race	4.7%	2.4%
Declined / Unavailable	2.4%	0.0%

*The percentages can be found online using the United States Census Bureau's QuickFacts which is at: <https://www.census.gov/quickfacts/fact/table/US/PST045218>. Just enter in the name of the county.

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 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 ... persons [with disabilities] 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 85, the applicant states:

“As a not-for-profit 501c3 organization, VMC has an obligation to accept any eastern NC resident requiring medically necessary treatment.”

In Section L, page 85, the applicant states that during the 18 months immediately preceding the application deadline, 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 86, the applicant projects the following payor mix for the proposed services during the third full fiscal year of operation following completion of the project, as shown in the table below.

VMC (proposed) Projected Payor Mix 3rd Full FY, CY 2025 to 09/30/2026	
Payor Category	GI Endo patients as Percent of Total
Self-Pay	2.5%
Medicare*	50.4%
Medicaid*	11.9%
Insurance*	3.33%
Other (Tricare, Workers Comp, etc.)	1.9%
Total	100.0%

*Including any managed care plans.

As shown in the table above, during the third full fiscal year of operation, the applicant projects that 2.5% of total services will be provided to self-pay patients, 50.4% to Medicare patients and 11.9% to Medicaid patients.

On pages 86-87, the applicant provides the assumptions and methodology used to project payor mix during the third full fiscal year of operation following completion of the project. The projected payor mix is reasonable and adequately supported based on the applicant's assumption that payor mix is not expected to change from the last full fiscal year.

The Agency reviewed the:

- Application
- Exhibits to the application

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

- (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, page 88, 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

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

In Section M, page 89, the applicant describes the extent to which health professional training programs in the area will have access to the facility for training purposes and provides supporting documentation in Exhibit 12. The applicant adequately demonstrates that health professional training programs in the area have will have access to the facility for training purposes based on the following:

- The applicant's commitment to accommodate students from health professional training programs in the area.
- In Exhibit 12, the applicant provides lists of educational institutions and programs which VH and VMC have formal relationships.

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 all the reasons described above.

- (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 proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

N.C. Gen. Stat. §131E-176(24a) states, “*Service area means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.*” The 2022 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), defines the service area as “...*the county where the proposed GI endoscopy room will be developed.*” The facility will be developed in Pitt County. In Section C, page 35, the applicant projects that 35% of its patients will originate from Pitt County. Thus, the service area for this facility consists of Pitt County. Facilities may also serve residents of counties not included in their service area.

The 2022 SMFP shows there are 19 existing GI endoscopy rooms in six facilities in Pitt County, as shown below.

Pitt County GI Endoscopy Services – FY2021 Data			
Existing Facilities	Endoscopy Rooms	Endoscopy Cases	Endoscopy Procedures
Atlantic Gastroenterology Endoscopy Center	2	3,269	3,418
Carolina Digestive Disease	2	3,333	3,504
Carolina Endoscopy Center	3	7,831	7,831
East Carolina Endoscopy Center	2	1,884	2,150
Quadrangle Endoscopy Center	6	3,701	4,256
Vidant Medical Center	4	5,491	7,962

Source: Table 6F: Endoscopy Room Inventory (page 93 of the 2022 SMFP)

Regarding the expected effects of the proposal on competition in the service area, in Section N, page 91, the applicant states:

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

Regarding the impact of the proposal on cost effectiveness, in Section N, page 91, the applicant states:

“VMC will use the proposed new endoscopy room to enhance the operational efficiency of GI endoscopy services and to increase patient access. These efforts will contain costs and improve access to GI endoscopy services.”

See also Sections C, F, K, and Q of the application and any exhibits.

Regarding the impact of the proposal on quality, in Section N, page 91, the applicant states:

“VMC’s comprehensive quality assurance program ensures continuation of high standards of care for all people in their service area. The proposed new endoscopy room will be seamlessly integrated into VMC’s overall GI endoscopy service program and assures patients receive the highest level of service VMC can offer.”

See also Sections C and O of the application and any exhibits.

Regarding the impact of the proposal on access by medically underserved groups, in Section N, page 91, the applicant states:

“VMC’s mission is to improve the health status of the region. VMC is dedicated to offering needed GI endoscopy services to anyone in the community, especially the medically underserved populations. VMC will use the proposed additional GI endoscopy room to assure services are available to all members of the community – Particularly the medically underserved.”

See also Section L and C of the application and any exhibits.

The applicant adequately describes the expected effects of the proposed services on competition in the service area and adequately demonstrates the proposal would have a positive impact on cost-effectiveness, quality, and access because the applicant adequately demonstrates that:

- 1) The proposal is cost effective because the applicant adequately demonstrated: a) the need the population to be served has for the proposal; b) that the proposal would not result in an unnecessary duplication of existing and approved health services; and c) that projected revenues and operating costs are reasonable.
- 2) Quality care would be provided based on the applicant's representations about how it will ensure the quality of the proposed services and the applicant's record of providing quality care in the past.
- 3) Medically underserved groups will have access to the proposed services based on the applicant's representations about access by medically underserved groups and the projected payor mix.

Conclusion

The Agency reviewed the:

- Application
- Exhibits to the application
- Information 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 based on all the reasons described 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

The applicant proposes to develop no more than one additional GI endoscopy room for a total of no more than six GI endoscopy rooms upon project completion.

In Section Q, Form O, the applicant identifies the facilities located in North Carolina owned, operated or managed by the applicant or a related entity. The applicant identifies a total of ten of this type of facility located in North Carolina.

In Section L, page 85, and Exhibit 1, the applicant states that, during the 18 months immediately preceding the submittal of the application, no incidents related to immediate jeopardy had occurred in any of these facilities. After reviewing and considering information provided by the applicant and considering the quality of care provided at all ten 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.

G.S. 131E-183 (b): The Department is authorized to adopt rules for the review of 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 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 application is conforming with all applicable Criteria and Standards for Gastrointestinal Endoscopy procedure rooms in Licensed Health Service Facilities. The specific criteria are discussed below.

SECTION .3900 – CRITERIA AND STANDARDS FOR GASTROINTESTINAL ENDOSCOPY PROCEDURE ROOMS IN LICENSED HEALTH SERVICE FACILITIES

.3903 PERFORMANCE STANDARDS

An applicant proposing to develop a new GI endoscopy room in a licensed health service facility shall:

(1) *identify the proposed service area.*

-C- In Section C, page 51, the applicant states the proposed services area will be Pitt County.

(2) *identify all existing and approved GI endoscopy rooms owned or operated by the applicant or a related entity located in the proposed service area.*

-C- In Section C, page 51, the applicant states VMC operates 5 GI endoscopy rooms and East Carolina Endoscopy Center operates 2 GI endoscopy rooms.

(3) *provide projected utilization for each of the first three full fiscal years of operation following completion of the project for all GI endoscopy rooms identified in Item (2) of this Rule.*

-C- In Section C, pages 52, the applicant provides projected utilization for each of the first three full fiscal years of operation following completion of the project for all its GI endoscopy rooms.

- (4) *project to perform an average of at least 1,500 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project in the GI endoscopy rooms identified in Item (2) of this Rule; and*
- C- In Section C, page 52, the applicant projects an average of 1,648 GI endoscopy procedures per GI endoscopy room during the third full fiscal year of operation following completion of the project.
- (5) *provide the assumptions and methodology used to project the utilization required by this Rule.*
- C- Following form C.3.b, and Section Q, the applicant provides the assumptions and methodology used to project GI endoscopy procedures at its facility. The discussion regarding projected utilization found in Criterion (3) is incorporated herein by reference.